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Master's degree in Engineering and Management

Master of Science Thesis



**Additive Manufacturing adoption in Dental
Practices: state of the art and future perspectives**

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Ai miei genitori

Abstract

Additive Manufacturing technologies are changing the way products are created in many industrial segments. The medical and the dental sectors are experimenting an increasing adoption of 3D printing technologies for the production of medical devices and surgical aids. In particular, the flexibility and mass customization possibility perfectly fit with the requirements of the dental sector, opening new business opportunities.

The aim of this thesis is to present the actual economical and technical scenario regarding the use of 3D printing in dental sector and, in particular, in the dental offices. Differently from the technical perspective, it is difficult to find scientific researches on the AM phenomenon in the dental sector from an economic point of view. For this, important data and opinions were collected from dentists through a questionnaire and contacting 3D printer vendors. Precious suggestions were collected in order to have a clear view regarding the actual limits and the future opportunities of this technology.

The first part of the thesis presents the history of AM and gives an essential technical background analysing the principal technologies actually used. Subsequently, the second chapter focuses on the economic characteristics of AM. In particular, the benefits and the limits of this technology were considered with a focus on the various sector in which it is successfully used.

In the second part, the applications of 3D printing in the dental sector are presented focusing on how the use of this device can change the traditional workflow by using digital procedures; this part was supported by a case study regarding the production of a temporary dental crown. The fourth chapter describes the benefits that AM can bring in each dental practice and the economic effects of the digital in-office production switch.

Finally, in the last chapter, questionnaires answers were analysed making some conclusions on the actual adoption status and the introduction limits of this technology.

Table of Contents

1	Chapter 01: Additive Manufacturing Technologies and Materials	1
1.1	History of Additive Manufacturing	1
1.2	The additive manufacturing process steps	3
1.3	Technologies overview	4
1.3.1	Vat Photo Polymerization	5
1.4	Post-processing operations	18
1.5	Conclusions	19
2	Chapter 02: Economic characteristics of AM	20
2.1	Introduction	20
2.2	Economic opportunities of AM	20
2.2.1	Design improvement	20
2.2.2	Mass Customization	21
2.2.3	Flexibility	22
2.2.4	Manufacturing decentralization	23
2.2.5	Buy-To-Fly ratio	23
2.3	AM obstacles and limitations	24
2.3.1	Cost of machineries and materials	25
2.3.2	Production time	26
2.3.3	Quality obtained	26
2.3.4	Traditional attitude	27
2.4	The “Economies of One” production model	27
2.5	How AM impacts different sectors	30
2.5.1	Aerospace	30
2.5.2	Automotive	30
2.5.3	Architecture	31
2.5.4	Medical	32
2.5.5	Resources industry	33
2.5.6	Retail	33
2.6	AM market trends	35
2.6.1	Worldwide revenues	35
2.6.2	Industry sectors	36
2.6.3	Market shares	37

2.6.4	3D printing Hype effect	38
3	Chapter 03: Current status of Additive Manufacturing in dental sector.....	42
3.1	Introduction	42
3.2	The digitalization of dentistry sector	42
3.2.1	Traditional Workflow	44
3.2.2	Digital Workflow.....	45
3.2.3	Conclusions about the case study	51
3.3	AM technologies used in Dental sector	51
3.4	Legislation regarding medical devices.....	52
3.5	Other application of AM in dental field.....	55
3.5.1	Surgical Guides	55
3.5.2	Clear Aligners.....	57
3.5.3	Dental Models	59
3.5.4	Wax pattern	60
3.6	Conclusions	62
4	Chapter 04: AM potential changes in Dental sector.....	63
4.1.	The disruptive nature of AM.....	63
4.2.	How AM can alter the traditional business model	64
4.3.	The chair-side workflow	65
4.4.	Key benefits of AM in dental sector.....	68
4.4.1.	Less time and cost.....	68
4.4.2.	Better communication with the patients	69
4.4.3.	Flexibility	69
4.4.4.	Improved quality	70
4.4.5.	Reduction of environmental impact.....	71
4.5.	Obstacles to rapid growth.....	71
4.5.1.	Material limitations.....	71
4.5.2.	Skilled operator required.....	72
4.5.3.	Legislation issues.....	73
4.5.4.	Traditional attitude.....	73
4.6.	Future trend of AM in dental sector	73
4.7.	AM drives mass customization. A case study.....	74
4.7.1.	History of Invisalign	74
4.7.2.	Workflow of the treatment	75

4.7.3.	The role of 3D printers.....	75
4.7.4.	Company growth	76
4.7.5.	Conclusions about the case study	77
4.8.	Conclusions.....	78
5	Chapter 05: AM adoption in dental practices.....	79
5.1	Introduction	79
5.2	The survey preparation and the submission	79
5.3	Structure of the survey	80
5.4	The analysis of the answers.....	81
4.9.	Final remarks.....	90
	Acknowledgements.....	92
	Appendix: Questionnaire	93
	Bibliography	99

1 Chapter 01: Additive Manufacturing Technologies and Materials

“Additive manufacturing (AM), or three-dimensional (3D) printing as it is often referenced, offers a new paradigm for engineering design and manufacturing that could have significant economic, geopolitical, environmental, intellectual property, and security implications.”

Thomas A. Campbell – ICTAS Institute (USA)

Additive manufacturing is a production process that involves the creation of objects using a layer-by-layer technique, which consists of overlapping multiple layers of material, to replicate a 3D CAD model. Many people think that this technique was born just few years ago but it was already known in the 80s. To better know the origins of AM, the first part of this chapter describes the most important historical stages.

The last parts give a technical overview, necessary to understand the next chapters, starting from the production stages and analysing the most common technologies focusing on printer processes, materials, application and pros and cons.

1.1 History of Additive Manufacturing

The discovery of the 3D printing is attributed to Charles Hull. In 1983 he worked in a small company that produced furniture and was very frustrated by the time he was losing in producing small, custom parts. While using UV light to harden tabletop coatings, he had the idea of curing photosensitive resin, layer-by-layer, to create a 3D part. It was only in 1986 that Hull coined the term “*Stereolithography*” in his U.S. Patent entitled “*Apparatus for Production of Three-Dimensional Objects by Stereolithography*”, marking the beginning of the 3D printing industry and founding his own company in Valencia, California, called 3D Systems. During 1988 the company released the first commercial 3D printer, the SLA-1. In the same year, Carl Deckard, a student at the University of Texas, invented and filed a patent for a new 3D printing technology called Selective Laser Sintering (SLS).



Figure 1. SLA-1: the first 3D printer released by 3D System

In 1989 Scott Crump, the co-founder of Stratasys, submitted the patent of the Fused Deposition Modelling (FDM), the simplest and most common printing technology. The company he created is one of the market leaders for high precision 3D printers.

In 2005, Adrian Bowyer, a mechanical engineer from Bath University (UK) founded the RepRap (Replicating Rapid Prototyper) project, with the aim to create a low-cost 3D printer, that can print most of its own components. Thanks to this self-replication capacity, Bowyer imagined the possibility of distributing RepRap low-cost machines, to individuals and communities, giving them the possibility to develop (or download from the Internet) complex products, without the need for costly industrial infrastructure.

In 2009, AM officially became a manufacturing industrial technology. In fact, during this year, the ASTM Committee F42 was formed, which published a document containing the standard terminology on additive manufacturing. Since 2009, the ASTM Committee F42 has met twice a year to promote knowledge, stimulate research and implement technologies through the development of standards for AM technologies.

In the same year, the FDM technology patent expired reducing significantly the prices and allowing the birth of the firsts 3D desktop printers developed by new market players.

A very important company in this period was MakerBot founded in January 2009 by Bre Pettis, Adam Mayer and Zach Smith, one of the founders of RepRap. MakerBot created an open-source model, called the Cupcake CNC, with the aim of bringing 3D printing in the

houses at an affordable price. Any suggestion for improvements came from users following the scope of open-source products.

Formlabs, a company founded in 2011 by three students of MIT Media Lab represents another important market player. The company went down in history for earning \$3 million in a Kickstarter campaign, to produce and sell its first 3D printer, FORM 1, which uses Stereolithographic technology.

1.2 The additive manufacturing process steps

The parts production process is composed mainly of seven steps that are shared between all AM printing technologies. Understanding the overall process is important in order to learn about the most common printing techniques, which will be discussed in the next section.

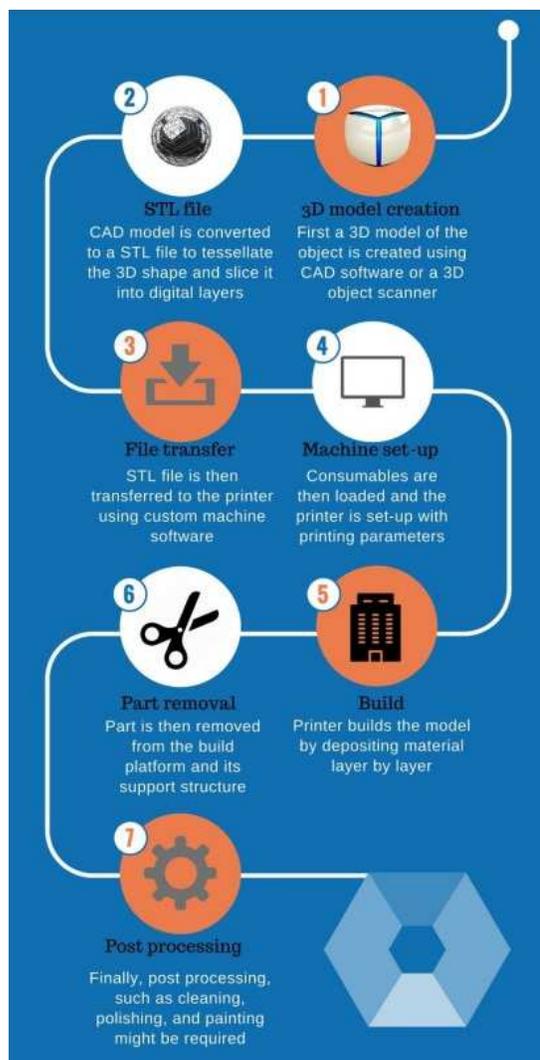


Figure 2. The AM production steps

figure 2 illustrates the seven steps characterizing the process.

Step 1 - 3D Model Creation

Producing a digital model is the first process in AM process. The digital model can be generated in different ways:

- using a Computer Aided Design (CAD) modelling software;
- digitalizing an existing object through 3D scanning;
- combining digitalization and digital retouching techniques to modify the model before printing.

- **Step 2 – STL file creation**

In order to be interpreted by the printer, the CAD model is transformed into a particular format, that depends on the type of technology used. The most common is the STL (STereoLithography) which is obtained by a meshing operation of the digital model.

In the meshing operation, the model is represented through simple geometric shapes such as triangles, quadrilaterals, or other simple convex polygons which, combined in a particular way, form the mesh. The number of figures that form a mesh determines the resolution.

- **Step 3 – STL slicing and file transfer**

The 3D model is chopped into hundreds or thousands of horizontal layers through a slicing software giving to the machine the instruction of exactly what to do, step by step. STL file is then transferred to the printer.

- **Step 4 – Machine set up**

Consumables like polymers, binders and other materials are loaded and the printer is settled-up with printing parameters.

- **Step 5 – Build**

In this phase the machine builds the model by depositing material layer by layer. The production process might take hours or even days.

- **Step 6 – Part Removal**

The built part is removed from the build platform and its support structure. The complexity of this operation depends on the AM technology we are dealing with;

- **Step 7 – Post processing**

During this phase the printed product is cleaned and polished. Some parts might be cured under UV before handling it.

1.3 Technologies overview

After describing the necessary production steps that all the AM technologies shares, the focus is moved on the various existing technologies. Nowadays, the market offers a wide range of processes and materials, which could be easily confused by the less experienced operators. In addition to this, many manufacturers have created unique names for processes, and acronyms for materials, which are often similar between different producers. Due to the confusion caused, an international processes standardization, the ISO/ASTM 52900, was created in 2012 by ASTM International, establishing seven technologic categories.

The figure 3, designed by 3D Hubs, gives a clear picture of the printing processes, the technologies, the materials and the main market players.

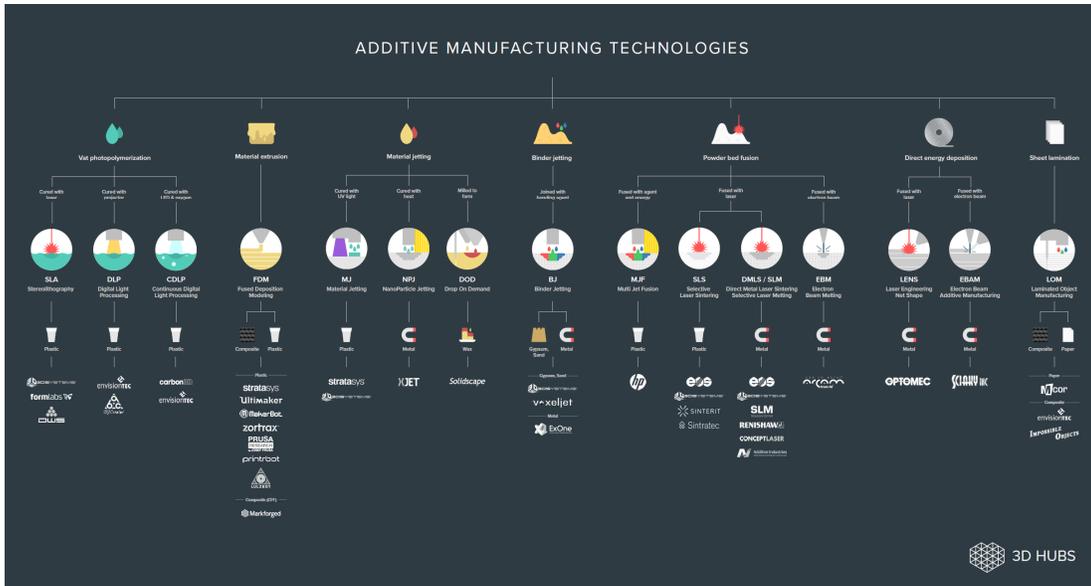


Figure 3. Overview of 3D printing technologies, with material and main producers

1.3.1 Vat Photo Polymerization

Vat Photo Polymerization is an AM process that consists in solidifying a liquid photopolymer, contained in a vat, in a selective way through a light-activated polymerization. This process is widely used in many fields as dental application, prototyping and jewellery to create objects in plastic or particular resins depending on the final application of the pieces.

The most common technologies of Vat Polymerization are Stereolithography (SLA) and Digital Light Processing (DLP). The principal different is that SLA uses a single point laser to solidify the resin, while DLP uses a project.

1.3.1.1 Stereolithography

As already seen in the first part of the chapter, SLA is the oldest additive manufacturing technique. It was invented by Charles Hull, who patented the technology in 1986 and founded the 3D Systems company.

Each SLA 3D printer is composed of a vat filled with a photosensitive liquid, a perforated platform immersed in the vat, that can move up and down, a high-powered UV laser and a computer interface that controls the laser and the platform movements.

The UV laser is directed to the printing area using computer-controlled mirrors, called galvanometers, to cure and solidify the resin. The product is created layer by layer. After the

first layer is created, the platform moves, and the laser solidifies the next section; the process is repeated until the part is completed.

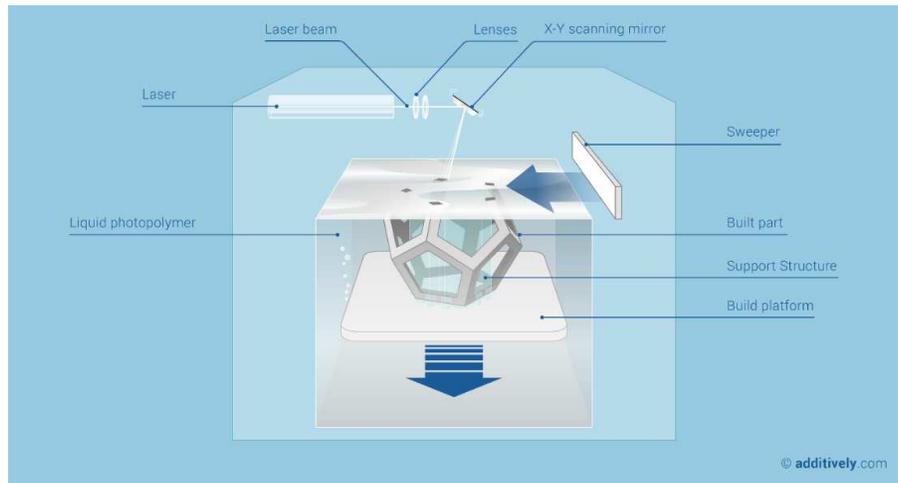


Figure 4. Scheme of a SLA top-down 3D printer

3D SLA printers can work by following two approaches: bottom up and top down.

In bottom up printers, the laser beam is positioned at the base of the vat that has a transparent bottom. In the first phase of the process there is a first layer of untreated resin between the base of the vat and the platform. This layer is cured and solidified by the light, the machine separates the layer from the base of the vat and the building platform moves up creating another gap of uncured resin. The process is repeated until the piece is completed. The width of this shift influences the height of the layers and is typically between 25 and 100 microns. The separation phase (of the treated layer from the base) is critical because strong tensions can be created damaging the piece. Furthermore, the new layer created can remain stuck to the base of the vat. To contrast this problem, non-stick coatings are applied to the base of the vat and must be replaced regularly to ensure better performance.

In top down printers, the light source is above the build platform. For the first layer, the platform is positioned on top of the resin vat, leaving a thin layer of resin. Once the light solidifies the first layer, the platform moves down creating a new layer of uncured resin. The process is repeated until the piece is completed and is totally immersed into the liquid. The resin used with this type of technology must have an adequate viscosity so that it can be uniformly distributed on the cured layer once the platform moves down.

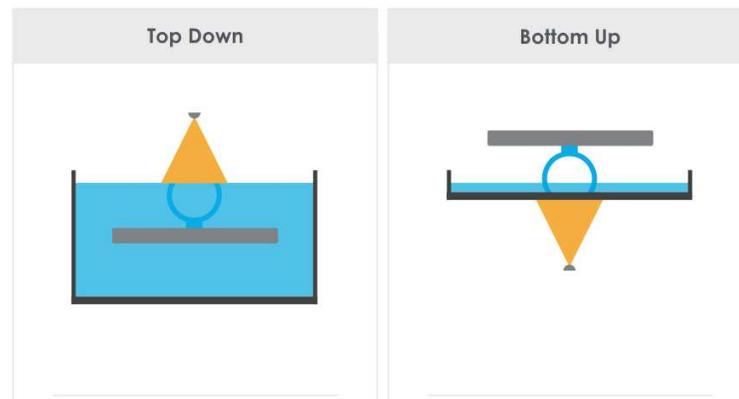


Figure 5. Top Down vs Bottom Up approach

1.3.1.2 Digital Light Processing

The Digital Light Processing (DLP) printing process is similar to the SLA. The main difference is that DLP uses a digital light projector screen to cure a single layer all at once, increasing the printing speed in comparison to SLA. The light is directed to the build platform through a Digital Micromirror Device (DMD) that create a 2D image. The resolution of a printed part corresponds to the number of micromirrors inside a DMD device.

The two technologies described above share, in addition to the production process, also the advantages and disadvantages.

For what concerns the advantages we have:

- Products with high level of quality and finely detailed features also with complex geometrical shapes;
- Relative quick process;
- Build areas can be high without sacrificing precision.

For what concerns the disadvantage we have:

- Printing costs are comparatively high;
- This technology offers limited material and colour choice;
- Often is necessary a post curing for parts to have better mechanical property;
- The part requires support structure during the building process.

Thanks to the several types of resins available on the market, is possible to use the SLA and the DLP for producing numerous components with different functions. The different resins can be divided in:

- Standard resins: to produce low-cost detailed prototypes, concept and art models in order to test ergonomic and aesthetic characteristics;
- Engineering resins: thanks to their mechanical and thermal properties are used for functional prototypes, consumer products and low-friction mechanical parts;
- Dental and medical resins: which are biocompatible and are used for medical equipment like surgical guide.
- Castable resins: used for the creation of jewellery with casting technology; moulds created by this material burn out without leaving any residue.



Figure 6. Ring created by casting technology using a DLP printed model (on the left)

1.3.1.3 Material extrusion

This printing method was invented in 1980 by S. Scott Crump, who patented it under the name of Fused Deposition Modelling (FDM). The term and its abbreviation are trademarks of Stratasys Inc, a company co-founded by Crump. Another way to call it is Fused Filament Fabrication (FFF). Nowadays, material extrusion is the most widely used printing technique, especially for consumers with low budgets who need hobby-application and affordable 3D printers.

The process starts with a filament spool that is loaded into the machine and proceeds towards the extrusion head composed of a heated nozzle. The material is heated and flows through the nozzle in order to be deposited layer by layer. The extrusion head can move horizontally and the platform can move up and down to deposit the molten material where required. When a layer is completed, the printing platform moves allowing the following layer to be added on top of the previous.

The material extrusion process requires the control of many factors to obtain a high-quality product. Some important parameters are building speed, extrusion speed and nozzle temperature that influence the consistence of the extruded filament. Furthermore, gravity

and surface tension must be accounted when high tolerance is required. The final resolution is influenced by the nozzle diameter and the layer thickness, varies from 0.178 mm to 0.356 mm; typically, smaller nozzle diameter and lower layer width increase the final resolution.

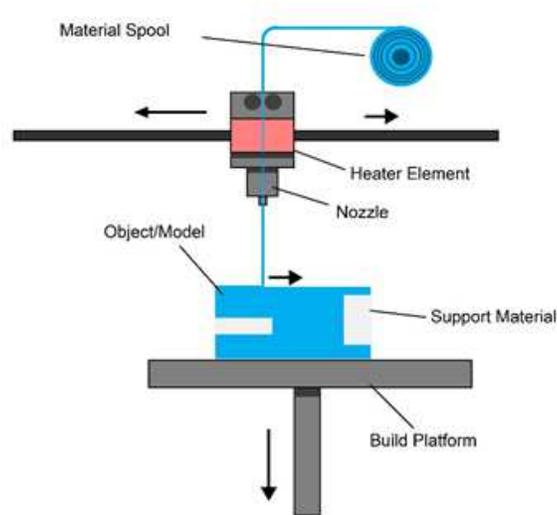


Figure 7. Material Extrusion process

The principal pros of using the FDM technology are:

- Wide selection of printing materials;
- Easy and user-friendly printing technique;
- Low initial and operating costs;
- Use of ABS plastic with good structural properties.

Some of the drawbacks are:

- Poor part strength along one direction, perpendicular to build platform, due to the anisotropic nature of the parts;
- Visible layer lines that require a post processing treatment.

The principal advantage of the FDM is the wide range of material used, varying from common thermoplastics to engineering materials. The ABS (Acrylonitrile Butadiene Styrene) is the most used material thanks to the wide range of colours, the stability over the time and the good mechanical properties that guarantee the production of functional prototypes. The PLA (PolyLactic Acid) offers good details, has an affordable price and is biodegradable but has lower mechanical properties compared to ABS; for this last reason is

commonly used for non-functional prototyping. Other used materials are: Nylon, PETG, PEI and TPU.

This printing method is widely used in industrial application for product development, prototyping and manufacturing processes. However, FDM desktop printers are the most affordable and user-friendly AM machines and, for this reason, are used by inventors, schools, hobbyist and small firms. It is possible to buy on Amazon, cheap FDM 3D printers for just 200 Euro and all the needed materials.

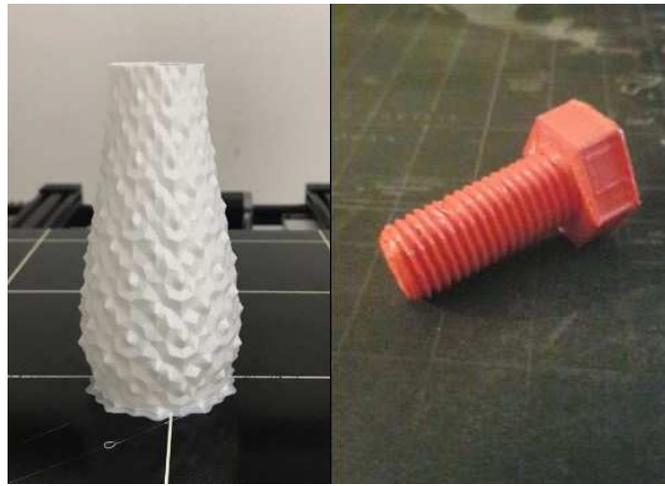


Figure 8. Objects printed by a low cost FDM printer. Photos taken from Amazon customer reviews

1.3.1.4 Powder Bed Fusion

The Powder Bed Fusion (PBF) method encloses different technologies; the most used are Selective Laser Sintering (SLS), for polymers, Direct Metal Laser Sintering (DMLS) and Selective Laser Melting (SLM), for metals.

In each of the PBF technology a heat source, as a laser or an electron beam, is used to fuse selective region of a material in powder form to produce the desired 3D object, layer by layer, like the other AM process already discussed.

In the next sections we will analyse each of these technologies to understand the main differences and the main applications.

1.3.1.4.1 Selective Laser Sintering

The Selective Laser Sintering (SLS) technology was invented by Carl Deckard in 1984.

The printing process relies on the fusion of microscopic plastic particles (nylon powders) using a laser that melts them together creating a single three-dimensional object.

The printing process starts heating the polymer powder to a temperature close to the melting one. The powder is contained within a bin at the side of the printing area. A recoating blade places a thin layer of material on the construction platform. The laser scans the cross-section of the 3D model allowing the powder to reach the melting temperature and solidify. Once the layer has been scanned, the construction platform moves down (50 -200 microns thicknes) and the recoating blade deposits a new layer of powder. The process is repeated until the part is completed. Unsintered particles acts as a base for the part under construction eliminating the necessity of additional supports and permits the slow cooling of the piece, improving the mechanical properties. Once the printing procedure is finished, the object must be cleaned from excess powder. The latter must be filtered to remove the larger particles before being used for the next print. Typically, 50% of the powder can be recycled, making the SLS one of the least wasteful 3D printing processes.

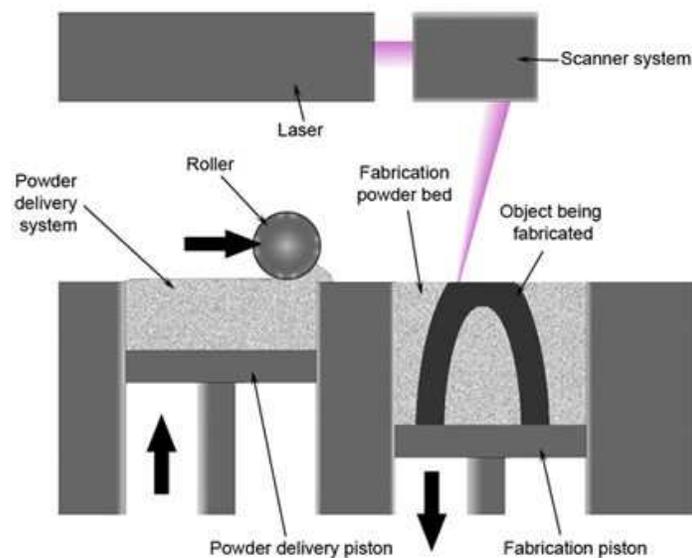


Figure 9. Selective Laser Sintering printer. The powder is applied by a roller.

Parts produced with this type of technology are slightly rough and grainy at the touch and must receive post-processing treatments such as sandblasting, painting, ecc.

The main parameters that govern the accuracy and the surface finish of a SLS printed part are the laser spot size and the layer height (typically 100 microns). Particles size is another parameter that influences the result of a part. In fact, finer powders produce a smoother part surface, but can cause adhesion problems during the recoating stage. Coarser powders cause a rough effect on the piece, although they do not create adhesion problems.

The principal advantages of this technology are:

- No need for support structures;
- Good mechanical properties of the part produced;
- Excellent layer adhesion.

The main limitations of SLS are:

- High cost of the printer;
- Need of a skilled operator;
- Long heating and cooling time that increase the lead time.

The most widely used material is the Polyamide, commonly known as Nylon, which guarantees excellent mechanical properties and can be used for prototypes and functional parts. Other important materials are composites Nylon based like the Glass-filled Nylon and Carbon fiber filled. These materials ensure maximum physical performance with a low weight of the piece.

This technology, due to the high costs, is directed to professional users. Some common applications are rapid manufacturing of medical and aerospace hardware, rapid prototyping of wind-tunnel test models and investment casting patterns.



Figure 10. Aircraft Model for Wind Tunnel Testing printed used SLS technology

1.3.1.4.2 Direct Metal Laser Sintering and Selective Laser Melting

Direct Metal Laser Sintering (DMLS) and Selective Laser Melting (SLM) are printing technologies that use a method similar to SLS for the production of metal parts.

The difference between the DMLS and the SLM is that, the former, does not melt the powder but heats it at a temperature such that the particles can join at a molecular level, while the

latter, uses a laser, which completely melts the powder in order to form a homogeneous part. Because of this technological difference, the DMLS can be used to produce parts using metal alloys, while the SLM can only be used with pure metal powders.

These types of technologies require the use of supports to avoid distortions, even though there is non-sintered powder around the workpiece. One of the problems that can occur is warping due to residual stresses produced during printing and due to high process temperatures. To relieve any residual stress, the parts are heat treated immediately after printing.

The advantages of DMLS and SLM are:

- Production of geometrically complex parts;
- High density of the final product resulting in good mechanical properties;
- High dimensional accuracy.

The disadvantages are:

- Expensive and slow process;
- Tolerances and surface finishes are limited;
- Small building size compared to the other technologies.

The materials commonly used with these two technologies are aluminium alloys, titanium, cobalt chrome, steel and nickel with which prototypes and final components can be produced. The mechanical properties are equivalent or even better than those obtained with traditional processing techniques.

Thanks to the high precision and accuracy it is possible to produce parts for the goldsmith sector and the use of Titanium, a biocompatible material, makes these technologies suitable to produce medical and dental prostheses.



Figure 11. Titanium Skull Section printed by DMLS technology. Customization has a crucial role for prostheses creation.

1.3.1.5 Material Jetting

Material Jetting (MJ) is similar to the inkjet printing technology used for documents. The key difference is that instead of jetting ink on paper, utilizes polymers or waxes that are cured by light, building up one layer at a time. Material is jetted by a nozzle which moves on the construction plane. This additive manufacturing technique is the only one that allows the multi-material printing process, combining different print materials on the same print job, often used to print the support structure with dissolvable material. For this purpose, Drop On Demand (DOD) printers have two nozzles, one to deposit the build material and the other for the support material.

The process starts with the print head that is positioned above the build platform. The material leaks under droplets from the print head and is deposited in the required position using thermal or piezoelectric methods. When the droplets are solidified via a UV light, the build platform goes down one layer thickness and further layers are added on top of the cured one, until the part is completed.

Two important parameters, that influence the surface finish, are the jet droplet size and the layer height. Controlling these factors is possible to create low (16 microns) layer heights obtaining a very smooth surface, that make the Material Jetting one of the most accurate 3D printing techniques.

The main advantages of this technology are:

- High accuracy and homogeneous part;
- Very smooth surface;
- Is possible to create parts with different colours and materials.

The drawbacks are:

- Poor mechanical properties;
- Support material is often required;
- High material costs.

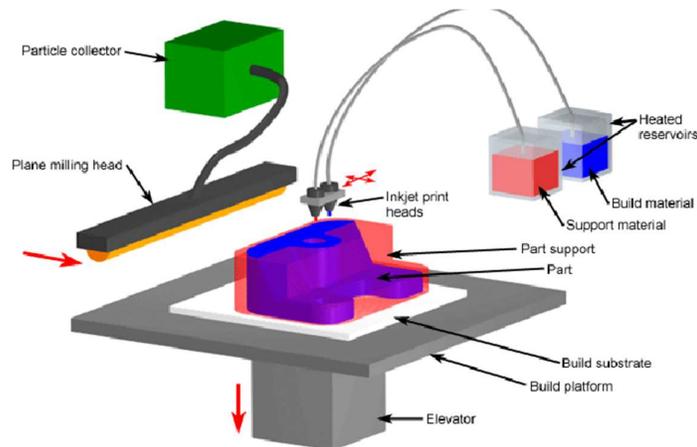


Figure 12. Material Jetting printer

The most widely used material in MJ are the photopolymers and casting that are usually proprietary of the machine producer. In recent years, have been developed material resistant to high temperature, transparent and suitable for medical applications.

The principal use is the production of realistic-looking prototypes thanks to the multi-material capability. One of the most interesting uses, developed by Stratasys, is the production of realistic anatomical models useful for planning and training a surgical operation or for education in medical university.

1.3.1.6 Binder Jetting

Binder Jetting is an additive manufacturing method that uses a liquid binding agent to selective bound together powders, layer by layer, to create a solid part. The printing procedure is similar to the Material Jetting one, the main difference is the liquid used.

The printer is principally composed of a powder bin, print heads, a build platform, a material container and a powder recoater. Binder Jetting technology uses some principles of the SLS with the main difference that throughout the entire process of printing heat is not involved.

In the first phase of the printing process, a single layer of powder is deposited on the build platform. The print head sweeps over the powder surface jetting binder droplets (typically with a diameter of 80 microns) that fuse together the particles to form each layer. The build platform moves down, another layer of uncured powder is created and the process is repeated until the part is completed.

After the process is completed, the part has to be left in the powder to be cured and increase the resistance of the component. When this post-printing process is finished the unbound powder on the piece is removed via compressed air.

The principal advantages are:

- Heat-caused disorders, like warping, are not present, since there is no heat involved;
- Big parts can be printed;
- Inexpensive materials;
- Unused powder is 100% recyclable.

The main disadvantages are:

- Poor mechanical properties;
- Grainy surface finish.

Binder Jetting can be used to create sand cast moulds and core, used for metal casting processes. The products obtained are low-cost and have complex geometries compared to traditional techniques. The material used for this purpose is the Silica Sand.

Another application of the Binder Jetting is the production of metal parts with complex geometries. The metal parts obtained have low mechanical properties. In order to produce functional pieces, a secondary process is required for enhancing the part's strength and density. The two main techniques are Infiltration, using Infiltration of bronze via capillary action, and Sintering, in which the parts are exposed to high temperature in a furnace. Some metal materials are Stainless steel (with bronze infiltration), Inconel alloy and Tungsten Carbide.

It's important to know that Binder Jetting does not need support structure reducing the post processing time and the quantity of material used.

1.3.1.7 Direct Energy Deposition

Direct Energy Deposition (DED) processes creates structures by melting a material, usually metal, in the form of powder or wire, through a concentrated heat source (laser, electron beam or arc). The machine consists of a nozzle mounted on a multi-axis arm that deposits the molten material in a selective way, creating the various layers.

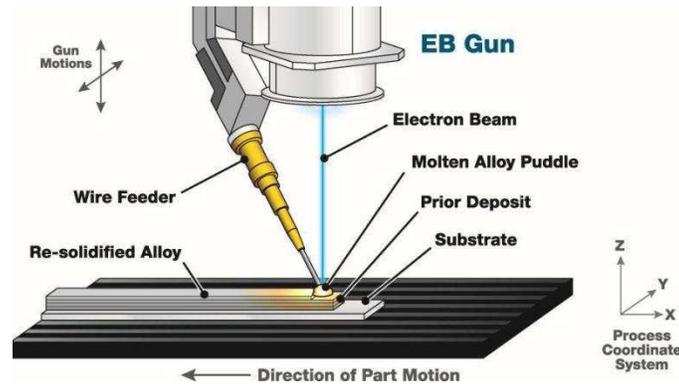


Figure 13. Direct Energy Deposition process

The cooling times are limited and this positively affects the final grain structure of the part. The height of the layers is typical between 0.25 mm and 0.5 mm.

The principal advantages are:

- Multi material capabilities;
- High mechanical properties of the part;
- High printing speed.

The main disadvantage of this method is the cost. In fact, the machine requires a big initial investment (nearly \$500,000) limiting the access of this technology only to big companies.

This process is commonly used to repair or add material to existing components; it also offers the possibility to print simultaneously using different materials, unlike Power Bed Fusion technology. The material used are Titanium, Tantalum and Cobalt Chrome.

1.3.1.8 Sheet Lamination

The Sheet Lamination printing technology includes two different technologies: Laminated Object Manufacturing (LOM) and Ultrasonic Additive Manufacturing (UAM). In the first, layers of paper are cut and joined by adhesive, creating aesthetic and visual models, that cannot be used for functional purposes. The most commonly used material is A4 paper. In

the UAM approach sheets or ribbons of metal are joined using an ultrasonic welding. In this case a CNC post treatment is required in order to separate each model created.

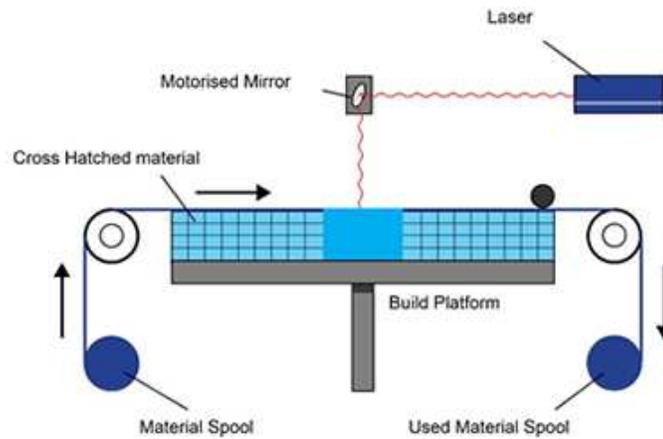


Figure 14. Metal Sheet Lamination function scheme

The benefits of these technologies are:

- Fast and low cost;
- Easy material handling;
- Cutting process is really fast.

The drawbacks are:

- Good finishes can be achieved only by post-processing process;
- Is possible to use only material than can be laminated.

This method requires materials that are capable to be rolled like paper, plastic and some metal sheet. Using paper is possible to create parts for ergonomic studies and topography visualization, whereas with metals is possible to produce components for automotive and aerospace industries.

1.4 Post-processing operations

The operation carried out after the printing process are extremely important for the correct outcome of a part. Despite the printing process in completely automatic, the post-processing phases require specific knowledge and machines in order to enhance the properties of the material and achieve a better surface finish.

Parts have to be extracted from the printers and separated from the building platform. During this process the support structures still fixed at the parts have to be removed.

Supports provides a stand during the deposition of the layers and are necessary to avoid the collapse of the structure during the creation, when the material is still soft. Efficient supports must be easy to remove and, if possible, should be placed in non-functional parts of the workpiece so as not to affect visible surfaces. The necessity, the position and the quantity of support vary with the shape of the part and the printing technology used.



Figure 15. An arch shaped structure needs of a support

Many printed parts need to be cured before handling; the most common curing technology consist of an exposition to UV light. The necessity and the type of curing process depends on the piece's final use and the printing technology. As will be seen in chapter 3, STL printing process requires UV post curing especially for medical devices, requiring high physical characteristics.

1.5 Conclusions

As seen, the AM umbrella covers many technologies that allow the different users, from hobbyists to high tech industry players, to simplify the production of goods. Engineers and researchers work constantly to improve actual technologies performance and to develop new printing method.

2 Chapter 02: Economic characteristics of AM

2.1 Introduction

There are many researches that study AM production methods, materials and technologies but, despite the high economic influence that characterizes this technology, researches on the numerous effects from a business prospective are still scarce.

AM has the ability to change the market structure bringing disruptive consequences in sectors characterized by the need of high flexibility, customization and short time to market. In the next section the AM phenomenon will be analysed, starting from the economic characteristics and the limits of this technology, and continuing with the applications and the market trends.

2.2 Economic opportunities of AM

Compared to traditional production systems, AM finds fertile ground in industry sectors in which there is a demand for innovative and complex products; in fact, using a layer-by-layer production method, the only limit is the creativity of the designer or the end user looking for a personalized product.

2.2.1 Design improvement

The creation of parts by layers addition, allows the engineers to develop products with complex shapes, difficult to produce with traditional methods of subtractive manufacturing or injection moulding, overcoming the technical production barriers.

In aeronautical sector 3D printing allows the creation of complex structures in order to produce lightweight components maintaining the same mechanical properties. Figure 16 shows an example of aeronautical component that has been completely redesigned obtaining a reduction of weight of more than 45%. This re-design can improve the performance and reduces the environmental impact of many products.

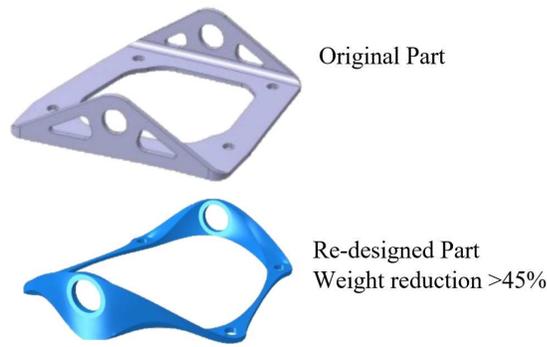


Figure 16. An example of redesign of an aeronautical component

2.2.2 Mass Customization

AM allows firms to easily access to Mass Customization, “a marketing and manufacturing technique which combines the flexibility and personalization of custom-made products with the low unit costs associated with mass production.” (Source: Investopedia)

A clear example of mass customization is provided by MINI, a British company owned by BMW, that in 2018 launched a customer-friendly customization software by which each user can create unique parts for his mini, such as side scuttles and LED door sills. The client can design his own part on the “your-customized.mini” website freely choose the colour and decoration or enter a drawing or a text using the online tool. Once satisfied of the result, the client, can order the piece which will be received directly at home ready to be easily installed on its custom mini.

MINI SIDE SCUTTLES CUSTOMISED.

Make your own personal mark on the cityscape. With individual side scuttles, add a new favourite piece to your MINI.

€145.00

GET INSPIRED



Figure 17. The side scutter includes the side direction indicators and is an element that gives individuality to each mini.

Image taken from the MINI website

Thanks to 3D printing, firms can increase the perceived value of the product and raise the customers willingness to pay allowing to charge a price premium. Considering the previous example, the starting price of a mass-produced side scuttles is 76 euros, while the price of a personalized one starts from 145 euros. The price premium of 69 euros is a brilliant example

of how customization create uniqueness, increasing the value of a product and therefore the price without incurring in manufacturing cost penalty thanks to the use of AM. In addition, is not possible to overlook the customer satisfaction that MINI brings by providing this innovative service which can be considered a winning marketing strategy.

2.2.3 Flexibility

With traditional manufacturing systems, product variety causes an increase in the complexity of the supply chain that leading to higher costs. Adopting AM is possible to obtain an unconventional high flexible production system.

The papers “*Economic Implication of Additive Manufacturing and the Contribution of MIS*” explains the difference between traditional manufacturing systems and additive manufacturing using two production dimensions: Efficiency and Flexibility. Efficiency is achieved by product design standardization and high degree of automation whereas Flexibility is obtained by fast reacting to production volume changes and design modifications and offering a wide product variants. The author, prof. Frederic Thiesse, defines a frontier, represented in figure 18, that separates “*feasible production scenarios from the Star Trek Replicator and other fictional devices from the world of magic*” ironically underlining that it is impossible to obtain a system that ensures high efficiency and flexibility at the same time. The AM adoption, however, moves this technological frontier extending the scope of traditional manufacturing systems and opening new opportunities for manufacturing companies. As an example, using AM firms can easily adjust the design of a product during the manufacturing phase without penalties.

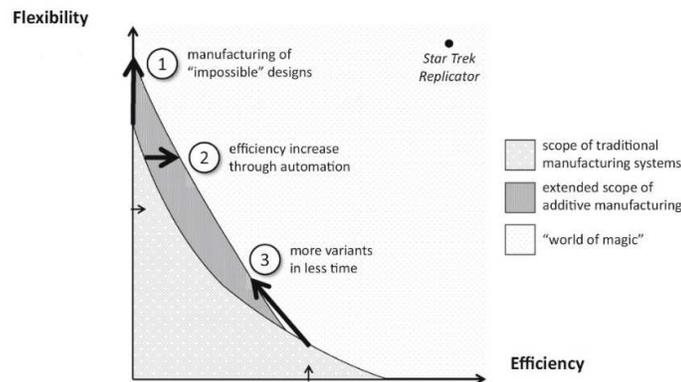


Figure 18. Impact of 3D printing on manufacturing systems

Finally, it should be noted that 3D printing systems are easily scalable and then is possible to add machines when there is an increase in demand without incurring in sunk costs and asset specificity issues.

2.2.4 Manufacturing decentralization

The ability to produce small batches of complex parts anywhere in the world, reduces the benefits associated with economies of scale requiring mass production on a single site with the aim to distribute the important fixed costs. The high cost of shipping finished parts could move production near the final place of use, avoiding the risk of delivery delays that often dramatically increase final costs. In the light of these considerations, producing in low-wage countries may no longer be convenient. A further advantage could be the possibility of producing spare parts in remote areas that are difficult to reach in a short time. Just think of the project launched in 2014 by NASA, in collaboration with Made in Space with the aim to produce directly in space the needed tools and spare parts for the International Space Station. This approach can reduce the need of transport spare parts on the Space Station drastically decreasing the costs. Just to make an idea, carrying one kilogram into the space costs nearly \$5,000.



Figure 19. Test of a 3D printer in a zero-gravity chamber

2.2.5 Buy-To-Fly ratio

The term Buy-To-Fly (BTF) was coined in the aeronautical industry and indicates how much material is purchased to produce a part respect to the material effective present in the final part. This indicator gives an idea of the quantity of material discarded during the production process compared to the raw material used.

$$\text{Buy - To - Fly ratio} = \frac{\text{weight of raw material}}{\text{weight of component}}$$

With the current status of technologies is impossible to achieve a ratio of 1, which means no waste materials, but additive technologies reaches values very close to this ideal level. Using subtractive methods BTF is heavily influenced by the shape of the part to be produced. The production of parts with a big hole typically involves the waste of a large amount of material. For example, the realization of the piece in figure 20 requires the use of a bar with a diameter greater than the maximum diametrical dimension of the piece to be realized, which must be drilled internally, giving a BTF ratio of 9:1. Thanks to AM technology it is possible to make the same part, layer-by-layer, with a BTF ratio of 2:1.



Figure 20. An example in which the use of AM brings benefits

Economic advantages deriving from the use of additive technologies can only be obtained when the cost of raw materials is high. This is often the case in the medical and aeronautical industries where light, resistant and often biocompatible materials such as titanium and zirconia must necessarily be used. In addition, each production case must be assessed individually because, as discussed in the next chapter, the cost of materials for 3D printing is significantly higher than the cost of the same amount of material for common manufacturing.

2.3 AM obstacles and limitations

The various technological and economic opportunities that AM offers are balanced against the limits and growing challenges that this technology has to faces.

2.3.1 Cost of machineries and materials

The cost of printing machines and raw materials highly influence the operating expenses. Despite the expiry of patents and the market entry of new printers' manufacturers, the prices remain high, especially for large, high-definition machines used for the production of final components. The cost of low-entry level machines has dropped significantly in recent years and in fact it is possible to find printers, which mainly use Fusion Deposition Moulding technologies, at the same price of a A4 papers laser printer. As an example, on Amazon website is possible to buy a basic model for only 249 euros. The drop of the prices allows the diffusion of AM for home printing or rapid prototyping of non-functional parts because, often, no high qualities are needed.

On the other hand, the high cost of printing materials makes marginal production cost higher than traditional technologies. From a technical perspective, the materials used do not have standard shapes and are more complicated and costly to obtain. Titanium powder, used to produce components for the aeronautical sector, can cost up to 10 times more than titanium bars and this significantly increases the cost of the final components despite the use of less material.

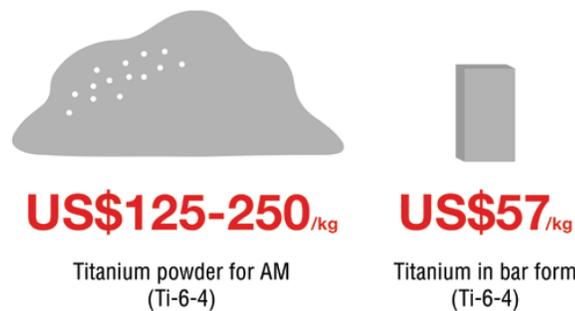


Figure 21. Price for kilogram of Titanium in powder and bar form

The price of raw materials could decrease with the entry of new competitors into the AM materials industry. However, many 3D printer manufacturers push customers to use the materials they supply, by creating printers that can only use proprietary resins or use warranty clauses and electromechanical or software blocks; this strategy reduces the competition in the 3D materials market, keeping the prices high. Formlabs, on Form 2 and Form 3 devices, uses a sales model similar to the document printers one; in fact, the resins are marketed in the form of cartridges that the customer can quickly insert into the printer just like a common ink-jet printer.



Figure 22. Substitution of a cartridge on a Formlabs Form 2 printers

2.3.2 Production time

Compared to traditional mass production systems, such as injection moulding, production times resulting by the use of additive technologies are relatively longer. For these reasons, 3D printers are used for large-scale production only in situations in which mass customization is required. However, it is important to note that production times can be significantly reduced if more parts are created in parallel. In fact, depending on the size of the pieces, it is possible to insert several parts within the same printing batch, which are produced simultaneously.



Figure 23. Different dental models produced in the same batch

2.3.3 Quality obtained

Traditional subtractive manufacturing systems involve the production of a part by working a block of raw material. This workflow ensures that the internal properties of the part remain unaltered after machining obtaining high quality parts over a prolonged production run.

Actually, also with additive technologies it is possible to produce quality parts. However, there are many technical variables, such as environmental conditions (humidity, temperature, etc.) and material characteristics that can affect the microstructure of a component. As a consequence, can happen that two products, created using two identical printers in the same building, have different qualities causing a discrepancy in the batch quality. The alteration of the internal structure of a printed piece can be verified only through the use of ultrasounds or computerized tomography, two expensive and slow control techniques.

This problem of uncertainty places important limits on the production of devices for the aeronautical and medical sector, in which, as we will see in the next chapter, certifications of each product are necessary. This issue also poses a strong barrier to medium batch production in sectors where manufacturing quality have primary importance. For small batches AM still remains valid as the cost reduction achieved by the flexibility provided abundantly compensates the higher costs for quality controls.

2.3.4 Traditional attitude

One of the biggest challenges that obstacles the rapid diffusion of AM is the traditional attitude characterized of traditions and fixed mindsets. The most frequent question that 3D printer vendors receive from potential customers is: “*Why do we have to change if we always done in this way?*”. This point of view can be easily fixed in a company’s culture slowly the AM diffusion. This attitude can be dangerous for the companies is not willing to innovate. In fact, in the medium-long term, these firms can lose competitive advantage because of the change in sector dynamics and the arrival of new entrants able to exploit the resources of AM. This problem is even more rooted in small business realities, such as dental offices, as will be discussed.

2.4 The “Economies of One” production model

The industrial revolution, thanks to the development of mass production systems, has made possible the replacement of human work with machine capable of producing larger quantities in less time. In an economic model characterized by traditional production systems, a company gains competitive advantage producing high quality components at a lower price compared to its competitors. This model subdivides costs in Fixed and Variable: the former includes the facilities and machineries costs and does not depends on quantities, while the latter includes expenses that varies with the amount produced like labour cost and material.

The *Economies of scale* model involves the production of large quantities of goods, allowing the distribution of fixed costs on a major number of products, decreasing the per-unit cost. With the introduction of 3D printing, the production of small batches and high customized product is easier, allowing the birth of a new model called "*Economies of One*". The term was coined with the intent to highlight that, using 3D printing, is possible to create one batch or even one single piece without incurring in fixed costs.

According to many researches, AM will have disruptive effects on some sectors and products, changing the actual way of doing business: "*In essence future manufacturers will be governed by two sets of rules: economies of scale for interchangeable parts produced at high volume, and economies of one for highly customizable products that can be built later by layer*".

With innovative manufacturing systems, the traditional *Design-Build-Deliver (DBD)* model does not work at all. In fact, this model typically used for scale economies requires a net separation roles between the operators involved in the development stages:

- **Design** - designers have to design parts according to determinates rules that limit the product complexity and guarantee a cost-effective production;
- **Build** - producers focused on create goods in an efficient and low-cost way typically in low-wage countries;
- **Deliver** - supply chain specialists that procure low-cost raw material and ensure an efficient transportation of the final goods.

In a 3D printing world, an ever-increasing number of hobbyists and small producers can create new objects without following any strict design rule but simply using their own imagination. This projects usually are shared in communities and web forum to obtain suggestion and allow other users to print the same object in another side of the world. Some famous web communities are: Sculpteo, 3DShare, 3DLT, Thingiverse, Shapeways, Layer by Layer and Prusaprinter. With this approach users can download from one of these platforms the digital format of an object and produce it thanks to a desktop printer. This effect can sensibly modify the actually market dynamic.



Figure 24. The digital file of sunglass visor clip can be freely download on Thingiverse.com

Many companies offer an on-demand printing service, allowing an large public to exploit the additive world benefits without investing in a printer. As an example, Stratasys offers a 3D printing service by which clients can upload the 3D file, choose material and printing method and receive after some days the part directly at home. With this approach the fixed costs, associated with the investment in a printer, became a variable cost, allowing to use the best technologies without incurring in high costs.

In Table 1 is presented a comparison between Economies of Scale and “Economies of One” regarding different economic aspects.

	Economies of Scale	Economies of One
Source of competitive advantage	Low cost, high volume, high variety	End-user customization
Supply chain	Sequential linear handoffs between distributed manufacturers with well-defined roles and responsibilities	Non-linear, localized collaboration with ill-defined roles and responsibilities
Distribution	High volume covers transportation costs	Direct interaction between local consumer/client and producer
Economic model	Fixed costs + variable costs	Nearly all costs become variable
Design	Simplified designs dictated by manufacturing constraints	Complex and unique designs afford customization
Competition	Well-defined set of competitors	Continuously changing set of competitors

Table 1. Economies of scale vs Economies of One

2.5 How AM impacts different sectors

Many industries can exploit the benefit introduced from AM respect of traditional manufacturing. The potential of this technology varies from each industry landscape and in the following parts have been analysed.

2.5.1 Aerospace

As already said in section 2.2, AM technologies are effective in the aerospace sector in order to produce better designed product decreasing the buy-to-fly ratio, a crucial indicator in aeronautic design, due to the costs of the raw materials.

The dominant market players Airbus and Boeing already use this technology to efficiently produce components for military and commercial jet without reporting any failures of these parts. The particular design that can be obtained by AM reduces the total weight of the aircraft with a significant cost saving and reduction in environmental impact. Just think that each kilogram less means a reduction of 1,300 \$ of fuel every year to imagine the benefits that AM can bring.

The most used technologies are from the family of the Powder Bed Fusion, because of the needed of metal parts with high mechanical properties.

2.5.2 Automotive

The automotive industry is currently characterized by high cost pressure. The spare parts market is assisting a reduction in margins due to the necessity to maintain into the inventory components for old vehicles models. In addition to this, as discussed for the example of MINI in section 2.2.2, the customers are looking for high customized parts for their cars increasing production's complexity.

With direct manufacturing production is possible to produce spare parts for old vehicle on demand, sensibly decreasing the inventory costs. In addition, the producer can easily add value to cars by customization. As an example, Bugatti offers to customers the possibility to personalize the dashboard of Bugatti Veyron, a 1 million dollars car. Another example comes from BMW, that produce a light water pump wheel for the Z4 GT3, a high-performance super sport car. These two examples emphasize the fact that, with the actual technology state, 3D printing is a valid production method only for small batches of high-end products. It is

not possible to apply AM for the production on pump wheel of the numerous Fiat Panda produced each year.

In this segment are exploited Powder Bed Fusion technologies, Fusion Deposition Modelling and Stereolithography depending on material and quality needed.



Figure 25. 3D printed water pump wheel produced by BMW

2.5.3 Architecture

Additive technologies can eliminate the artisanal process commonly adopted to produce building architectural models which reproduce the building design and represent a valid instrument to present the project to clients. The artisan creation method is time consuming and cost ineffective, because involves the creation of the model starting from thin sheets of wood catted in numerous parts that subsequently are glued. Using an entry-level 3D printer, the models can be automatic created at a lower cost, even letting the printers working during the night, simplifying the work of architects.

Usually the Fused Deposition Modelling is the most suitable technique used because models are typically composed of resin and does not require accurate finishes and high physical properties.



Figure 26. 3D printed apartments model

2.5.4 Medical

Customization, flexibility and biocompatibility are fundamental requirements in the production of medical devices such as surgical aids, hearing aids and prosthetics. Thanks to this technology is possible to scan the patient's body and create tailor made devices reducing surgery time, costs and post-operative complications. As we will see, 3D printing found fertile ground in dentistry for the production of dental crowns, aligners and surgical guides. In the recent years, the printing of human organs is becoming reality. Organs are created layer-by-layer using living cells in a gel vector. It is also possible to create skin, vascular grafts and heart tissues.

The most widely used technique is the Stereolithography, thanks to the fact that is possible to use biocompatible resins. In addition, Fused Deposition Modelling is successfully used in prosthetics to print biocompatible titanium devices proper biocompatibility.



Figure 27. 3D printed hearing aids shells with customized for each patient's ears

2.5.5 Resources industry

Typically, the resource industry involves the exploitation of natural resources in remote areas such as oceans and deserts that sensibly increase the transportation cost and, as a result, the maintenance costs. The availability of spare parts on the site is crucial for maintenance operation and to limit downtimes. The price volatility of commodities impacts the profits of this sector and maintenance costs minimization is a key point in order to increase the margins.

AM can reduce the need of massive storage of spare parts directly on the site; in fact, thanks to this technology is possible to produce a spare part when and where in needed, overcoming the geopolitical barriers that can delay the shipping of days.

This production on-site procedure can be limited by the unwillingness from the suppliers to give the CAD drawings for IP issues. To overcome this problem, a nondisclosure agreement can be settled by the parts.

As for the other segments in which the principal purpose is to produce spare parts, technologies used are Powder Bed Fusion, Fusion Deposition Modelling and Stereolithography depending on material and quality needed.

2.5.6 Retail

In the last years the customers' preferences are changed, crisis the large multinational that were relying on a mass production and extensive supply chains. An EY research reports that clients "*are demanding LATTE (Local, Authentic, Traceable, Transparent and Ethical) products*". The extensive research of authentic and customized products pushes the firms to add, at the mass production model, a mass customization model to satisfy the request of particular customers. The market of shoes is full of clients looking for exclusive products with a high willingness to pay for them and the producer can gain competitive advantage by capture this value added bring by customization. As an example, Nike allow the user to personalize sneakers directly on the website using 3D modelling. As the example of MINI customization is a winner market strategy.

The techniques used are principally Stereolithography and Fusion Deposition Modelling.

Applications and the benefits of using AM are summarized, for each industry, in Table 2.

Industry	Applications	Benefits Gained
Aerospace	Prototyping Component manufacturing Reducing aircraft weight Engine components for the Airbus Flight-certified hardware Manufacturing of satellite components	Produce very complex work pieces at low cost Allow product lifecycle leverage Objects manufactured in remote locations, as delivery of goods is no longer a restriction A reduction in lead-time would imply a reduction in inventory and a reduction in costs On-demand manufacturing for astronauts Eliminate excess parts that cause drag and add weight Improve quality
Automotive	Prototyping Component manufacturing Reducing vehicle weight Cooling system for race car	Help eliminate excess parts Speed up time to market Reduce the cost involved in product development Reduce repair costs considerably Reduce inventory Could effectively change the way cars will look and function in the future Improve quality
Healthcare and Medical	Fabricating custom implants, such as hearing aids and prosthetics Manufacturing human organs Reconstructing bones, body parts Hip joints and skull implants Robotic hand	Reduced surgery time and cost Reduced the risk of post-operative complications Reduced lead-time
Dentistry and Dental Technology	Dental coping Precisely tailored teeth and dental crowns Dental and orthodontic appliances Prototyping	Great potential in the use of new materials Reduced lead-time Prosthetics could be fabricated in only a day, sometimes even in a few hours
Architectural and Construction	Generating an exact scale model of the building Printing housing components	Producing scale models up to 60% lighter Reduce lead times of production by 50—80% The ability to review a model saves valuable time and money caused by rework Reduce construction time and manpower Increase customization Reduce construction cost provide low cost housing to poverty-stricken areas
Retail/ Apparel	Shoes and clothing Fashion and consumer goods Consumer grade eyewear Titanium eyeglass frames Production of durable plastic and metal bicycle accessories	On-demand custom fit and styling Reduce supply chain costs Create and deliver products in small quantities in real time Create overall better products Products get to market quicker
Food	Chocolate and candy Flat foods such as crackers, pasta and pizza	The ability to squeeze out food, layer by layer, into 3-D objects Reduce cost Feasibility of printing food in space

Table 2. Application and benefits of the use of additive manufacturing

2.6 AM market trends

After having analysed the economic characteristics of AM some figures and charts regarding the revenues and the adoption in different sectors have been presented.

2.6.1 Worldwide revenues

For the year 2014, Wohlers Report calculates a CAGR of 35.2% for the AM industry, resulting in a \$4.103 billion revenues. This was defined “*the industry’s strongest growth in 18 years*” highlighting the enormous economic potential of this technology. From this time AM continues to growth rapidly, surpassing in 2017, the \$7.000 billion revenues for products and services worldwide and growing almost twice from 2014.

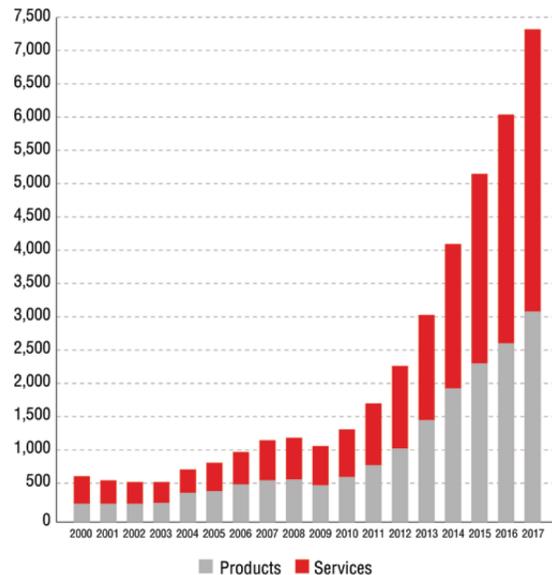


Figure 28. Revenues of AM products and services worldwide. (Source: Wohlers Report 2018)

Another important data, standing from the Wohlers Report 2018, is the incredible growth in sales of metal AM systems. In fact, sales rose from 983 systems in 2016 to an estimation of 1,768 systems in 2017, resulting in an increasing of nearly 80%. This result shows that world producers of metal parts are becoming more and more interested in using this new technology thanks also to technological progresses and the increasing competition in 3D printers market that lowering prices.

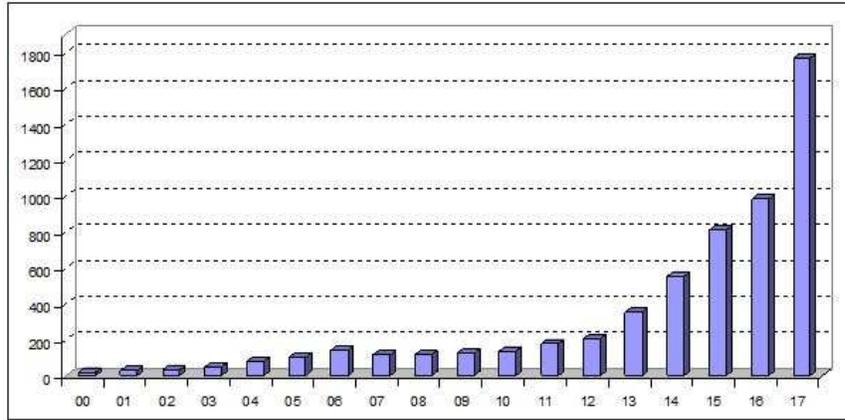


Figure 29. The incredible rise in metal AM system sales (Source: Wohlers Report 2018)

2.6.2 Industry sectors

As seen, AM method found fertile ground almost in every business field. Wohler Associates, in its AM annual report made a survey interviewing a sample of manufacturers of industrial AM systems and service providers worldwide. In the survey it was asked at each company to indicate the field of the companies they serve and the approximated revenues in order to give a picture of the AM adoption in different sectors. The results for the years 2013, 2015 and 2017 are presented in the figure below and are a valid instrument to visualize the increasing/decreasing trends.

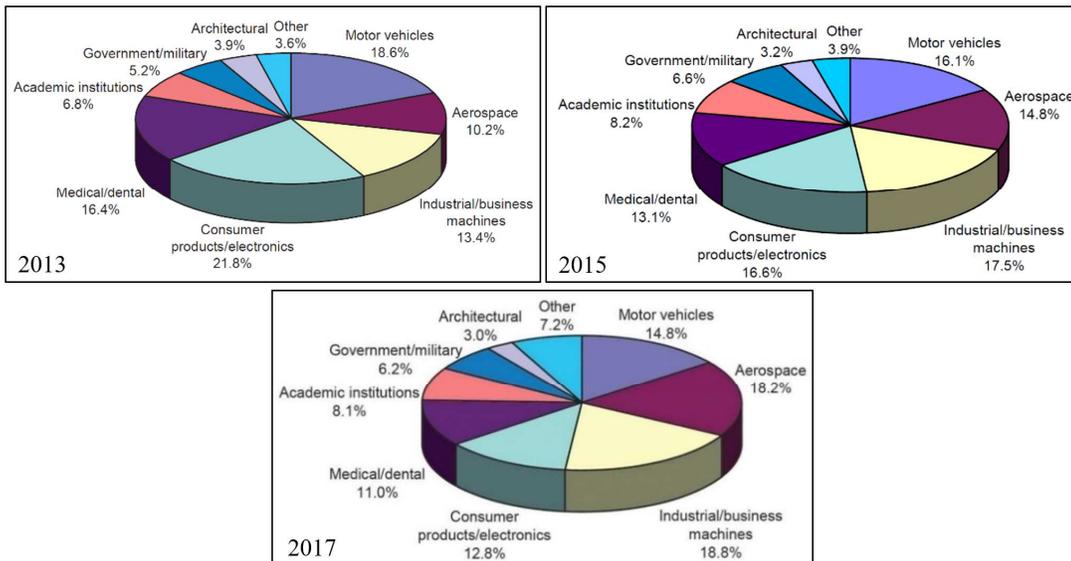


Figure 30. AM sectoral distribution for different years.

Observing the graphs, is easy to identify the five dominant fields during the period 2013-2017: Motor Vehicles, Aerospace, Industrial/business machines, Consumer products/electronics and Medical/dental. The Graph below represents adoption evolution of AM in the five dominant fields during four years. It is possible to declare that there is an increase in adoption only in the Aerospace and Industrial business industry. The adoption from the remaining sectors shows a decreasing trend leaving space to the Other sector (oil and gas, non-consumer sporting goods, commercial marine products, and various other industries) and Academic institutions.

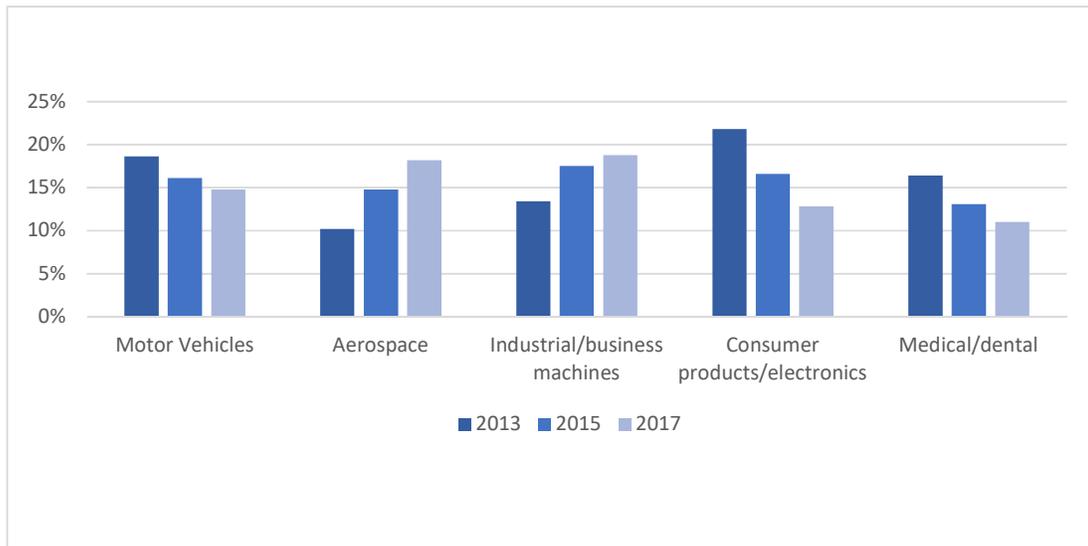


Figure 31. Evolution of AM sectoral distribution

2.6.3 Market shares

The pie chart in figure 32 represents the estimate (Wohlers Report 2015) unit sales market share of the leading manufacturers of 3D printing systems. Stratasys, that in 2014 sold 6,665 systems, dominates with a market share of 51.9%, followed by 3D Systems with 16.5% of market share. It is curious to note that, despite, in 2014, Stratasys registered a market share drop of -2.8%, still is the leader in sales for the 13th consecutive year.

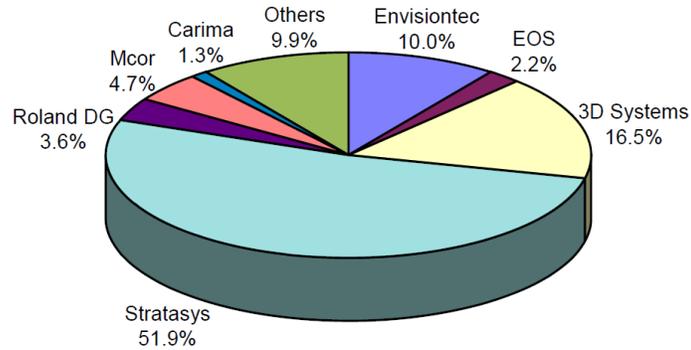


Figure 32. 3D printers market share (Source: Wohlers Report 2015)

Regarding the geographical distribution of the systems production and sales, the U.S. no longer owns the first position. In fact, in December 2012, Stratasys, an ex-US based company, merged with Objet, Israeli-based and the new legal entity, called Stratasys Ltd., was registered in Israel. The figure below shows how the U.S. production shockingly drop from nearly 60 % in 2013 to 17.2 % in 2014, underlining the enormous influence of Stratasys in this sector. For the other geographical areas, the position of Europe risen from 19.2 % in 2013 to 22% in 2014. Also, Asia registered an important grew, from 5.4 % in 2013 to 9 % in 2014.

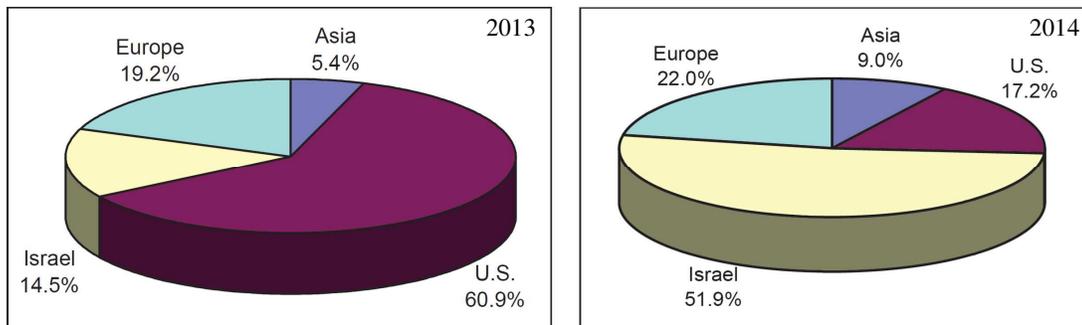


Figure 33. Geographical distribution of market of system production and sale in 2013 and 2014

2.6.4 3D printing Hype effect

Each innovation, during its lifecycle, lives an Incubation period that is particular interesting to analyse. This time is characterized by a limited diffusion and an immaturity of the new technology, but despite this fact, in many cases, the expectations are high, and the promises are exaggerated. This phenomenon is called *hyperinflated expectations* or *hype*.

Garter, a consulting company for technology, proposed a visual interpretation of the phenomenon in a *hype cycle* form (see figure 34).

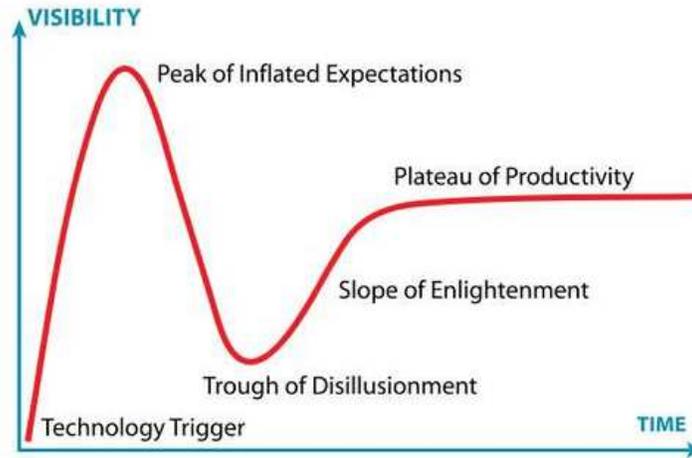


Figure 34. The Hype Cycle

The cycle is characterized by five subphases:

- **Technology Trigger:** the concept of a technology compares on the market, in a prototype form, attracting the media attention. The optimism of the creators raises the expectations.
- **Peak of Inflated Expectation:** progresses in technology and the first applications sensibly increase the expectations, that became unrealistic, and the creators gain a lot of visibility;
- **Trough of Disillusionment:** some problems regarding the product stand up and the market lose interest. The product has to be improved to meet the expectation of the customers;
- **Slope of Enlightenment:** the technology is maturing and improving;
- **Plateau of productivity:** the technology gets mature and people better understand it applications. Important revenues are generated.

Expectations, technological improvements and, on the other side, loss of interest and technological problems, affect the evolution of share prices of companies that launch an innovative product. A correlation between the stock price and the Hype Cycle can be hypothesised and it is possible to verify this effect in the 3D printing industry. In figures 35 and 36 are represented the share prices of two leading companies of this sector, 3D Systems and Stratasys. The hype effect it was traced in blue in figure 35. From the drawing is possible to hypothesize that the peak of inflated expectations was reached from Stratasys at the beginning of 2014 when stock price reached the maximum, 136.46 USD. A sensational result

considering that in 1994 the price was only 1.83 USD. For 3D Systems the peak arguably was reached in the same period, when the price raised at the historical maximum of 96.42 USD per share.



Figure 35. Stock price evolution of Stratasys. The blue line highlights the Hype effect



Figure 36. Stock price evolution of 3D Systems

The hypothesis regarding the peak of inflated expectation finds confirmation in the annual studies of Gartner for the years from 2010 to 2014, that shows the position in the hype curve of different technologies. From figure 37 is possible to confirm that the peak from Consumer 3D printing was reached between the 2013 and 2014, proving the result of figure 35.

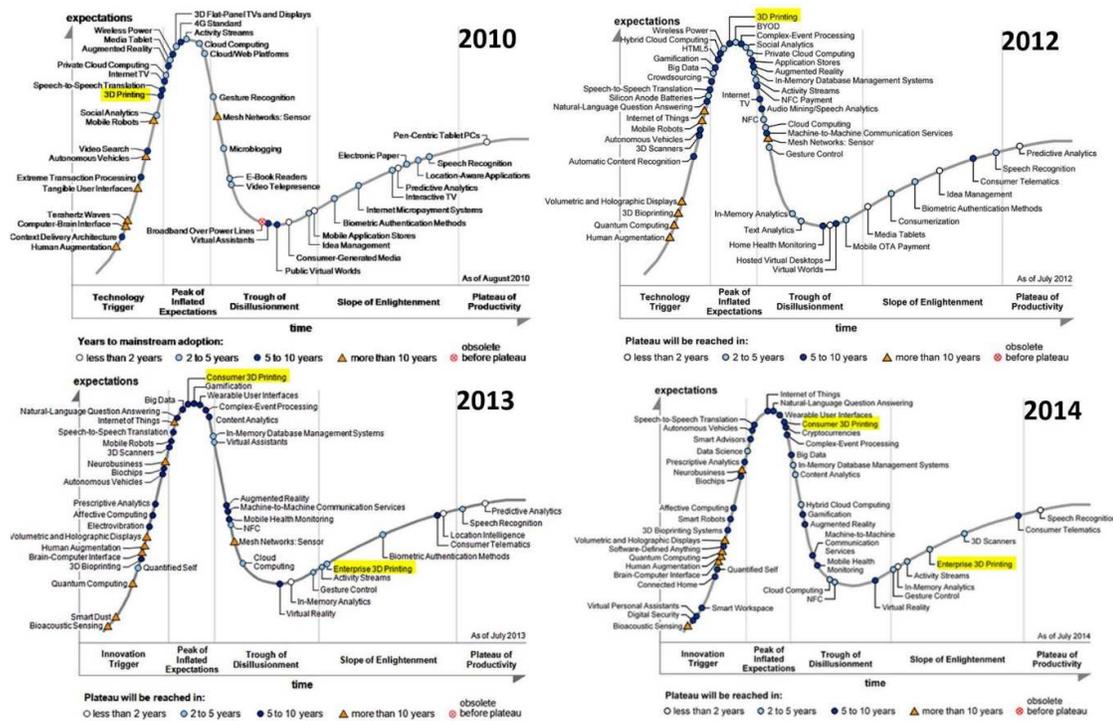


Figure 37 : Gartner Hype Cycle for different years.

3 Chapter 03: Current status of Additive Manufacturing in dental sector

3.1 Introduction

Dental care has always been a fundamental need for every human. The first traces of rudimentary dental instruments date back to the time of the Neanderthal man. In the Middle Ages, dentistry was not considered as a profession and treatments were often carried out by barbers and monks. Modern dentistry began to develop between 1650 and 1800 thanks to a French surgeon called Pierre Fauchard. Since then, the dental industry has been interested in continuous innovations such as better extraction tools, dentist's chairs and hand drills. Technological progress has led to the study of new materials, treatment techniques and new devices that have made modern dental care painless and safe, enabling it to satisfy a primary physical and aesthetic need.

In the following paragraphs the concept of Digital Dentistry is presented by using a case study on the production of a crown for dental implants, making a comparison between the analogical and digital procedures. This chapter focuses on the technologies used in Digital Dentistry, including additive manufacturing which is treated in the final part.

3.2 The digitalization of dentistry sector

The dental sector has always been interested by the use of the most advanced technologies and the best materials, in order to facilitate the dental treatments routine and to plan the most difficult surgical operations.

Digital Dentistry is the greatest progress that has occurred in recent years in the dental industry, which is based on digital tools that simplify the work of dentists and dental technicians in the diagnosis, communication and treatment of the patients. The most commonly used technologies in Digital Dentistry are Intraoral scanners, CAD/CAM, Digital radiography, 3D Printing and Photography.

To make a comparison between the Traditional and the Digital approach was considered the example of a patient who needs to have an installation of a fixed dental prosthesis. The production process described is also used, with some variances, to produce Clear Aligners, Surgical Guides, Dental Model and Wax Pattern, which will be presented later.

A dental implant is a fixed device, used to replace missing or extracted teeth, consisting mainly of three parts:

- **Screw**, which replaces the natural root of the tooth and is screwed directly to the maxilla or the mandible;
- **Abutment**, a connecting element between implant and crown;
- **Crown**, an artificial reproduction of the natural human crown.

In the figure 38 is presented a dental implant with its main components.

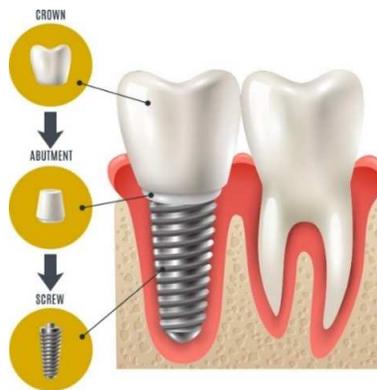


Figure 38. On the left a dental implant. On the right a natural tooth.

The first two components, screw and abutment, are standardized and marketed in different dimensions and shapes, depending on the bone resistance, the tooth they have to support and the thickness of the mandible or maxilla of the specific patient. The crown, instead, must be specifically produced for the patient under treatment, with dimensions, shape and colour that fits the rest of his teeth. The focus of this analysis, therefore, is the production of the crown.

In the figure 39 are presented the different phases to obtain a crown. In the left and the right part of the picture are represented both the Traditional and the Digital approach.

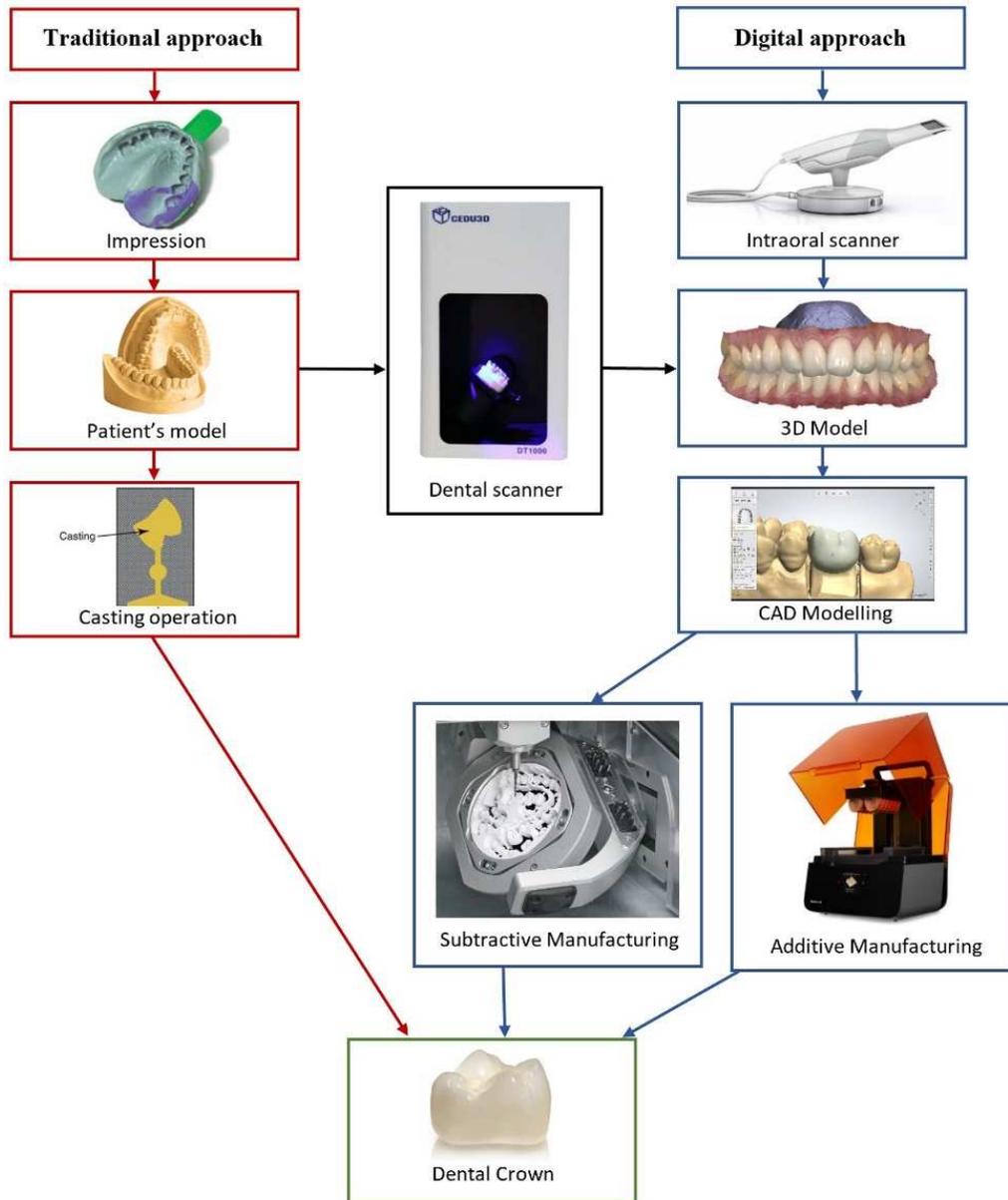


Figure 39. Traditional vs Digital workflow

3.2.1 Traditional Workflow

Neglecting the surgical operation of fixing the screw, the first operation that the dentist executes is to take an impression of the patient's dentition in order to obtain a reproduction of the patient's mouth, necessary to construct the crown.

The traditional method to collect the impression involves the use of an arch-shaped Dental Impression Spoon filled with a special soft paste, which, positioned in the mouth of the patient, quickly hardens and take the shape of teeth and gums. The main drawback of this

technique is the feeling of suffocation felt by some patients, due to the size of the support and large quantity of paste, resulting in a vomiting feeling.



Figure 40. Positioning of the Dental Impression Spoon

To obtain the model of the patient's mouth, it is necessary to pour plaster or resin into the mould, an operation often entrusted to orthodontics and that must be executed in a short time because the paste can collapse making the impression unusable. For this reason, in the traditional workflow, every day an employee from the dental lab collects impressions to be poured. The traditional method continues with a casting operation using the lost wax process, described in paragraph 3.5, in order to create a metal substructure that must be coated with various layers of ceramic material replicating the colour and appearance of a tooth. This process can be considered completely artisanal and requires high-level skills and accuracy from the operator to ensure good results with the drawback of very long production time.

After having briefly dealt with the traditional method, we will focus on the innovative tools that Digital Dentistry may offer.

3.2.2 Digital Workflow

The first difference between a Traditional and a completely Digital Workflow regards the creation of the patient's impression.

3.2.2.1 The Intraoral Scanner

The core innovation of the dental sector digitalization is the intraoral scanner, developed in 1980 by Dr. Werner Mörmann and Marco Brandestini; the first model was called CEREC and was marketed from 1987 onwards, marking the birth of digital dentistry.

The intraoral scanner is a device that, thanks to a luminous scanner, takes a digital impression of the dental arches. Its operation is based on a beam of light that is projected onto the surface of the teeth and is captured by high-definition cameras measuring the distortion. A software detects the information from the device, processes it and returns a 3D image of the patient's

mouth used for the construction of the crown. Initially, the scanner creates a "point cloud" from which derives a polygonal grid called mesh. The resulting file can be exported in .STL format, the universal language of all CAD/CAM (CAD - Computer Aid Design / CAM - Computer Aid Manufacturing) and additive manufacturing systems.

Compared to the traditional method, the digital impression execution is completely different: the dentist holds the device like a pen and slowly passes the scanner's head on the dental arches of the patient following the scanning process on the screen. The system signals any points where the scan was not performed correctly that will need to be re-scanned. The process typically lasts 5 minutes and returns a .STL file specific for each patient, used to produce dental devices through Subtractive or Additive Manufacturing. Once the .STL file has been archived, the crown model is created by CAD modelling programs.

The main advantages of using intraoral scanners are:

- Elimination of psychological stress caused to the patient: in fact, the process of taking the impression is fast and involves only the use of a small device in the mouth of the patient;
- Immediate verification of impression quality;
- Laboratory costs reduction (sending the impression in a digital format to the dental laboratory);
- Time saving: files can be sent directly to the dental laboratory after few minutes;
- Elimination of a physical archive: the digital impressions can be saved in a database saving office space;
- Impressions stability: differently from plaster model that can deteriorate with time and use, digital impressions are stable over the time.

A Ohio State University research that compares intraoral scanners and plaster impressions concludes that *"Intraoral scanners are accepted by orthodontic patients, and they have comparable efficiency with conventional impression methods depending on the type of scanner."* However, this research is in contrast with the opinion of many operators that affirm that sometimes using an intraoral scanner is not possible to detect details in hidden surfaces.

The main disadvantages of using this technology is the low learning curve and the equipment cost, which starts from 20,000 euros, due to the miniaturization of the high precision optical components.



Figure 41. Intraoral scanner used on a young patient. The result of the scan is instantly displayed on the screen.

3.2.2.2 CAD Modelling

There are many specific software for crowns design, which contain anatomical libraries of standard teeth. The software automatically suggests an optimal solution of the tooth, which can be modified by the operator adapting it to the needs of the patient. The software creates a .STL file that is used to produce the device with Subtractive or Additive methods.

3.2.2.3 Subtractive manufacturing

In Subtractive Manufacturing parts are produced mechanically removing the material from a solid block in order to obtain the desired shape. Typically, in dental sector, a Milling Machine controlled by a computer is used. After loading the CAD file, the computer provides information to the machine such as toolpaths, cutting speed, cutting depth and table feed, elaborated by the CAM software. This software gives the possibility to reuse the workpieces, used to produce other crowns, on which there is still available material, maximizing the efficiency. Once this phase is completed, the operator loads the machine with the raw material that is processed in order to obtain the desired geometry. The process starts with a high diameter tool, that removes large quantities of material from the periphery of the workpiece and ends with a smaller high accurate mill to reproduce the details of the crown. Once the piece is created, the crown has to be detached from the workpiece, refined, cleaned and, depending on the material, sintered into a furnace.

Dental milling machines are typically identified by the “number of axis”, referring to the mobility degree of the tool holder, that affects the accuracy and the details of the produced crown:

- 3-axis machine can be used when precision and complex shapes are not required, in fact the tool can only work along the x, y and z axes;
- 4-axis machine allow the rotation of the workpiece holder around an axis to better reproduce curvatures and details;
- 5-axis mill ensures the best results. In these machines, in addition to the movement of the head along the x, y and z axes, the workpiece holder can rotate around two axes. When necessary, this mill can also work using only the 3-axis movement.

The most commonly adopted material for crowns production with subtractive manufacturing is the Zirconia, a particularly hard and bright mineral ceramic that offers resistance and aesthetic results with a good real teeth effect. This material is commercialized in two different variants: Monolithic Zirconia by which is possible to produce a whole prosthesis starting from a block and classical Zirconia, used only for the teeth base and then covered by ceramic. Zirconia is typically commercialized in disks. In Figure 42, a zirconia disk during a milling operation is illustrated.

The CAD/CAM subtractive techniques were developed before the AM techniques, allowing for a significant reduction in machining times and increasing the precision of the parts obtained, making prostheses difficult to distinguish from real teeth.

The main disadvantages are the machine tool and software costs and the waste of processed materials mechanically removed from the starting block (according to the logic of Subtractive Manufacturing). Moreover, machines are not easy to use and require personnel able to carry out constant maintenance, making their use suitable for dental laboratories.

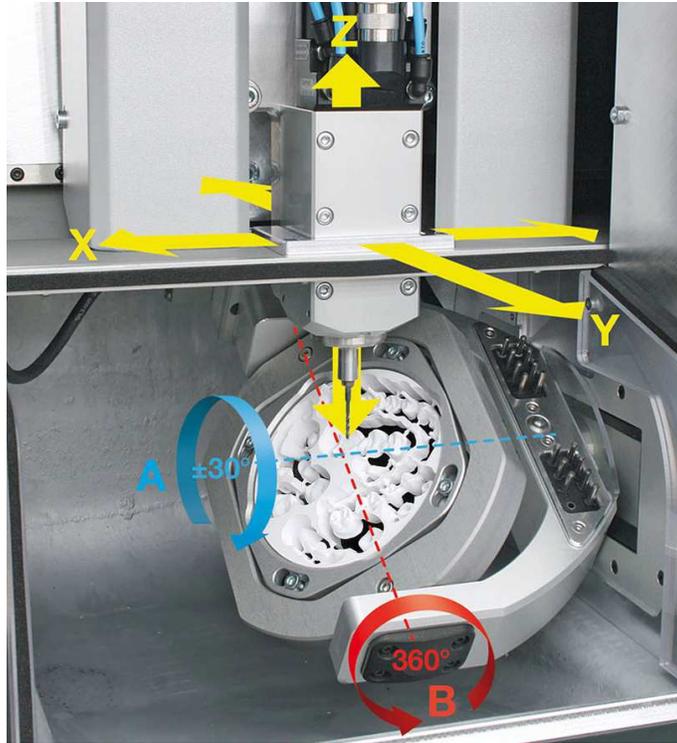


Figure 42. A 5-Axis Milling Machine is mainly composed of Machine Frame, Tool Holder and Workpiece Holder. The machine in the picture has the possibility to automatically change the cutting tool

3.2.2.4 Additive manufacturing

“The accuracy of dental restorations fabricated using the additive manufacturing methods is higher than that of subtractive methods. Therefore, additive manufacturing methods are a viable alternative to subtractive methods.”

Dr. Ji-Hwan Kim, Korea University, The Journal of Prosthetic Dentistry Online

This is the result of one of many studies that question the quality of orthodontic components obtained by 3D printers. This is an innovative method in the dental sector and can bring significant advantages over the traditional metal casting and milling, which are well established on the market.

In the next section, the case study will be concluded with an analysis of the production of the dental crown using additive manufacturing. Subsequently, the technologies used in the dental sector will be illustrated and an overview of the legislative framework for medical devices will be provided. The final part will be dedicated to other applications in the dental field.

3.2.2.5 AM production of Crowns

First, it is extremely important to say that, today is not possible to create directly a permanent dental crown using a 3D printer. In fact, the biggest challenge facing 3D printer manufacturers is to develop biocompatible, durable and dentine-like resins that can remain in the patient's mouth for a long time.

Unfortunately, no resin has yet received biocompatible certification for permanent dental restorations. DWS has developed a new material called Irix Z, composed of Zirconium Oxide, that will be launched on the market once the certifications will be ready, making this technology even more competitive.

At the actual state of technology is possible to produce only temporary “Long term class IIa” crowns (see next paragraph regarding the legislation) by 3D printer. This temporary crown is slightly lowered and is designed to not create significant stress at the root of the implant, in order to ensure a proper integration of the screw into the bone. Temporary restorations are intended to be used to rapidly substitute a missing tooth waiting for the permanent restoration that replaces it after one/two months.

The printing process starts with the import of the .STL file of the crown created by the CAD software. The operation is planned through another software that allows the operator to choose the orientation of the crown (or crowns) and the position of the supports. At this point, the automatic printing process can start without need of further operations. The printer display shows the completion time.

After the printing process is finished, the crown is detached from the building platform and washed. A post-curing process is executed in order to enhance the mechanical properties of the parts.



Figure 43. Temporary Crowns created by AM guarantee a natural-looking result

3.2.3 Conclusions about the case study

3D printing is becoming a viable alternative to traditional dental crown production methods. Nowadays, the majority of dental clinics use traditional method of dental impression spoons to collect the physiological information of the patient's mouth. In order to exploit the benefits of the digital impression, the plaster model can be scanned through desktop dental scanner and the production process can continue following the digital path as shown in the Figure 39. This process, nowadays, represents the most common workflow adopted in the dental sector and, compared to intraoral scanner, guarantees better results at a lower cost, but with the need to take the impression with the dental spoons.

The traditional workflow procedure is time consuming and labour intensive because involves a completely hand-made process. The results are influenced by the ability of the operators which labour can be defined artisan and artistic.

AM technologies have been adopted in dental laboratories. In fact, a survey conducted by Davide Sardella, a colleague from the Polytechnic of Turin, highlights that 64,70% of the laboratories, taken as a sample, have made investments in Additive Technologies.

With the continuous technological development of 3D desktop printers, the improvement of CAD software, increasingly easy and intuitive to use, simplified resin refill systems and lower prices, the major market players are promoting the adoption of 3D printers directly in dental offices simplifying the supply chain of dental devices.

3.3 AM technologies used in Dental sector

The principal printing technologies used in the dental field are Stereolithography (SLA) and Digital Light Processing (DLP), which have already been presented in Chapter 1. These technologies have become established in dental market because they ensure high quality parts with fine details, necessary in the production of prostheses or surgical aids.

The major manufacturers of 3D printers have developed new technologies that have brought some improvements to the SLA and DLP. For example, Formlabs has developed Low Force Stereolithography (LFS), a redesign of the SLA concept, aim to reduce the forces created between the layers during the printing process. This new technology, launched in April 2019, is based on the use of a tank covered by a flexible film. When the piece is lowered to create the untreated layer, this films absorbs and reduce the detachment tensions acting on the layer constructed.

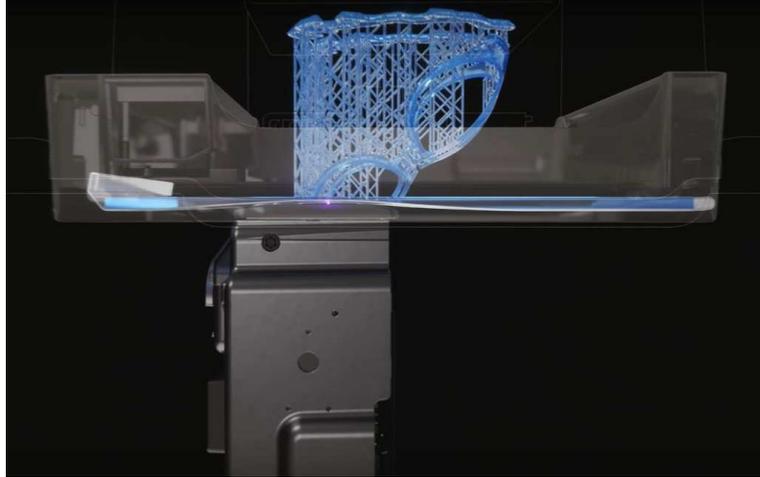


Figure 44. LFS process: the flexed film helps to reduce the tension inside the part

Finally, Powder Bed Fusion technology can also be used in dentistry, in particular, for directly print metal substructure for hybrid porcelain-metal crowns, eliminating the casting operation but maintaining a prevalent traditional and labour intensive production method.

3.4 Legislation regarding medical devices

In the dental industry, as in any other medical industry, it is necessary that the materials meet some specifics regarding biocompatibility. The material biocompatibility consists in the characteristic to establish not unfavourable interactions with the living systems coming into contact. It is a fundamental requirement for implantable and non-implantable dental device that must be assessed and certified according to the guidelines of the regulations.

In Europe, the manufacturers of dental prostheses and aids must respect the *Council Directive 93/42/EEC* that divided the devices for medical purposes in Classes I, IIa, IIb and III. Classification is made considering the invasiveness of the device, its dependence from a source of energy and the body contact duration.

The contact duration is classified in:

- *Transient*: device in contact for less than 60 minutes;
- *Short term*: device in contact for not more than 30 days;
- *Long term*: device in contact for more than 30 days;

The legislation divides the devices into *invasive* and *non-invasive*:

- *Non-Invasive* device is a device that does not penetrate any part of the body, either through an orifice or through the skin.

- *Invasive device* is “a device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body” (Council Directive 93/42/EEC). Invasive devices are divided in Surgically Invasive devices, which penetrate through the body surface during and not during surgery and Implantable devices, developed to be totally implanted in the human body and to remain in place after the surgery. Any device that is introduced into the human body for a minimum period of 30 days is an implantable device.

The risk classes for medical devices, contained in the Council Directive 93/42/EEC are:

- **Class I:** They are low-risk devices, usually non-invasive and non-active (they do not need energy outside the human body to function). In dental field, some examples are: impression materials, latex gloves, polishing accessories. Usually they are intended for transient use.
- **Class IIa:** medium-risk devices often used over the long term (more than 30 days) in natural cavities, including the mouth (invasive device). Examples are dental restorative materials: resins, cements, adhesives, etc.
- **Class IIb:** medium to high risk, invasive long-term surgical devices that are kept in contact with deep wounds. Screws and abutments of dental implants fall into this category.
- **Class III:** high-risk devices, such as those implantable in contact with the heart, circulatory system or central nervous system, all those containing substances, devices that interact on the functions of vital organs. Belong to this category the prosthesis for maxillofacial surger.

All medical devices belonging to the risk classes IIa, IIb and III must be verified and certified by a Notified Body, an organization designed by the country in which the product is to be used, that carry out the verifications laid down in the normative.

Regarding dental devices that can be produced by the AM method we find temporary Dental Crowns, that belong to Class IIa (long-term invasive medical device) and Surgical Guides belonging to Class I, which will be discussed later. In particular, the resins used to produce these devices must be certified.

At present, European legislation does not provide specific rules for medical devices produced by Additive Manufacturing, which can fall into the broad category of “*custom-*

made device” regarding “*any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient*” (Council Directive 93/42/EEC). A custom-made device does not require any certification by the notified body, making production much quicker. In this case, the correct fabrication responsibility of the dental device is in the dentist hands

The absence of specific indication regarding medical devices produced by Additive Manufacturing makes the market very confusing, uncontrolled and therefore dangerous.

In America the situation is different. In fact, in 2016, the FDA (Food and Drug Administration) issued a document containing guidelines for medical devices manufactured through Additive Manufacturing that, in particular, provides directives on design, manufacture and test.

	Legislation Rules	Dental examples
Class I	<ul style="list-style-type: none"> • Non-Invasive Devices • Invasive devices for transient use • All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device 	<ul style="list-style-type: none"> • Dental impression materials • Handheld mirror for dentistry • Dental patient chairs • Dental curing light
Class IIa	<ul style="list-style-type: none"> • All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body • All non-invasive devices that may be connected to an Active medical device • All non-invasive devices intended for modifying the biological or chemical composition of blood if the treatment consists of filtration, centrifugation or exchange of gas or heat • All invasive devices <u>intended for short term</u> use with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I • All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class 	<ul style="list-style-type: none"> • Orthodontic wires • Fixed dental prostheses • Bridges and crowns • Dental alloys, ceramics and polymers • X-ray films

	<ul style="list-style-type: none"> • All surgically invasive devices intended for short term use • All implantable devices and long-term surgically invasive devices to be placed in the teeth • All active therapeutic devices intended to administer or exchange energy • All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body • Devices specifically intended for recording of X-ray diagnostic images 	
Class IIb	<ul style="list-style-type: none"> • All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body • All invasive devices <u>intended for long term use</u> with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I • All implantable devices and long-term surgically invasive devices • Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology 	<ul style="list-style-type: none"> • Denture disinfecting products • Invasive dental equipment
Class III	<ul style="list-style-type: none"> • Surgically invasive devices intended for transient use, specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body or for use in direct contact with the central nervous system • All surgically invasive devices intended for short term intended to have a biological effect or to be wholly or mainly absorbed • All devices manufactured utilizing animal tissues or derivatives rendered nonviable 	<ul style="list-style-type: none"> • Antibiotic bone cement • Maxillo-facial implants

Table 3. European legislation specific for each class and the example in dental industry

3.5 Other application of AM in dental field

3.5.1 Surgical Guides

A surgical guide is a transparent resin mask that is placed in patient's mouth and allows the dentist to insert the necessary screws for an implant, exactly at the planned place and with the proper angulation, guiding the drilling procedure of the bone.

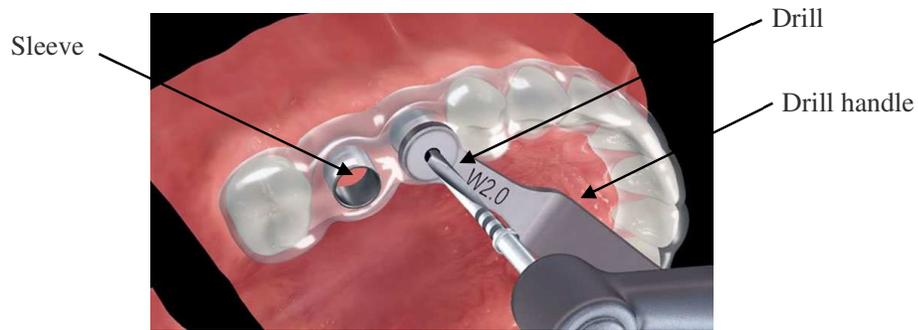


Figure 45. Surgical guide perfectly fits to teeth and gums

As show in the figure 45, a surgical guide is composed of a transparent surface that fit perfectly with patient’s gums and teeth and a stainless-steel Sleeve. For the drilling procedure, the guide is placed in position and a drill handle is inserted into the sleeve. The Drill Handle consists of a handle, held by the dentist, and a perforated cylinder, which is inserted into the sleeve to reduce its diameter. The lower bore allow the dentist to drill according to a precise inclination and a certain depth, reducing the error probability.

As an example, the surgical guides production procedure, developed by Formlabs, a leading company in 3D printing in the dental sector, has been summarized. The printer used is the Form 2, a desktop device based on STL technology.

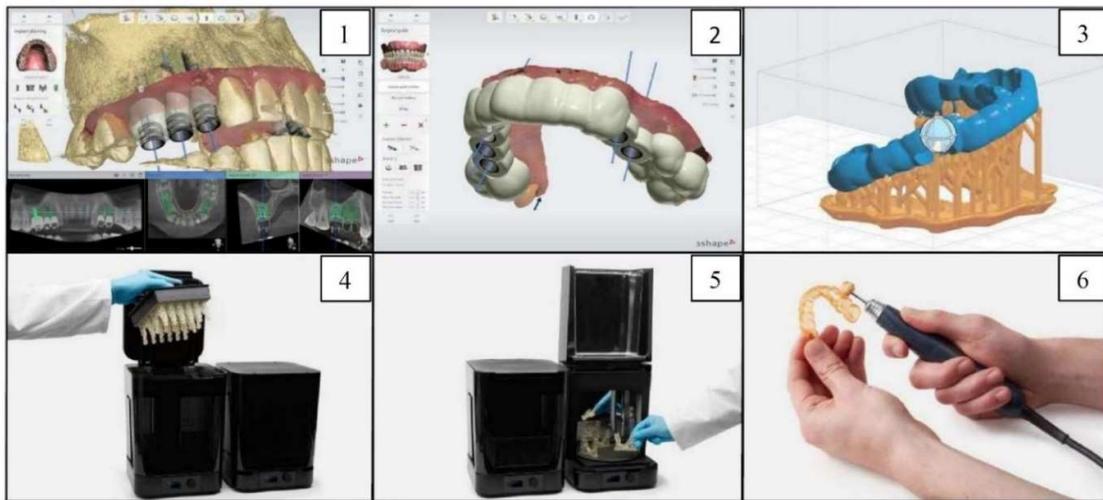


Figure 46. The principal steps for the creation of a Surgical Guide. Images taken from Formlabs guide.

The production process starts scanning the patient’s mouth using and intraoral scanner and acquiring images through a Cone Beam Computer Tomography (CBCT) scansion, necessary to plan the implant surgery and to choose the right size of the implant, depending on the

thickness of the bone. CBCT allow to obtain an accurate 3D imagine of hard tissue structures thanks to a radiographic imaging method.

Intraoral scansion and CBCT scan are imported in a dental CAD software. At this point the operator plans the screw position choosing the angulation and the depth (1). After this, the software automatically designs the surgical guide allowing to modify the area to be covered by the arc and the dimension of the guide (2). Once that the file .STL is ready, it is exported in another software to plan the printing procedure, choosing the guide orientation and generating the printing support, then the file is sent to the printer (3). Once the printing procedure is finished, a post-process must be carried out by the following operations: the part is washed with Isopropyl alcohol 96% (4) and post-cured through and exposure to light and heat in order to enhance mechanical properties and biocompatibility characteristics of the piece (5). Then, the supports are removed, the guide is polished (6) and the sleeve is assembled.

The material used for surgical guide, is a biocompatible photopolymer resin which belongs to risk Class I and is certified to remain in the mouth for 24 hours. This resin, once post cured, can be sterilized by autoclave, removing all kinds of microorganisms.

The surgical guide can be easily printed in the dental office reducing the single piece cost.

3.5.2 Clear Aligners

A Clear Aligner is a transparent mask that corrects the position of the teeth in case of moderate misalignments, replacing the anti-aesthetic traditional metal brace. The system is based on different transparent aligners tailored-made for each patient that apply particular forces on the surface of the teeth in order to slowly move it to the desired position. Typically, the aligners are replaced every one or two weeks to ensure proper tooth movement and must be worn at least for 22 hours per day. Total treatment duration varies depending on the severity of the misalignment. The most appreciated advantage by customers, compared to traditional braces, is the total invisibility of the device, which if necessary, can be removed to eat and ensure a proper oral hygiene.



Figure 47. Traditional brace and Clear Aligner respectively on the left and on the right.

The first marketer of this devices was Align Technology, that in 2000 launched the Invisalign system; these Aligners are produced using 3D Systems SLA printers. The case study regarding the mass customization introduced by this company will be illustrated in Chapter 4.

The development of 3D desktop printers allows to produce the series of Aligners needed for each patient. As in the case of the surgical guides, which has been previously treated, the production workflow recommended by Formlabs has been taken as an example; also in this case a Form 2 model based on STL technology is used.



Figure 48. The principal steps for the creation of a Clear Aligner. Images taken from Formlabs guide.

The process relies on the printing of various models that are used to thermoform the aligners. The first step is to acquire the patient's mouth digital impression. The .STL file obtained is exported to a CAD software for the design phase, which includes various steps: first the

operator delimits the area of the model to minimize the printing time and material consumption (1), then the Orthodontic Treatment is planned and an identification tag that includes the treatment stage number and the patient's ID number is modelled. During the planning of the treatment, the operator moves the tooth that need to be aligned in the correct position and the software automatically generate the various models of the dental arches, each of which includes the tooth in one of the intermediate positions (2). At this point the CAD models are exported in a PreForm that helps to plan the printing stage choosing how many parts include in the building platform and the relative orientation. The printing supports are auto-generated by the software and the print can starts. After this step, the parts are washed (3) and removed from the building platform (4). A Thermoform machine is used to form, using heat and vacuum creation, a transparent polyurethane mixture on the models just printed (5). Finally, the aligners are catted form the models, the sharp edges are smoothed and are parts cleaned (6).

3.5.3 Dental Models

A dental model is an accurate reproduction of the patient's dental arches, used to plan surgeries or to verify that implants, crowns and aligners perfectly fit with the patient's mouth. These are also used for educational purposes. In the traditional workflow, as previously seen, plaster models are the starting point to produce any dental product; with the introduction of intraoral scanners, dental models are archived in a digital format and the easiest way to build physical models is 3D printing. It is also possible to create models with removable Dies, as illustrate in the figure 49. Removable dies are fundamental parts of dental models, in fact, they provide a measure of the peripheral part of the tooth, called margin. In this way, the technician can create crowns or bridges that perfectly fit together.



Figure 49. A dental model with five removable Dies

The materials used do not require expensive and biocompatible resins because they are not used in the mouth.

The printing workflow is similar the already studied, with the only difference that the CAD software, in this case, allows the operator to choose where to section the model to create the dies.

3.5.4 Wax pattern

A wax pattern is used to create dental restoration parts through the lost-wax casting technique. In order to understand the use of this part, that can be 3D printed, is necessary to briefly describe the dental casting process.

Dental casting process is the oldest method to create crowns and partial dentures, in fact this traditional method can be applied without the use of CAD/CAM machineries. The starting point is to print the wax pattern. The process starts with a CAD manipulation of the patient's virtual model. In this phase the crown is modelled, and the parts are oriented so that the support does not interfere with the functional parts of the restoration. The wax pattern must perfectly fit with the die on the model. After the pattern is printed, the part is washed, and all the printing support are removed. At this point the casting process can starts following the phases, illustrate in the figure 50:

- A Sprue, whose function is to allow the flow of liquid material into the mould, is connected to the Pattern;
- A Sprue Base, which has the function of a funnel for the flow, is connected to the Sprue;

- An external Ring is added, the structure created is collocated inside the ring and is filled with gypsum;
- The ring is placed inside an oven and once heated the wax will melt leaving a mould with a canal and the same shape of the wax pattern;
- The metal is poured into the mould;
- The sprue is removed from the casting and the crown is polished.

Additive Manufacturing permits to considerably simplify this process because the creation of the wax pattern can be done quickly and automatically without relying on artisanal procedures.

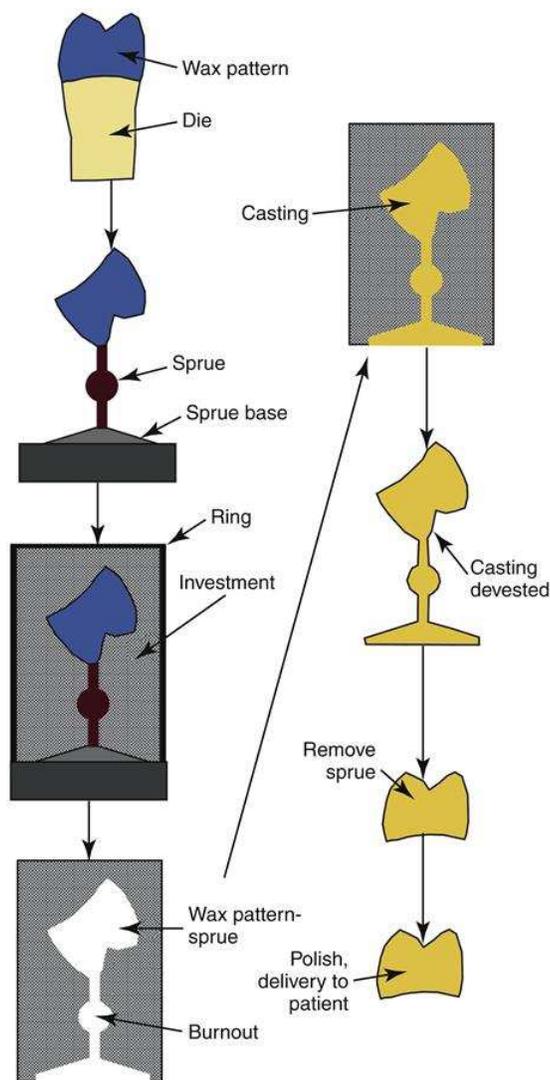


Figure 50. Dental crown production process using the lost wax method

3.6 Conclusions

The umbrella of 3D printing application in dental practices and laboratories were presented from a technical perspective, in order to better understand which are the necessities of this sector. As seen, the customization covers a primary role in the production of devices, followed by the necessity of biocompatibility and high accuracy. In the next chapter the use of AM in dental sector is described from an economical point of view focusing, in particular, on the possible changes that this technology can bring if used in the dental offices.

4 Chapter 04: AM potential changes in Dental sector

Additive Manufacturing can play a crucial role in the dental sector digitalization and nowadays can count a discrete adoption in dental labs. In the previous chapter, some applications of AM technologies have been analysed from a technical and process point of view. This technology, used in combination with CAD/CAM and 3D scanning, could sensibly change the way people think about dentistry and dental offices, facilitating the in-office production and the *chairside* phenomenon.

4.1. The disruptive nature of AM

Disruptive innovation is a term introduced by Clayton Christensen and Joseph Bower in an article titled “*Disruptive Technologies: Catching the Wave*”. The term outlines a phenomenon by which a radical innovation can alter human lives, market trends or entire business models. Is not rare that disruptive innovations are developed or exploited by small firms that can seriously threat big and affirmed companies.

According to Christensen studies is possible to subdivide innovations in Sustaining and Disruptive. A Sustaining innovation usually represents an improvement of a current product that does not sensibly impact the market and the society. In contrast, disruptive innovation, stimulates the creation of a new market, disrupting the existing business models and replacing the previous technology. Some historical examples of disruptor and disrptee innovations are presented in the Table 4.

Disruptor	Disruptee
Personal computers	Mainframe and minicomputers
Mini mills	Integrated steel mills
Cellular phones	Fixed line telephony
Community colleges	Four-year colleges
Discount retailers	Full-services department stores
Retail medical clinics	Traditional doctor’s offices

Table 4. Disruptor vs Disruptee

AM could disrupt different sectors, including the dental one, because it may introduce an enormous simplification in the production process, accelerating the time to market and

reducing the barrier to entry. As seen in the previous chapter, the use of AM technologies changes the traditional business model adopted in dental practices.

4.2. How AM can alter the traditional business model

The traditional workflow, already seen in Chapter 03, involves the outsourcing of the production of dental devices to a dental laboratory. This process starts with the shipping of the impression of the patient's mouth to the laboratory. This last one, in some days, even weeks, (depending on the workload and the technologies used) returns the devices certificated and ready to use in a sterilized package.

If the laboratory uses a traditional analogical workflow, the process for the creation of medical devices will be completely artisan, labour intensive and time consuming. In fact, as an example, the production of a crown can require one day due to the necessity to use a casting procedure to create a metal substructure and the long drying time of ceramic layers added on it. Nowadays, the traditional methods are destined to disappear giving room to innovative digital production methods.

The dental offices digitalization and the introduction of a 3D printer can radically change the traditional workflow, allowing the integrated production of medical devices directly in-office efficiently, in terms of costs and production time.

The starting point for digitalization is the introduction of an intraoral or desktop scanner in order to create a digital file representing the impression of each patient, used to design and print the dental devices. In this way, thanks to the use of 3D printing, the dental laboratory supply can be gradually removed.

The diffusion of AM can disrupt the traditional business relation between dental offices and laboratories, previously presented. The request of dental devices to dental laboratories can gradually decrease leaving room to an in-office production using a 3D printer. The dentist, or a dental technician working in the office, can use the impression obtained by scansion to create a CAD design of the device that will be subsequently printed.

SmarTech, a company that starting from 2015 is providing market reports on dental 3D printing, suggests that this phenomenon will start from big dental offices or dental chains. In fact, the higher capital purchasing budgets respect to single dentist offices and the aggregated high number of treatments per-month, make the investment in AM profitable. In figure 51,

a prediction of dental printers installation in laboratories and dental offices is illustrated, suggesting a future redistribution of roles.

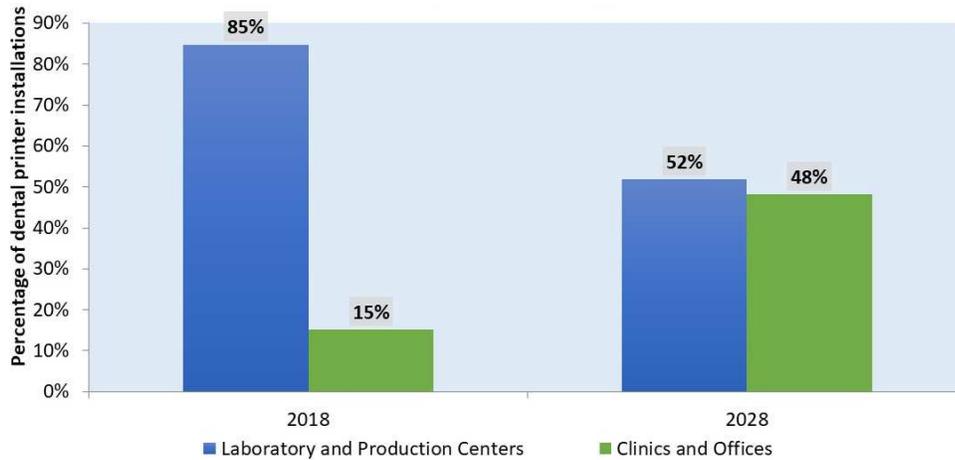


Figure 51. Current and projected 3D printer installations (Source: SmarTech)

This change of roles can represent a threat for the dental laboratories, which means that, the current clients can become future “competitors” pushing the labs to reinvent their business. Scott Dunham, the actual VP of SmarTech Analysis suggests that dental labs have to rethink their actual business models: *“labs of the future may need to shift their business focus to becoming enablers of 3D printing in the office by providing efficient, effective dental device design services, and providing clinical groups better support for their 3D printing operations by providing overflow capacity, training services, and more”*.

Considering this shift in labs role from producers of dental devices to enablers of 3D printing is possible to imagine that business opportunities for small labs will be drastically reduced. In fact, typically for small artisanal realities, the shift from analogical to digital requires economical investments that would not be covered.

The shift to an in-house production can be feasible for large dental practices or clinics that can benefit of cost reduction; this last one can also reduce the payback time of the investment.

4.3. The chair-side workflow

The traditional restoration workflow, from the patient’s point of view is time consuming because involves different appointments. As an example, for the complete installation of a fixed prosthesis from an edentulous area the appointments necessary are 3:

- the first appointment consists in an initial evaluation of the patient's clinical situation. During this first stage, the dentist, take an impression of the patient's mouth and the data are send to the laboratory, in order to create a custom-made surgical guide;
- in the second appointment a surgical operation for fixing the implant screw is carried out, using the surgical guide created by the lab. After, a second impression is taken and sent to the lab in order to create the crown;
- in the third appointment the crown is fixed, and the restoration is finished.

(It is important to note that, the stages just described can vary depending on the patient's clinical situation and the operating way of the dentist)

Using a chairside approach is possible to guarantee the replacement of a missing tooth in just one appointment.

Chairside is a term born in 80' with the introduction of CAD/CAM systems in dentistry. This term highlights the fact that it is possible to produce the medical devices needed for a specific operation, such as surgical guides and crowns, direct in-office while the patient waits. More generally, chairside refers to the production of medical devices direct in-office. The first application of this concepts was called CEREC (Chairside Economical Restoration of Esthetic Ceramics) and involves the creation of dental crown, for partial and complete, restoration using subtractive manufacturing techniques. Nowadays the CEREC Milling machines allow to create a crown or a bridge from a zirconia block in 15 minutes. The total operation, that includes the tooth CAD modelling lasts 30-45 minutes. During this time the patient can read a book or use entertainment devices in the lounge of the office waiting for the crown preparation.

Appling the chairside approach at the example of the fixed prosthesis used before, is possible to perform the operation in a single visit through the following operations:

- 1) Data capturing of the patient mouth with intraoral scanner and TCTB;
- 2) The crown and the position of the implant is planned through a CAD software;
- 3) Creation of the surgical guide;
- 4) The implant is fixed thanks to the surgical guide;
- 5) A second scansion is done in order to identify the position and inclination of the abutment;
- 6) The crown is designed and created;

7) The operation is finalized fixing the crown.

At this point the patient can leave the office with a complete restoration and a perfect esthetic result.

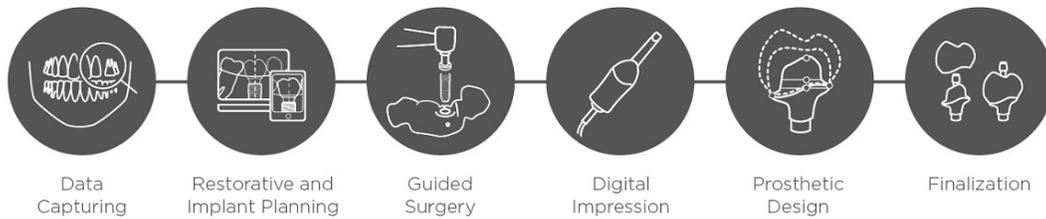


Figure 52. The chairside approach workflow

Guarantee a rapid replacement of a missing tooth is fundamental for both time saving and psychological effects. In particular, the frontal teeth have an aesthetic function and as an example, the accidental losing of one tooth can alter the social status of the patients.

AM has the potential to facilitate the chairside phenomenon because is less expensive compared to subtractive systems and requires less maintenance and machine set-ups. In addition, the efficient use of the materials resulting in a good buy-to-fly ratio (close to 1) impacts the waste of material reducing the costs.

Today, the use of 3D printers with a chairside approach is not possible. The printing process and the post-processing such as washing, and curing are too time-consuming. In particular the printing phase requires 30 minutes and the post-processing operations 25 minutes compressively. Adding the design of the crown, that last nearly 15 minutes, depending of the ability of the operator, the entire process lasts more than one hour.

In addition, as already said in the previous chapter, despite the progress in AM materials, a permanent restoration resin does not jet exist, limiting the potential application of this technology for the specific production of permanent crowns.

A research from Malmö, a Sweden University, on this theme concludes that *“With the current advancement within the industry of additive manufacturing it is not question if but matter of when the technique will be able to be used for chairside tasks as the manufacturing of interim prostheses (dental crown)”*.

The actual state of technologies does not guarantee a feasible use of AM for chair-side production, intended as the production of devices while the patient is waiting. For this

purpose, subtractive technologies allow to produce better devices in less time. The progresses of technology and material can add the possibility to use additive technology for produce one-day restorations in an efficient way. Today is not possible to make economical comparison between the use of subtractive or additive techniques for chairside because the latter does not already guarantee feasible result.

4.4. Key benefits of AM in dental sector

Additive Manufacturing brings important advantages in different fields. In this paragraph the key benefits of this technology in dental practices and laboratory are presented.

4.4.1. Less time and cost

Respect to subtractive manufacturing, AM can bring cost and time advantages to both dental laboratories and dental clinics that decide to internalize the production.

Using 3D printing is possible to easily set a mass customization model thanks to the possibility to contemporary produce dental devices for different patients during the same printing session. This simultaneous production brings a cost advantage respect to subtractive and artisanal methods, by which is possible to work only one device at time. Using additive manufacturing is convenient to produce at the maximum capacity of the building platform. In particular, with a DLP production method, no matter if one or more devices are produced, the printing time is the same, because the system allow to cure an entire layer at the same moment. Respect to subtractive manufacturing method, 3D printing does not require machine set-ups and tooling resulting in a decrease of production time.

The completely automatic and less labour-intensive process, compared to artisanal methods, allow to reduce the final devices costs for both dental laboratories and modern dental practices that decided to internalize the production process.

As an example, the price charged from a laboratory to a dental office for a temporary crown is 50 Euro. Using a 3D printer, the cost for the material of a single crown is only 0.41 Euro, returning nearly 49 Euro to repay the investment. Another advantage for dental practices is the saving in time for the production of easy dental devices direct in office such as surgical guides breaking the traditional supply chain.

4.4.2. Better communication with the patients

Using a 3D printer patient's mouth model is possible to improve the communication with the clients. On the wave of this advantage, an Italian start-up called Oral3D, developed and launched a complete system to easily print in-house dental model. The creator of this start-up Giuseppe Cicero, a 28 years old dentist, explains that the communication with the patients using a 2D image is really difficult and nowadays, many patients want to know exactly their clinical status before starting an expensive surgery. The use of a model is fundamental in these cases. In addition, 3D models can be used by dentists to better understand the patient's clinical situation allowing a better planning of the surgery. Figure 53 shows the difference between a traditional 2D image and a 3D dental model.

Furthermore, the gradually shift to digital impression formats requires a method to easily reproduce the digital file in physical model. A desktop 3D printer is the perfect device for this purpose.

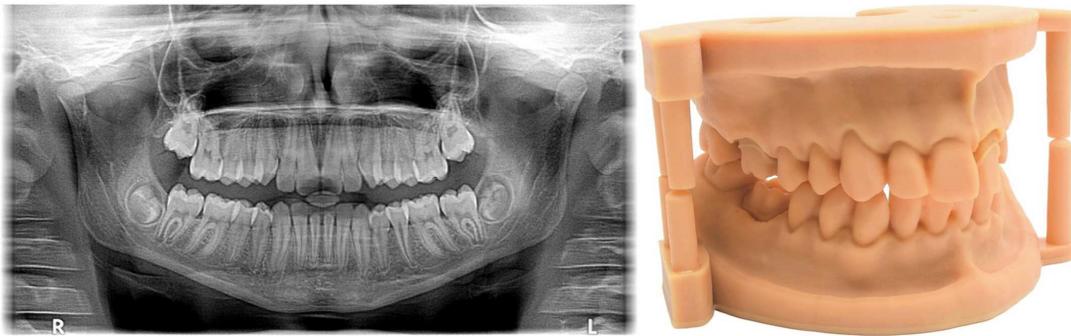


Figure 53. On the left a 2D image obtained by CBCT and on the right a 3D printed model

4.4.3. Flexibility

The adaptability is a well know characteristics of 3D printers. As already said in the previous chapter, this technology allows to set a flexible production. In particular, in the dental sectors is possible to create a wide range of dental devices, using different materials with the same printer. In fact, a cartridge-based system permits to easily switch the resin tank in order to create different products, from dental models to complete crowns. In figure 54 are presented a set of cartidges for Formlabs 3D printers for different uses.

The investment in a 3D printer allow to use a unique device for the creation of different products giving to the dental office or laboratory the possibility to build new devices and

experiment new medical techniques. In addition, the 3D printing represents a scalable production system, that allow to rapidly add production units if demand increases.



Figure 54. A set of different dental cartridges for Formlabs printers

4.4.4. Improved quality

Thanks to 3D printing is possible to create better quality dental models compared to traditional plaster-cast model. In fact, a model printed using a resin is more dimensionally precise and can be exposed to liquid without any implication.

In addition to this, a key characteristic of AM is the opportunity to easily produce any shape and this can improve, without any cost of complexity, the quality and the accurateness of dental crown and other devices. Using a subtractive machine is not possible to reach a high level of definition especially for the creation of dental crowns, that are particularly small. In fact, the subtractive tools are not efficient to reproduce particular corners or edges. This accuracy problem can be overcome using layer-by-layer manufacturing that enables to create a complexed shape crown as easily as a cube.

There are many researches that prove the quality of dental devices created by additive manufacturing and compare traditional and innovative methods.

The research “*A comparative study of additive and subtractive manufacturing for dental restorations*” compares the accuracy of dental restorations created by Additive Manufacturing, using SLA and SLS methods, and Subtractive Manufacturing on wax and Zirconia blocks. The results are evident: “*Of the 4 fabrication methods used, the SLA method ranked first, the SLS method ranked second, the wax method ranked third, and the ZIR method ranked fourth...The accuracy was better with AM methods than subtractive methods.*”

Another important research is “*3D printing – An alternative of conventional crown fabrication: A case report*” that compare the traditional crown production with the digital approach that involve the use of a 3D printer. The study concludes that “*3D printing appears to be very precise and fast technology because it completely replaces a lot of the handmade procedures from conventional crown fabrication. Therefore, the risk of laboratory mistakes is reduced and precious time is saved.*”

In artisanal production methods, such as lost-wax casting, a volume change in each stage of the process can be present. In many cases this involves a volume change in the final device. Of course, using traditional method is possible to construct high quality restoration but this outcome depends on the ability of the operator that can be difficult to control.

4.4.5. Reduction of environmental impact

Respect to subtractive or traditional methods AM drastically increases the manufacturing sustainability:

- The waste of material is insignificant compared to traditional casting methods thanks to the elimination of wax patterns and moulds, and this is not only an economic advantage but also beneficial for the environment;
- An in-office production, respect to traditional workflow, allows to eliminate physical delivery of dental impression to dental labs and medical devices to dental offices resulting in a reduction of pollutions;
- The energy consumption of a 3D printer is significantly less compared to subtractive methods.

4.5. Obstacles to rapid growth

Many limitations thwart the intensive use of AM techniques in dentistry; some of these are related to technological problems, other to costs and operator’s mindset, resulting in an immaturity from the side of the producer and users. The main limitations are presented in the next rows.

4.5.1. Material limitations

Referring to dental sector, the first barrier to widespread is posed by materials and legislation limits imposed by the actual development state of dental resins. In fact, the modern desktop

3D printers can create high definition dental devices that respect the strictly dimensional tolerances dictated by orthodontic, the only limit is posed by the material used. Currently, is not possible to print permanent restorations limiting the use of 3D printers at the creation of temporary crowns. For this reason, many potential customers believe that this technology is still immature and cannot completely substitute the role of subtractive manufacturing or traditional methods which use materials, like zirconium or ceramics, guaranteeing optimal aesthetical result and proven long-term quality.

Dental 3D printers producers are now focalized on the development of resins that allow the creation of permanent restoration. DWS, an Italian 3D systems producer specialized in dental solutions, is going to release the first certified nanocomposites-based resin for permanent translucent restorations, called Irix Max.

The introduction of advanced and certified resins can change the game in dental industry proposing a complete alternative to classic methods. However, the quality of the 3D printing final restorations should be proven in a long time period in order to guarantee an acceptable final outcome of the prosthesis as happened with zirconium crowns. The launch of this new material can completely disrupt the sector spreading the in-house production.

4.5.2. Skilled operator required

Even if modern desktop 3D printers and modelling software are becoming increasingly easier to use, the learning curve is still low, especially for CAD modelling software. The major difficult in fact is not represented by the use of the printer, that relies on a completely automatic process, but by the 3D modelling phase. Although, the latest software involve a series of tools that guide the user during the dental device design, a certain ability to use CAD software is needed.

This lack of skills does not interest in particular dental laboratories. In fact, the labs digitalization is already in an intermediate stage and operators are familiars with the use of CAM system thanks to the diffusion of subtractive methods.

In particular, lack of solid modelling skills affects dentists whose university preparation does not cover this field. Moreover, many dentists are not willing to spend precious training time to learn how to produce devices, focusing their attention at the clinical techniques in continuous evolving state. In large practices can be convenient to hire a CAD operator or

dental technician that can be trained on the use of innovative device and work in parallel to the dentist.

4.5.3. Legislation issues

The production of medical devices is regulated by the Council Directive 93/42/EEC and, as already said in the previous chapter, currently a specific regulation for printed devices misses. In any case, the medical device manufacturer holds the total responsibility for meet the requirements imposed by the law and is personally responsible for any problems caused by its device. In case of in-office production this responsibility falls in the hands of the dentists and this, combined with the lack of specific rules, can discourage them to adopt 3D printing especially for provisional and permanent restorations.

4.5.4. Traditional attitude

This strong limit was already discussed in Chapter 2 from a general point of view. Conservative attitude affects also the dentistry sector. Many dentists are not willing to be involved in the dental devices production and do not believe that this technology can bring many benefits in their offices. On the other hand, the limitation in material and the fact that it is not possible to produce permanent restoration give an immaturity feeling about this technology that increase this problem.

4.6. Future trend of AM in dental sector

Market researches on 3D printing in dentistry are still scarce. Some future trends about the dental AM market are presented by SmarTech report that predict huge opportunities for this segment. In particular, according to the report, the dental market revenues will growth up to \$9.5 billion in 2027 with a predicted CAGR (Compound Annual Growth Rate) of 18%. A huge growth considering that the estimated sales for the 2019 are \$2.7 billion.

Continuing with the prediction of SmarTech Analysis, by 2022 the dental devices annually produced by 3D printers will exceed the 500 Million and by 2027 3D printing technology will be the first manufacturing method to produce restorations and devices worldwide. As illustrate in figure 55 the production of dental devices by Additive Manufacturing will growth each year with a decreasing but still positive increment.

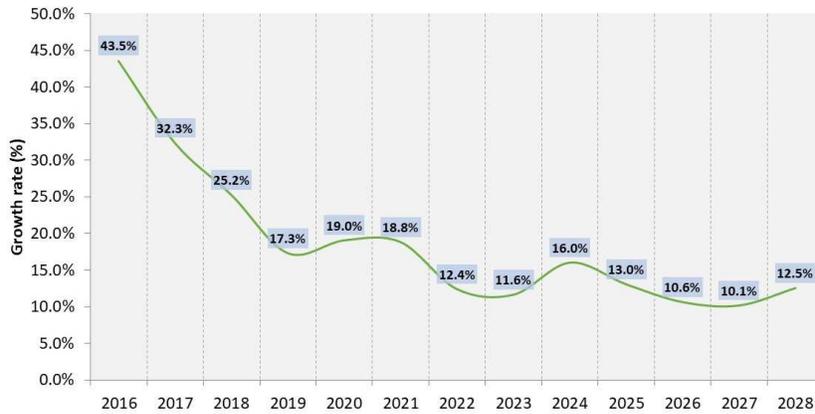


Figure 55. Dental 3D printed device volume annual growth. Source: SmarTech Analysis

4.7. AM drives mass customization. A case study

One of the best examples of mass customization supported by the use of additive manufacturing can be found in the dental sector. In 2000, Align technology launched an innovative transparent brace, called Invisalign, destined to disrupt the traditional way to align teeth. Invisalign was the first clear aligner designed and produced to substitute the traditional braces, made of steel wire, that are unaesthetic and difficult to be accepted by the users. The functioning of the aligners from a clinical perspective was presented in the previous chapter.

4.7.1. History of Invisalign

Align Technology was founded in 1997, by two student Zia Chishti and Kelsey Wirth, which did not have any knowledge about dentistry but strongly believe that a transparent brace could have revolutionized orthodontic treatments. After some years of developments and the FDA clearance, the first Invisalign system was commercialized in 2000. In the same year, the company started a big television marketing campaign, investing \$31 million, defined by The New York Times “*the most aggressive consumer advertising plan the dental profession has ever seen*”. Thanks to the big hype of this technology, Align Tech raised \$140 million from 1997 to 2000 and \$130 million in 2001 in the IPO (Initial Public Offering) on NASDAQ.

Initially, a dental spoon was used to collect patients’ impression but, in 2011 with the acquisition of Cadent, an Israeli manufacturer of intraoral scanner, the company integrated

digital scanning techniques adding the possibility to collect the patients' anatomy direct in a 3D format.

4.7.2. Workflow of the treatment

In order to better understand how the Invisalign service is delivered the workflow phases are presented in a schematic way:

- 1) The process starts with the collection of photographs of the patient's teeth and face, dental impressions and x-rays. This process is done in a licensed dental office;
- 2) The doctor prepares a prescription for the treatment in order to transmit all the clinical information to Align;
- 3) The information are sent to Align that creates a 3D digital roadmap, planning the movements of the teeth for each single aligner. The software used allows to create a after treatment prediction of the patient's smile giving an immediately feedback;
- 4) The customized aligners are manufactured and sent to the dentist;
- 5) The patients receive a series of custom-made aligners that have to be changed every 2 weeks;
- 6) A dentist monitors the progress of the treatment with regular appointments.

The company uses a global workflow. In fact, aligners are produced in a plant situated in Juarez, Mexico, but the digital treatment planning are created in one of the facilities located in San Jose (Costa Rica), Chengdu (China) and Cologne (Germany).

4.7.3. The role of 3D printers

"None of what we have been able to achieve would be possible without 3D printing technology"

Srini Kaza, VP, product innovation, Align Technology.

Align Technology has exploited all the benefits of additive manufacturing thanks to the extensive use of 3D Systems' printer machines. When the company born additive manufacturing was only a prototype technology in its early stages but, thanks to the partnership with the printers' product, it was possible to develop a system able to produce 320,000 unique medical devices per day that guarantee accuracy and scalability. In fact, Align Technology easily scaled its printing system adding new machines to meet the 600% increases of patients from 2009 to 2018. In a Forbes article, it was estimate that the company

uses from 50 to 60 ProX SLA 3D printers in nearly 1,500 m² factory floor, resulting in one of the biggest spaces dedicated to printing machines.

As already said in Chapter 03, the aligners creation relies on the production of different model for each stage of the treatments that after have to be thermoformed with a biocompatible and clear material. Without the use of AM technologies, it is technically impossible to produce up to 20 different models for each patient. In fact, subtractive manufacturing can work one piece at time resulting in a too long process and using injection moulding technologies 20 moulds should be created for each patient resulting in infeasible costs.

4.7.4. Company growth

Some figures about this company are presented in order to understand the success of this digital dentistry business model. The company started its business as a start-up and experimented a tremendous growth in few years, resulting in a revenues growth of 25.6% year-over-year. The worldwide shipment of Invisalign passes from 200,000 in 2008 to 1,200,000 in 2018 with an increasing worldwide growth during these years. In 2018 the growth was 31.9%, a new record for the company.



Figure 56. Invisalign shipment and growth trend

In 2018 the company reached the 6th millionth Invisalign patient with more than 1.2 million patients starting the treatment only in this year. Figure 57 shows an increase in utilization rate especially for the America area to 14 case treated per doctor contracted. In particular, the firm registered and increase in teenager's adoption, that composes the 25.5% of the total sales volume in 2017, with a rise of 40.4% from 2016. The growing number of young

customers is an important opportunity for the company because this user segment is the largest in terms of braces utilization.

Align can be considered a monopolist in the sales of clear aligners. This status was achieved also by a massive patent strategy, composed of 400 U.S and 300 foreign patents. In October 2017 some of these patents expired and this phenomenon will continue with a rate of 23 expiration for year until 2028 causing the increase in the aligners industry competition. Nevertheless, this competition does not sensibly affect the company that can rely on brand reputation, technology and production experience matured in 15 years.

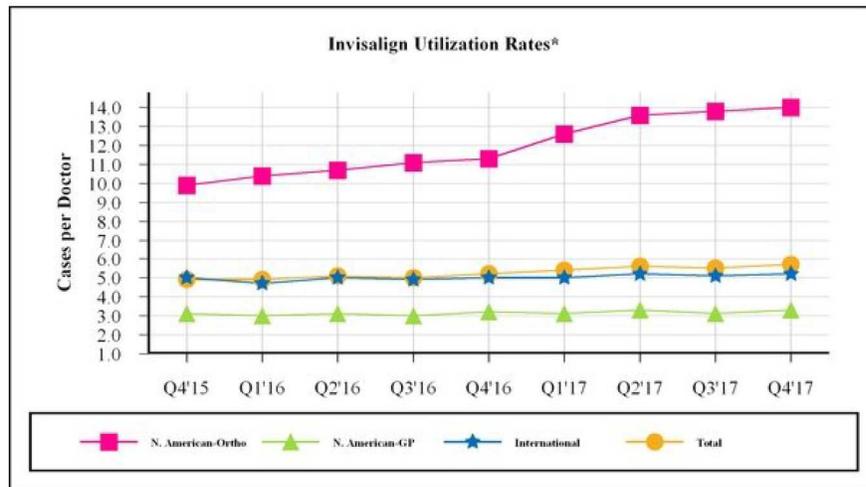


Figure 57. Invisalign utilization rate for each doctor contracted

4.7.5. Conclusions about the case study

Align Technology was able to exploit all the benefits of additive manufacturing, developing a system able to meet mass customization requirements, in an epoch in which 3D printing technology was in its early stage. The inventors of this revolutionary braces were supported by the incredible scalability offered by the 3D Systems printers that allow to add production units when the demand rises, following the growth of the firm. Align Technology has promoted the diffusion of software and intraoral scanner in dental practices becoming the pioneer in dentistry digitalization. The company was also able to leverage a sophisticated global supply chain to physically create the aligners in low-wage countries and plan the digital treatments in areas where high skilled operators are present.

Finally, this case highlights the disruptive potential of AM technology that has allowed to develop a new alternative to traditional braces and introduce a new competitor in the market that reduced the market shares of traditional braces vendors.

4.8. Conclusions

AM manufacturing application in dental sector is recent and in its early stages. Technical limitations enhance the barrier to the rapid diffusion of this technology. These limits leave space to subtractive manufacturing which nowadays owns the major market share of dental devices production both in laboratories and in clinics. AM could disrupt the actual workflow involving dental laboratories. 3D printing, compared to subtractive technologies, guarantees major flexibility and lower initial investment that can incentive the in-house production in dental practices.

In conclusion, additive manufacturing will surely have a role in the future of digital dentistry, completing the work started by CEREC and subtractive method and facilitating the internal production of medical devices.

5 Chapter 05: AM adoption in dental practices

5.1 Introduction

After having discussed the future possibility that AM technologies offers to dental practices, in this last chapter the actual situation regarding the adoption of digital technologies and, in particular, Additive technologies will be analysed, thanks to a survey submitted with the purpose to collect comments as well as data and try to confirm some hypothesis done in the previous chapters.

5.2 The survey preparation and the submission

The first phase of the survey involved the random extraction of a sample of 130 dental practices from the ANCAD (Associazione Nazionale Commercio Articoli Dentali) database that includes 401 contacts of dental practices of Turin and province, and the preparation of marked letters signed by the professor in order to present the survey to each participant.

In the second phase, a calling activity has been made to invite the selected dentists to participate at the survey. In particular, during this activity, an email address was requested to send the link by which is possible to participate at the questionnaire.

In the last phase the data obtained from the survey have been analysed and discussed with the professor in order to draw some conclusion.

	Absolute Frequencies	% of total sample	% of total offices contacted
No answer even if the phone number is active	22	16,9%	
Disabled phone number	18	13,9%	
Not interested to participate (a)	33	25,4%	
Email addresses collected (b)	57	43,8%	
Total sample	130	100%	
Total dental offices contacted (a) + (b)	90		63.33%
Survey responses	31		34.44%
Adjusted response rate		34.44%	

Table 5. Some figures about the survey

During the calling activity it emerged that the quality of the database is below of expectation. In fact, from the 130 selected dental offices it was impossible to contact 40 of them. In many

cases the number was disabled, or in case of active numbers, no one answered even if the calls were conducted in different days and times. These factors indicate that the database has not been updated recently and therefore includes definitively closed dental practices.

From the 90 effective contacted offices, 57 decided to participate providing the email address and 31 of them answered to the questionnaire with a response rate of 34.4 %. Some data are presented in Table 5.

5.3 Structure of the survey

The scope of the survey is to direct collect data on the adoption of intraoral or desktop scanner and 3D printers in the dental practices and to understand what are the reasons that limit the use of that technologies using some open questions and non-metric accordance scales.

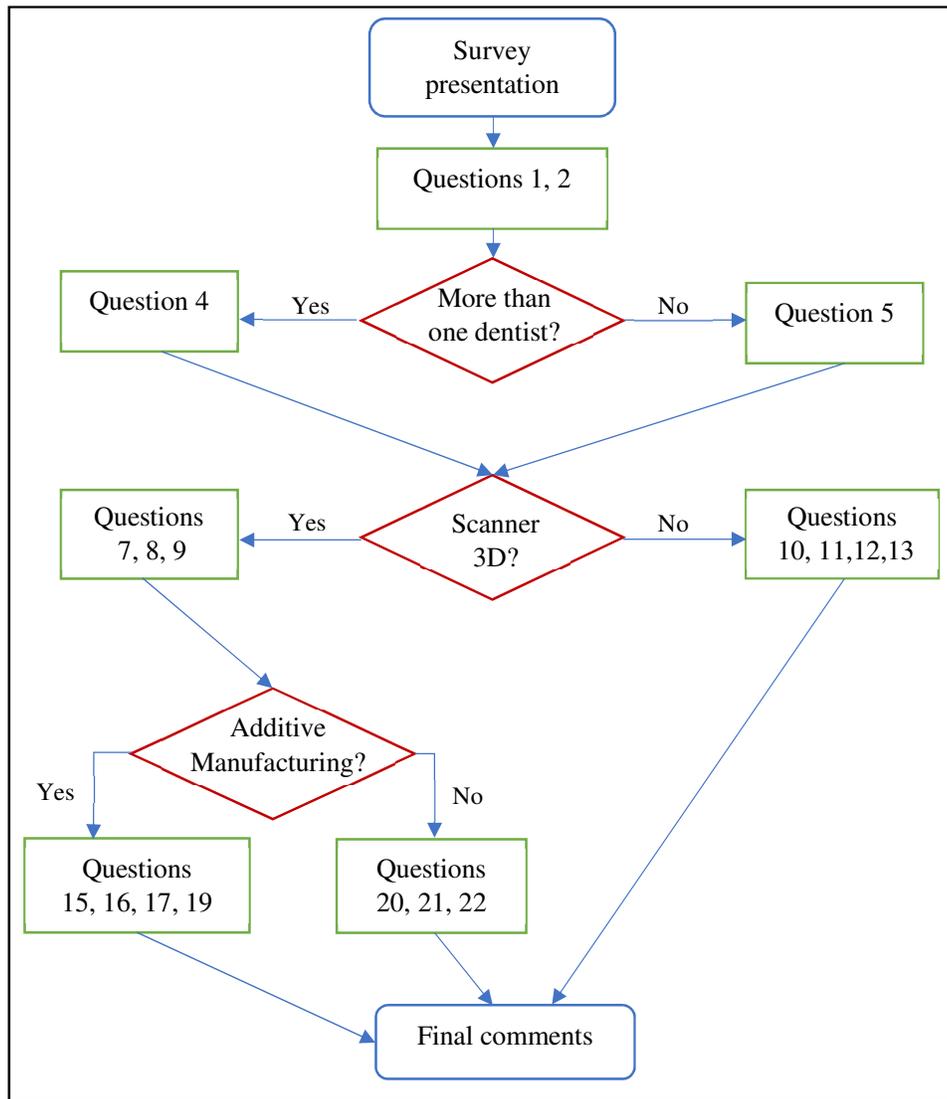


Figure 58. Flowchart scheme of the questionnaire

The survey is divided in different sections that are reached by the respondents in a different way according to the answers given. The scheme in figure 58 is useful to better understand the structure of the survey. The questionnaire is presented in Appendix A.

As already said in the previous chapters, a scanner is essential in order to use a 3D printer in the dental office. For this reason, some specific questions regarding the AM have only been proposed to offices that adopt an intraoral scanner, that are the potential user of this technology.

5.4 The analysis of the answers

The first section was proposed to collect some information regarding the dental offices in order to identify some characteristics in the sample selected.

The first question aimed to collect data on the average number of restorations, which can involve the use of scanner and 3D printers, performed each week in the practices object of study. In particular, a high number of restorations per week can stimulate the investment in technology and the production of devices directly in the office. Results state that 80% of the interviewed dentists execute less than 5 restorations each week and only the 20% more than 5.

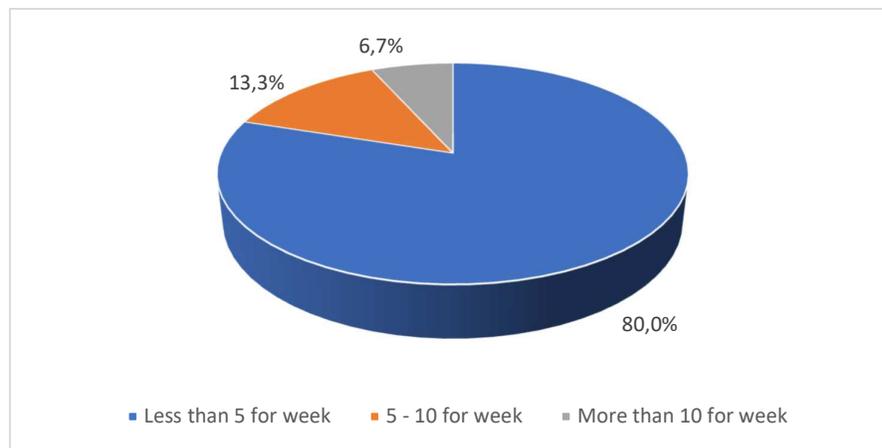


Figure 59. Question 1: On average, how many implantology and fixed prostheses surgery are carried out in your practice?

The third and fourth questions regard the age of the doctors who operate in the clinics. Before, in question 2, was asked if more than one dentist operate in the practice. In case of positive answer, it was asked to indicate the age of the firsts 5 doctors working in the clinics and in case of negative answer the age of the only one doctor was asked. For the single-doctor clinics the age was more than 45 years in every case, whereas in case of multi-doctor

clinics the average age was nearly 46 years. In particular this question was proposed in order to create an average age of each practice and verify if this parameter influences the adoption of digital technology considering that, in many cases, young dentists are more confident with information technology and in the recent degree courses the use of some of these technology are taught.

With the next question we enter in heart of the survey. In fact, the dentists were asked if they use an intraoral or desktop scanner, the first step in order to start a digital production of dental devices in-office, and in particular a necessary step to bring additive technologies in the practices. The results indicate that most of the practices (77.4%) rely on traditional impression methods and only 22,6 % use an intraoral scanner. It is already possible to affirm that this low percentage limits the adoption of additive technology and in general the digitalization of the workflow.

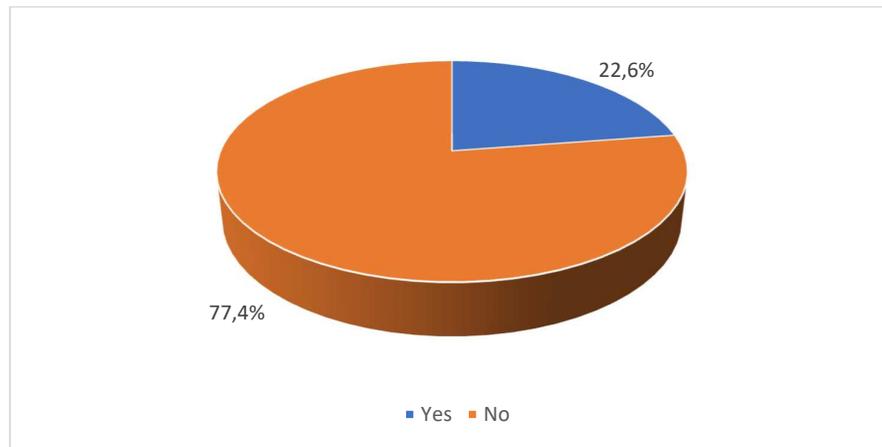


Figure 60. Question 6: Is at least one intraoral or desktop scanner used in the practice?

In the next question, directed only to dentists who do not use a scanner, an accordance scale was used in order to investigate the principal reasons of non-adoption. In particular, was asked to indicate the grade of agreement with some sentences studied to highlight the potential drawbacks of this technology.

Many dentists agree that intraoral scanning nowadays is still an immature technology underlining the fact that, probably, it is not convenient to invest in a model that costs up to 20,000 euros and can become obsolete in a short time.

The second result is that many dentists agree that the investment in a scanner is high in comparison to the benefits that introduces. Just think that from a practical point of view it is possible to collect an impression also with a common dental impression spoon, surely

without all the benefits of an intraoral scanner, but with a really low initial investment, which can be justified only in case of several impression per week.

For many respondents the learning curve of the scanner is not an issue, the reason can be found in the fact that dentists are familiar with the use of complex technologies and devices.

In general, the intraoral scanner is not seen as a technology that is going to be obsolete, representing the perfect candidate to replace the traditional methods and starts a digital dentistry approach.

No evidence has emerged from the “provocative” statements *“there is no reason to change from traditional methods”*.

The last statement shows the clearest result. In fact, the majority of dentists totally disagree with the statement *“I have never received purchasing proposal”* highlighting the fact that big efforts are made by manufacturers and retailers of 3D scanners to promote the sale of these devices.

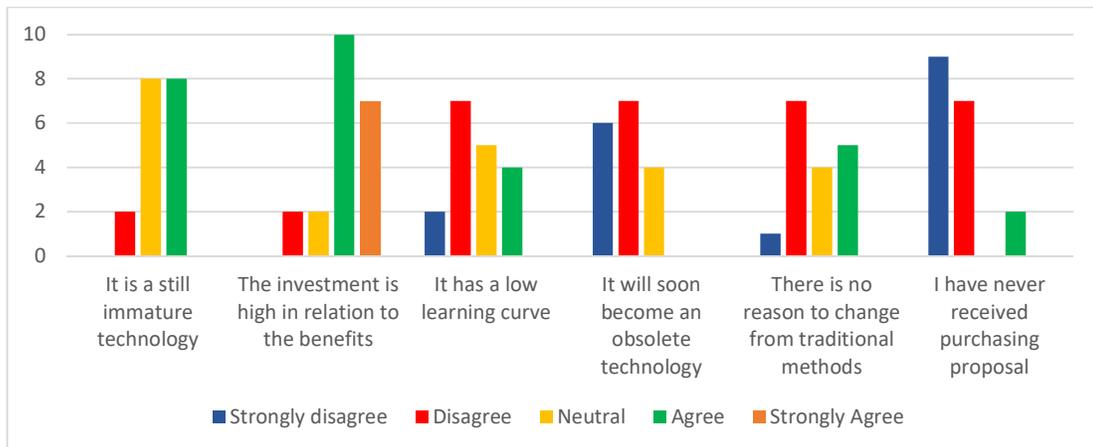


Figure 61. Question 10: Please indicate the reasons why you did not invest in this technology (3D scanner)

Subsequently, doctors were asked if some future investments in scanner technology have been planned, resulting in a total of 50 % of respondents who planned an investment in the medium (29.2 % within 5 years) and short (20.8 % within 1 year) term and the remaining 50 % that do not plan any investment in this technology. Some considerations must be done on these data. All the potential buyer of an intraoral scanner are future potential users of a 3D

printers that facilitate the creation of 3D dental models bringing many advantages to the scanner users.

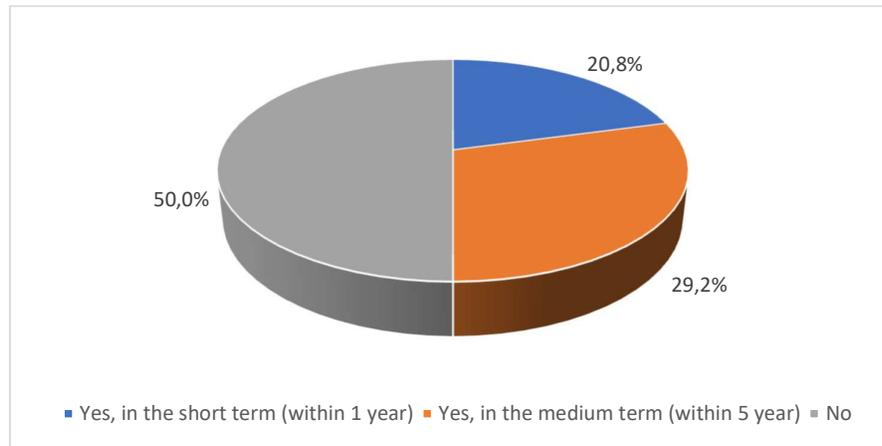


Figure 62. Question 11: Have you already planned future investments in Intraoral or Desktop scanner?

Before of the two last questions for the non-adopters of scanner, a short introduction on the possibility of use a 3D printer to produce in-office dental devices was presented to the respondents. Furthermore, was explained that the use of a scanner is necessary in order to use AM technologies.

The lasts two question were aimed to understand wheatear, in the future, the respondents will use a 3D printer and what could be the advantages and the drawbacks to produce dental devices directly in-office in order to understand what could be the limitation of internalize this steps and if there is room for this technology.

There is a large portion (50 %) of the respondents who actually are not sure about the future adoption of additive technologies. On the contrary, 25% believe that this technology will be used in the future.

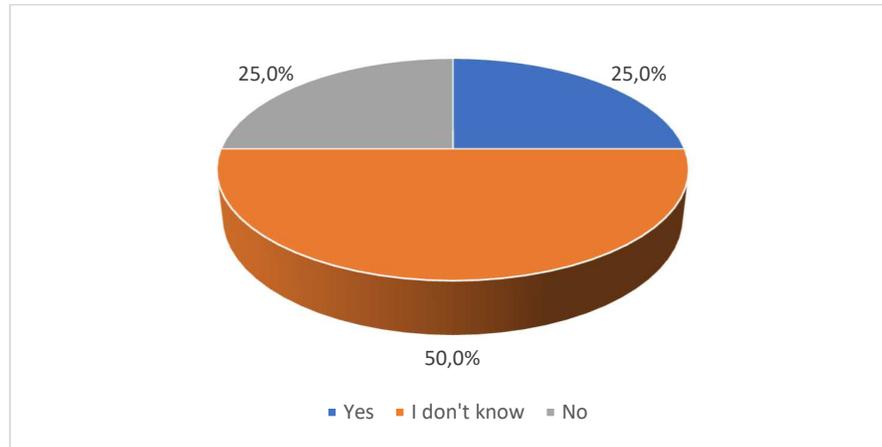


Figure 63. Question 12: Do you think you will use a 3D printer in your office?

The last question is an open one thought to collect opinion on the production of dental devices directly in-office and highlights the benefits and the drawbacks.

The main disadvantage that emerge from many comments regards the time dedicated for the production of these devices. One dentist answered: *“I do not want to spend time to this activity at the expense of the clinical part”*. This answer shared by many other dentists point out the fact that probably for the production of dental devices a dental technician has to be hired in the office. In fact, efforts dedicated to the clinical part are essential for each dentist, in order to stay informed on new surgery procedures and continuously increase the surgery abilities.

Many advantages have emerged from the comments of the respondents. In particular, for many dentists the quickness of production of devices is the key benefit of this technology resulting in an increased customer satisfaction. Another benefit that stand up is the *“operational flexibility and the autonomy”* that an in-office production can guarantee to the adopters, decreasing the dependence from the dental laboratories.

Different questions have been proposed to the scanner users. The first one regards the type of scanner that they use, intraoral or desktop. The majority of the dentists use an intraoral scanner in their office confirming that, actually, this is the most appreciated technology.

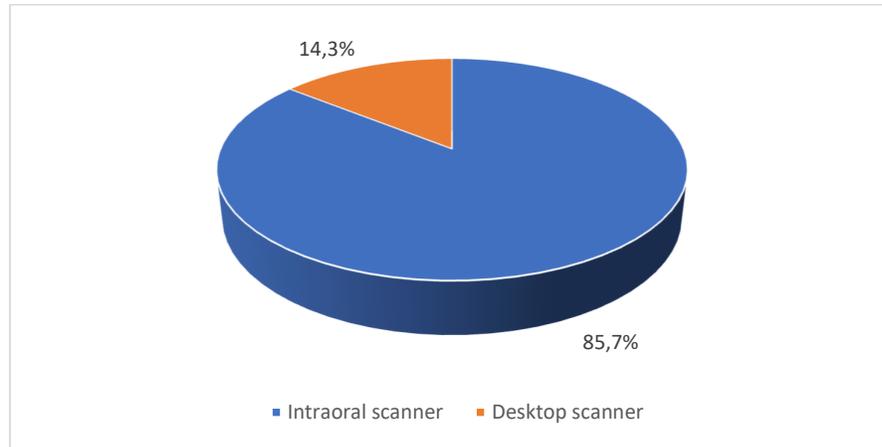


Figure 64. Question 7: Which type of scanner is used in the office?

The next question regards the year in which the first investment was done. The majority of the investments were done in the last four years. It seems that there is an increasing trend of the adoption of this technology in the last years.

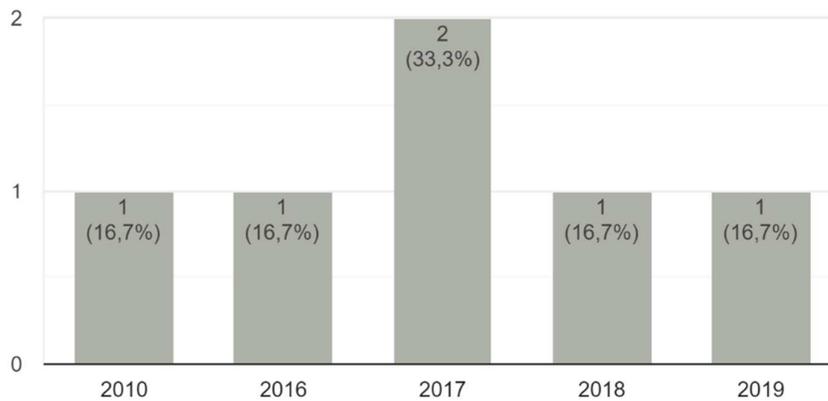


Figure 65. Question 8: In what year was the first investment in a scanner carried out?

Finally, an open question was used in order to confirm the key benefits resulting from the use of this technology. In particular, the rapidity of acquisition of the impression is the benefit shared from each of the users followed by the fact that this device offers an “immediate check of the impression quality”. Another point which has emerged from the survey is the possibility to better store the patients’ impression in a digital format, as already discussed.

The next section of the survey was dedicated only to the dental offices that actually use a scanner in order to know if they already use additive technologies and in case of not adoption what are the reason that limit the diffusion.

In figure 66 the results regarding the adoption of 3D printers are presented. The data provide a clear answer. From the 7 users of an intraoral scanner only 1 dentist uses a 3D printer.

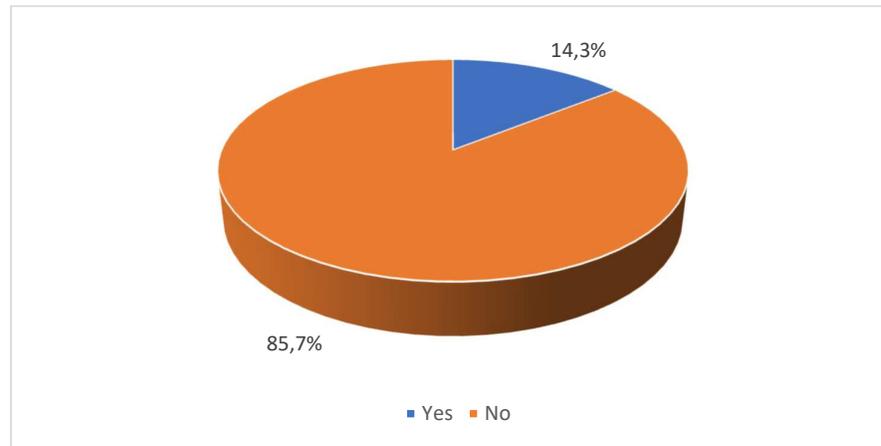


Figure 66. Question 14: Do you use a 3D printer in your office?

The aim of this core part of the survey was to understand which are the causes of non-adoption of a 3D printer. An accordance scale was used also in this case in order to prove the accordance of the respondents with some statements collected discussing the theme with some 3D printer vendors.

One results that came out from the questions is that the majority of respondents know additive technologies and this can be confirmed by the large disagreement percentage with the last statement “*I have never received purchasing proposal*”, a signal that market operators are try to push this technology inside the dental offices.

Regarding the learning curve of 3D printers, practically, all the dentists do not agree with the fact that this technology has a low learning curve, enhancing the fact that the modern machines are user-friendly and the cartage-based system allow to reduce complex operation of refill.

The first issue that came out from this part of the questionnaire was the fact that many dentists agree that this technology is not mature. This fact can discourage potential buyer from making an investment. As already said in the previous chapters, actually the biggest issue in dental 3D printing is the non-availability of materials to produce permanent restoration and this make the device incomplete from a functional point of view.

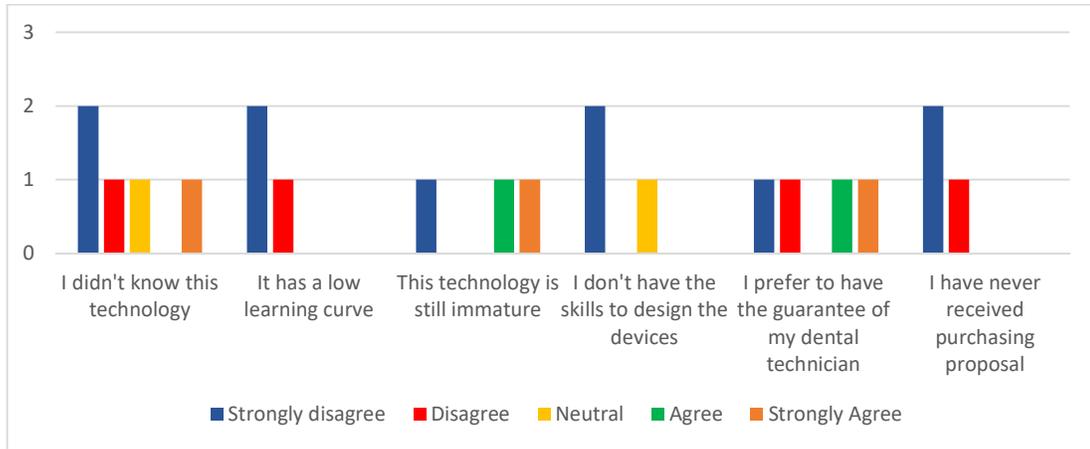


Figure 67. Question 20: Please indicate the reasons why you did not invest in 3D printing

Afterwards, the technical competences required to design a dental device seem to be not an issue for the respondents. No evidences stand out from the statement “*I prefer to have the guarantee of my dental laboratory on the devices that I use*” in fact, the results are perfectly distributed not highlighting a trend.

The next question has been thought to understand if the potential users of a 3D printer have planned investments in 3D printing. The results support the hypothesis that this technology will be introduced in the dental practices. In fact, the 66,7% of scanner users have been planned investment in 3D printing in the short term (16,7% within one year) and in the long term (50% within 5 years).

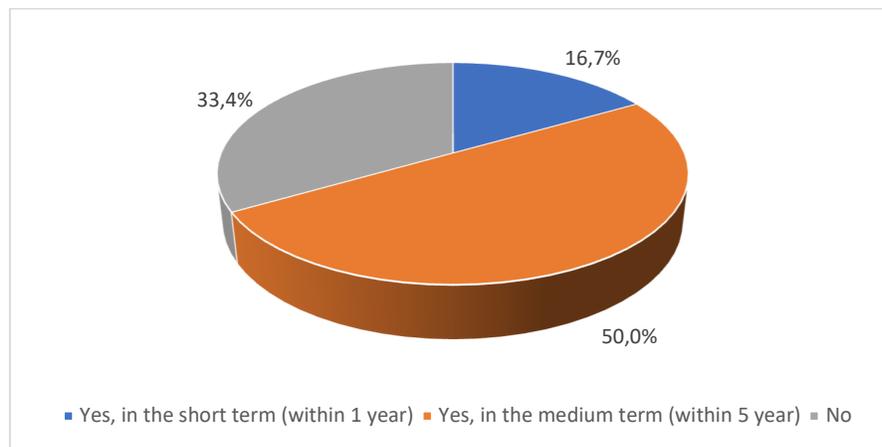


Figure 68. Question 21: Have you already planned future investments in a 3D printer?

The last question, posed to the users of a scanner, regards the adoption of a dental milling machine that relies on a subtractive manufacturing technology. Exactly 50% of the users of an intraoral scanner produce dental devices in their offices.

Crossing the answer to this and the previous question an evidence came out: all the actual users of subtractive technology have planned investments in additive technology in the short and long term; probably because they already appreciate the benefits resulting from the production of dental devices in the offices.

These figures are really important. 3D printers can substitute or support subtractive devices in dental practices.

Based on the survey result it seems that only one respondent actually uses a 3D printer in his practice representing the 14,3% of the potential users. In this case additive technology is used to print dental models, the investment was done in 2018 and was less than 7,000 euros. This respondent uses a 3D printer in his practice relying of the work of 2 dental technicians that produce the devices.

The final part of the questionnaire was dedicated to the collection of comments regarding the research and the subject of the survey. It was very satisfactory to note that, from the comments given, the initiative was appreciated, and many dentists are interested in the results of the research. The other point that came out from the final comments is that many dentists are waiting for a reduction in costs of digital technology in order to make investments.

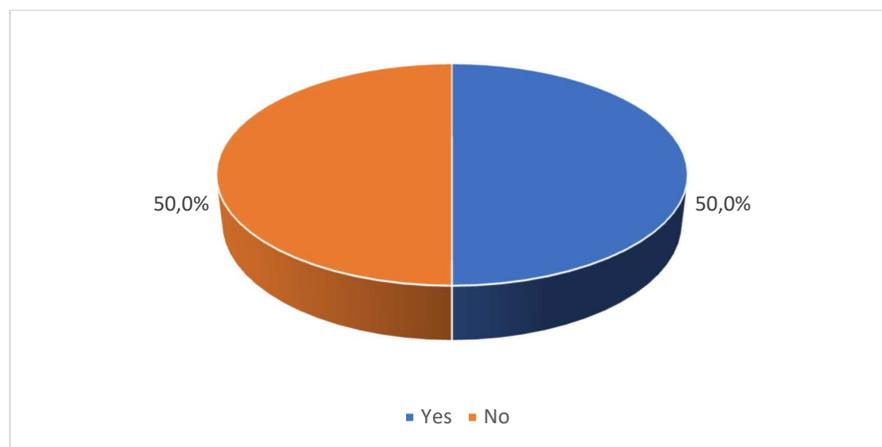


Figure 69. Question 22: Did you use or use a dental milling machine in your practice?

4.9. Final remarks

After analyzing the evidences emerged from the survey and joining the data collected and the information presented in the previous chapters, it is possible to figure out some conclusions.

The first point to highlight is that actually 3D printing is rarely used in dental practices. The survey confirmed an expected result: in fact, as already said, the introduction of this technology in the dental sector is still recent. In particular, the low adoption can be related to different factors.

The first, and let me say, biggest limit, is the low adoption of scanning technology, which is essential to start a digital production workflow and representing the real trigger for the use of 3D printing. In fact, with an intraoral scanner the use of a printer is fundamental because it can easily reproduce the impression model of the patients. Less than a quarter of the interviewed doctors use this technology. This low percentage reduces the need and the opportunity to invest in additive technologies. The limited adoption of the scanner is principally due to its high cost in relation to the benefits that it can bring; actually, the work of the scanner can be done with traditional methods obtaining a qualitative similar result. The reasons of the high cost of this particular device can be attributed to its complexity due to the use of miniaturized optic, and the presence of only few producers on the market which keep the price high.

Another crucial point is the immaturity of AM technology for the specific dental field confirmed by the answers of the potential users. From the previous chapters, emerges that the actual development of materials poses constraints regarding the impossibility to print permanent crowns, reducing the printer applications and discouraging the potential users to invest in 3D printing.

From the survey also emerges that there is an association between the use of the intraoral scanner and the number of restorations done per week. Clearly, a high number of restorations facilitate the investment in this device and a low adoption can be justified by the fact that the 80% of respondents execute less than 5 restoration per week.

The impossibility to use AM for a chairside workflow due to the long building times, reduces the use of this technology in this sector letting space to subtractive technologies actually used by half of the adopters of scanner.

In conclusion, it is possible to affirm that Additive Manufacturing has the potential to be used in every dental office, but, at the moment, many constraints reduce this phenomenon. Regarding the future perspectives, there is a certain interest in the adoption of digital technologies from the dentists side, proven by the high percentage of dentist that already planned investment in scanner and 3D printers. Definitely, in the next years we will assist to an increasing adoption that can be encouraged by a scanners price decrease and an advancement in 3D printing materials could spur this phenomenon. In addition to this, a solution that could speed up the diffusion of AM in the dental practices could be the combined commercialization of 3D printers together with a 3D scanner which can create a unique system. This is exactly what happened with CEREC technology, that combines 3D scanners and subtractive manufacturing devices.

Acknowledgements

Parto dal ringraziare il mio relatore, Prof. Luigi Benfratello, per la sua infinita disponibilità e la sua vicinanza a noi studenti.

Ringrazio i mie cugini Giacomo ed Edoardo, due bravissimi dentisti, che mi hanno supportato (e sopportato) su tutta la parte clinica della tesi dandomi preziosi consigli e permettendomi di conoscere il loro mondo.

Inoltre, volevo ringraziare Luca, un professionista del settore Additive. Grazie a lui ho potuto osservare questo mondo da un punto di vista commerciale, ricevendo numerosi suggerimenti ed informazioni.

Vorrei in particolare ringraziare la mia famiglia, che mi ha aiutato a portare avanti questo percorso di studi dandomi la forza, i consigli e la grinta necessaria ad affrontare i momenti più difficili.

Infine vorrei ringraziare tutti gli amici che, anche se da lontano, mi sono stati vicini. Inoltre vorrei scusarmi con loro per la mia lunga assenza in questi ultimi mesi. Da questo momento avremo modo di recuperare tutto!

Appendix: Questionnaire

Sondaggio sull'uso di tecnologie Additive Manufacturing negli studi dentistici

Gentile Dottore,

la ringrazio per aver scelto di partecipare al sondaggio. Le sue preziose opinioni daranno un contributo fondamentale a questa ricerca. Qualora volesse conoscere di più riguardo allo studio lo indichi nei commenti finali.

Cordiali saluti,

Ing. Stefano Conte
Politecnico di Torino

*Campo obbligatorio

1. Indichi il suo nome e cognome o il nome dello studio *

(Questa informazione non verrà utilizzata per fini commerciali o pubblicitari ma serve solo per individuare quali degli studi contattati hanno risposto al sondaggio)

Informazioni sullo studio dentistico

2. Mediamente quanti interventi di implantologia e protesi fissa vengono effettuati presso il suo studio?

Contrassegna solo un ovale.

- Meno di 5 a settimana
 5 - 10 a settimana
 Più di 10 a settimana

3. All'interno dello studio operano più dentisti? *

Contrassegna solo un ovale.

- Sì *Passa alla domanda 4.*
 No *Passa alla domanda 5.*

Più dentisti: Sì

4. Indichi la fascia di età dei dentisti che operano nello studio

Contrassegna solo un ovale per riga.

	25 - 35 anni	35 - 45 anni	Più di 45 anni
Dentista 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dentista 2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dentista 3	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dentista 4	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dentista 5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Passa alla domanda 6.

Più dentisti: No

5. Indichi la fascia di età del dentista che opera nello studio

Contrassegna solo un ovale.

- 25 - 35 anni
- 35 - 45 anni
- Più di 45 anni

Passa alla domanda 6.

Scanner Intraorale e Scanner Desktop

Lo Scanner Intraorale viene utilizzato per rilevare l'impronta del paziente direttamente in formato digitale mentre lo Scanner Desktop viene usato per convertire un modello in gesso in un formato digitale.



Scanner Intraorale



Scanner Desktop

6. All'interno dello studio viene utilizzato almeno uno di questi scanner? *

Contrassegna solo un ovale.

- Sì *Passa alla domanda 7.*
- No *Passa alla domanda 10.*

Scanner: Sì

7. Quale tipo di Scanner utilizza?

Contrassegna solo un ovale.

- Scanner Intraorale
 Scanner Desktop

8. Quando è stato effettuato il primo investimento per l'acquisto dello scanner?

(Specifichi anno)

9. Quali sono i principali benefici introdotti da questa tecnologia?

Passa alla domanda 14.

Scanner: No

10. Indichi i motivi per cui non ha investito in questa tecnologia

(Indichi il grado di accordo con queste affermazioni)

Contrassegna solo un ovale per riga.

	Molto in disaccordo (1)	In disaccordo (2)	Nè d'accordo nè in disaccordo (3)	D'accordo (4)	Molto d'accordo (5)
È una tecnologia ancora immatura	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
L'investimento è elevato in relazione ai benefici	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ha una bassa curva di apprendimento	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Presto diventerà una tecnologia obsoleta	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Non c'è motivo di abbandonare i metodi tradizionali	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Non mi è stato mai proposto l'acquisto	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

11. Ha già pianificato investimenti futuri per l'acquisto di uno Scanner Intraorale o Desktop?

Contrassegna solo un ovale.

- Sì, a breve (entro 1 anno)
 Sì, a medio termine (entro 5 anni)
 No

Tecnologie Additive

Grazie all'uso di una stampante 3D è possibile creare nel proprio studio dispositivi dentali come Corone provvisorie, Dime chirurgiche, Aligners trasparenti e Modelli tridimensionali. Per l'utilizzo della stampante è necessario disporre dell'impronta del paziente in formato digitale e quindi lo scanner intraorale o desktop è strettamente indispensabile.

12. Pensa che in futuro utilizzerà una stampante 3D nel suo studio?

Contrassegna solo un ovale.

- Sì
 Non sono sicuro/a
 No

13. Indichi quali vantaggi e svantaggi porterebbe la produzione di dispositivi dentali direttamente nel suo studio.

Passa alla domanda 23.

Stampante 3D

14. Utilizza una stampante 3D nel suo studio? *

Contrassegna solo un ovale.

- Sì *Passa alla domanda 15.*
 No *Passa alla domanda 20.*

Stampa 3D: Sì

15. Quando è stato effettuato il primo investimento nella stampa 3D?

(specificare anno)

16. Cosa produce con la stampante 3D?

(può selezionare più di una risposta)

Seleziona tutte le voci applicabili.

- Dime chirurgiche
 Corone provvisorie
 Aligners trasparenti
 Modelli dentali
 Altro: _____

17. Qual è l'ammontare del primo investimento da lei effettuato nella stampa 3D?

Contrassegna solo un ovale.

- Meno di 7000 €
 7'000 - 15'000 €
 Più di 15'000 €

18. Quali sono i principali benefici introdotti dalla stampante 3D?

19. Ha utilizzato oppure utilizza una fresatrice dentale nel suo studio?

La fresatrice dentale rappresenta il primo esempio di utilizzo di tecnologie innovative per produrre corone dentarie direttamente nello studio dentistico

Contrassegna solo un ovale.

- Sì
 No

Passa alla domanda 23.

Stampa 3D: No

20. Indichi i motivi per cui non ha investito nella stampa 3D

(Indichi il grado di accordo con queste affermazioni)

Contrassegna solo un ovale per riga.

	Molto in disaccordo (1)	In disaccordo (2)	Nè d'accordo nè in disaccordo (3)	D'accordo (4)	Molto d'accordo (5)
Non conoscevo questa tecnologia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bassa curva di apprendimento	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Credo che questa tecnologia non sia ancora matura	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Non ho le competenze tecniche per progettare i dispositivi dentali	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Preferisco avere la garanzia del mio odontotecnico	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Non mi è stato mai proposto l'acquisto	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

21. Ha già pianificato investimenti in una stampante 3D?

Contrassegna solo un ovale.

- Sì, a breve (entro 1 anno)
- Sì, a medio termine (entro 5 anni)
- No

22. Ha utilizzato oppure utilizza una fresatrice dentale nel suo studio?

La fresatrice dentale rappresenta il primo esempio di utilizzo di tecnologie innovative per produrre corone dentarie direttamente nello studio dentistico

Contrassegna solo un ovale.

- Sì
- No

Commenti

23. Indichi qui ulteriori commenti riguardo alla ricerca e al sondaggio

Sondaggio concluso

La ringrazio per il tempo da lei dedicato.

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