“Healthcare meets tech: The impact of 3D printing for orthopedic immobilizer devices”– An Industry Analysis

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Dissertation written under the supervision of

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Abstract

Title: "Healthcare meets tech: The impact of 3D printing for orthopedic immobilizer devices"– An Industry Analysis

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To immobilize or replace a limb, custom-made medical devices must be produced by the orthopedic industry, such as casts, orthoses and prostheses. While very little major progress has been made in this area, the development of new technologies makes it now possible to produce immobilization devices through 3D printing that are specific to the anatomical characteristics of patients.

This dissertation aims to determine the advantages of 3D orthoses and external prostheses, their barriers and limitations, as well as the feasibility of implementing the technology on the Belgian market.

In order to test the viability of the production of 3D printed immobilization devices as an alternative approach, six expert interviews were conducted. The interviewees focused on main stakeholders: orthopedic surgeons, orthotists, 3D manufacturers and regulators.

The results subsequently provided viable indications of therapeutic effectiveness and benefits for the patient's quality of life. The main barriers to adoption are the economic parameter as well as the maturity of the technology. However, technological advances, well-defined cross-collaboration, and an adapted business model combining a 'SaaS' and 'end to end' solution can overcome these barriers and ensure successful implementation. In conclusion, 3D printing technology in the orthopedic industry proves to have an achievable diffusion. If executed diligently, 3D printed orthoses and prostheses may become common devices.

Keywords: 3D printing, Orthopedic immobilization device, New technology, Therapeutic impact, Social impact, SaaS

Resumo

Título: "Assistência médica encontra tecnologia: Qual é o impacto da impressão 3D em aparelhos imobilizadores ortopédicos" – análise da indústria
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Para imobilizar ou substituir um membro, os aparelhos médicos feitos sob medida devem ser produzidos pela indústria ortopédica, como moldes, ortóteses e próteses. Embora muito pouco progresso tenha ocorrido na área, o desenvolvimento de novas tecnologias possibilita a produção de aparelhos de imobilização através da impressão 3D, específicos às características anatómicas dos pacientes.

Esta dissertação tem como objetivo determinar as vantagens das ortóteses 3D e próteses externas, barreiras e limitações, bem como a viabilidade de implementar a tecnologia no mercado belga.

Com o propósito de testar a viabilidade da produção de aparelhos de imobilização impressos em 3D como uma abordagem alternativa, foram realizadas sete entrevistas com especialistas. Os intervenientes principais foram entrevistados: cirurgiões ortopédicos, ortopedistas, fabricantes 3D e reguladores.

Os resultados subsequentemente proporcionaram indicações viáveis da eficácia terapêutica e dos benefícios para a qualidade de vida do paciente. As principais barreiras à adoção são a vertente económica e a maturidade da tecnologia. No entanto, os avanços tecnológicos, a colaboração cruzada bem definida e um modelo de negócio adaptado que combina uma solução *'SaaS'* e *'end to end'* pode superar as barreiras existentes e garantir uma implementação bem-sucedida. Em conclusão, a tecnologia de impressão 3D na indústria ortopédica demonstra uma difusão viável. Se executadas diligentemente, ortóteses e próteses impressas em 3D podem se tornar aparelhos comuns.

Palavras-chave: Impressão 3D, Aparelho de imobilização ortopédica, Nova tecnologia, Impacto terapêutico, Impacto Social, *'SaaS'*

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1. Introduction

1.1 Context

The additives manufacturing (AM) technology or Three Dimensional (3D) printing has progressively gained importance over time and developed in many economic sectors such as the construction, automotive, consumer goods and the healthcare industry through its variety of applications. (Jiang et al., 2017). Over the past 35 years, the healthcare industry has been benefiting from 3D printing novel technology due to its ability to create customized product of complex shapes with high precision (Kaye et al., 2016). 3D printing presents a great potential in different fields of the medical industry that need patient-specific treatment. The technology operates in post surgeries treatment as orthoses, implants and prostheses. AM is also used to prepare surgeries through anatomical modeling. It enables surgeons to gain insight into a patient's specific anatomy and be better prepared for complex surgery. Moreover, AM is used for the customization of drugs dosage as it allows for the production of smaller quantities of products, which can usually not be done cost-effectively in the biomedical sector. AM can also produce customized drugs that require complex products in a faster and cheaper way than the traditional method, then make it more easily accessible to the public (Ngo et al., 2018).

1.2 3D bioprinting

The emergence of 3D bioprinting, which implies applications going from biomedical hearing aids to biomedical implants, consists of the inclusion of cells and tissues through 3D printing to create regenerative tissues of the human body. 3D bioprinting is one of the main drivers of the growth of 3D printing in the healthcare industry. In the future, 3D bioprinting aims at being able to regenerate tissues, skeletal structure and organs of the human body, and assure a 100% match transplantation when, so far, transplantations are done through donors and face risk of organism rejection (Milan et al., 2019). However, 3D bioprinting is challenged by the complexity of its technology, and research is still in its development phase. To date, although the technology is in a too early stage to explore its impact on medical operational performance, it is showing considerable promises (Milan et al., 2019).

1.3 Focus of Interest

The dissertation will focus on the impact of 3D printing in the orthopedic industry, i.e. orthosis and prosthesis, as the digital shift from "traditional technique" to 3D printing technique is disrupting its medical environment. This transformation implies a change in the business model, as well as a cultural and organizational change related to the interactions with the multiple stakeholders. To explore its full potential and drive better operational performance, the different players face the challenge of embracing the digital transformation of 3D printing in an effective manner (Hess et al., 2019).

1.4 Problem Statement

While the emergence of many new technologies has a considerable medical impact in the healthcare industry, the implementation of 3D printing technology must first prove its positive medical care for orthoses and prostheses compared to traditional technology. Then, the various stakeholders involved must collaborate to overcome the barriers related to cultural, organizational and operational changes in order to successfully commercialize 3D printed devices.

1.5 Research Questions

The analysis of the dissertation will be guided by the following research questions:
RQ1: To what extent does 3D printing technology enhance orthopedic treatments of orthosis and prosthesis when compared to traditional techniques?
RQ2: What is the potential value of applying 3D printing to these orthopedic treatments on the Belgian market?
RQ3: How can it be effectively implemented throughout this market?

1.6 Relevance

Due to the digital transformation of 3D printing technology in the medical industry, the following master dissertation aims at validating the impact that the technology will have on the orthopedic patient treatment. Current research underlines significant potentials and a strong awareness of the technology in this industry, as well as important barriers to make 3D printed orthosis and prosthesis a commonplace. The dissertation aims to reduce uncertainty about the mainstream diffusion of the technology and to provide an industrial outlook on the technology.

1.7 Scope of analysis

The research of the dissertation and the industry analysis will focus on Belgium as geographical area. Early adopters of 3D printing technology, such as the United States, will provide guidance to explain some of the developments. The dissertation will be targeting every stakeholder involved in order to analyze the effect of the entire 3D printing technology for the orthopedic treatment.

1.8 Dissertation Structure

The following dissertation is divided into four parts that concern 3D printing technology for orthoses and prostheses.
The first part reviews the literature required to provide the necessary background for the establishment of the research. At first, an analysis of the medical industry in terms of orthosis and prosthesis treatment is presented. Then, the history of 3D printing technology, and its important milestones, is explored, as well as a detailed explanation of the functioning of the technology. Additionally, the disruptive and innovative role of 3D printing technology in the orthosis and prosthesis industry is highlighted. Lastly, a focus on 3D printing technology in the orthodontic industry is used as a benchmark example.

The second part of the dissertation presents the research methodology. This includes the collection of data from different sources, and the consolidation with existing data from the literature review. The objective is to establish the right methodology in order to validate the existing findings and bring additional information to the research.

The third section provides a discussion and analysis that addresses the three research questions, including the advantages of the technology, its limitations, and the scenario for successful implementation. Additionally, the Spentys case is introduced to exemplify the role of the 3D manufacturer.

In the fourth part, an overall conclusion is drawn from the various sections of the dissertation. This part closes with the limitations of the research and the opportunities for further studies.

2. Literature Review

2.1 The medical surgery industry: Orthosis and prosthesis post treatment

The ever-increasing aging of the population has an impact on the number of disabled and amputee patients (Simpson et al., 2019). Proportionately, there is a growing need for orthosis and prosthesis devices to treat patients in the rehabilitation process (Simpson et al., 2019).

2.1.1 Orthosis and prosthesis definition

An orthosis is an external device (Figures 1 & 2) that supports limbs in weakened or deformed parts of the body for different properties: correcting and accommodating deformity; controlling biomechanical alignment; protecting and supporting an injury; assisting in rehabilitation; reducing pain; increasing mobility; and increasing independence. In order to have the best possible fit, and to achieve the above-mentioned goals, the orthosis is designed according to the shape of the body. Depending on the type of support provider, there is a wide range of prefabricated or custom-made orthoses available (Australian orthotic prosthetic association, 2019)

Figure 1: Orthosis Immobilization Wrist

Figure 2 : Orthosis Immobilization Ankle

While an orthosis is a support device, a prosthesis is an artificial apparatus that replaces a missing limb. Its function is to ease the life of amputees. It implies a high degree of complexity because the properties of the prosthesis vary between the upper and lower limbs, while trying to achieve the best aesthetic appearance at the same time (Figure 3) (Georgia Tech, 2019). It must address stability and shock absorption for the lower limb as well as energy storage and return. Upper limb prostheses must be capable of grasping and reaching functionality in order to accomplish tasks such as eating, weight-lifting and writing (Georgia Tech, 2019).

Figure 3: Prosthesis Carbon for Lower Limb

2.2 The 3D printing technology

2.2.1 3D printing definition

The 3D printing technology, also known as additive manufacturing, is "*a process of creating a three dimensional object or rapid prototyping of 3D models from a digital file, by laying down successive deposits of material on top of each other as the printing machine reads data from the computer- aided design (CAD). Each layer is equivalent to a cross section of the CAD model and they fuse together to create the final shape.*" (Kaye et al., 2016). 3D printing enables the production of prototypes, mock-ups, customized products and replacement parts by using different types of materials, such as resin, polymer, wax, ceramic and many more (Milan et al., 2019).

2.2.2 The evolution of 3D printing

Hideo Kodama, from the Nagoya Municipal Industrial Research Institute, was the first person to describe the process of solid prototyping, back in 1981. His invention was the foundation of 3D printing technology (Kaye et al., 2016). A few years later, in 1986, Charles Hull designed and created the first 3D printer, a process known as stereolithography (SLA). It involves a principle of photopolymerization to create a 3D model through a specific resin that is sensitive to ultraviolet, and it uses a laser to solidify the liquid resin. Subsequently, other developments have come to maturity such as powder bed fusion, fused deposition modeling (FDM), inkjet printing, contour crafting (CC) and more (Prince, 2014).

Over the years, as materials and equipment of printers are developing and becoming increasingly sophisticated, 3D printing has been applied in various industries. Moreover, the technology has become more accessible due to patents' expiry dates. It gave the opportunity for innovative projects to be undertaken in different industries through the development of new devices, and it has enabled the use of the technology from prototypes to products (Ngo et al., 2018). In the construction industry, for example, WinSu, a Chinese architect, printed small 200 m^2 houses entirely in 3D, in less than a day, for poor people in the Shanghai region. He was able to develop large-scale 3D printed surfaces that meet the requirements of industrial construction (Wu et al., 2016).

2.2.3 Technological innovation: advantages and business model

3D printing technology has specific advantages over other types of technology. It allows product customization and the personalization of complex shapes with high precision. It has the ability to produce on-site and single-use products. There is no delay between design and production, which allows for rapid manufacturing. Moreover, there is less waste than with other technologies (Kaye et al,. 2016).

The technology that most closely resembles 3D printing and shares common characteristics is mass customization. However, they also contrast on specific points that will be analyzed in the next paragraph (Berman, 2012). Although firms are able to manufacture personalized products in small batches through mass customization, in the same way as 3D printing technology, their manufacturing and logistical processes differ. In terms of manufacturing technology, 3D printing uses raw materials based on an automated process where the product can be quickly designed and modified, and manufacturing can be easily outsourced. Mass customization uses pre-assembled components parts that must first be molded and usually require expensive tools. Unlike 3D printing, mass customization relies mostly on multiple suppliers due to the multiplicity of components, which requires a high degree of supply chain integration to ensure efficient logistics. 3D printing technology benefits from a small number of suppliers to readily purchase its raw materials and can easily switch suppliers. All this represents economic benefits, making the manufacturing and logistics process of 3D printing faster and cheaper than mass customization. Nonetheless, both types of manufacturing share similar economic advantages. Both do not carry finished products' inventory because customization is done on a pre-order process and pre-production payment improves working capital management (Berman, 2012).

Technology implies the integration of new business models due to the various changes in the supply chain processes mentioned above. The different advantages and variety of applications of 3D printing generate a real substitute for the current production process, which in turn creates an opportunity, but also a challenge, for established firms to undertake a new production process, or to reply to a new type of competitor (Jiang et al., 2017).

2.3 The 3D printing applied in medical surgery: Orthosis and prosthesis post treatment

The ever-evolving environment of the medical industry which is influenced by regulations, policies and technologies, requires healthcare providers to adapt to the environment by keeping patient care at the hearth of their operations (SME MMI., 2018). 3D printing technology is having a growing influence in the medical industry where anatomical modeling, prototyping and dental implants are the most popular applications. Regarding orthosis and prosthesis, it is facing an increasing adoption trend, with 26% of medical hubs in the US having adopted the use of 3D printing for these devices (Figure 4) (SME MMI., 2018).

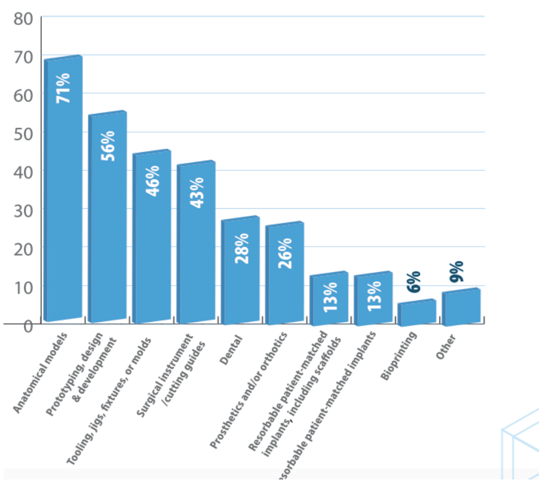


Figure 4: Most Popular Application of 3D printing in USA

2.3.1 3D printed orthosis and prosthesis

3D printed orthosis and prosthesis are based on a 4-step process to achieve the end result of converting a numerical model into a physical model. It starts with the acquisition of 3D images using computer-aided design (CAD) software. The second phase involves the processing of the image data, which implies image segmentation and modelization. The CAD file is converted into an STL file for the third phase. The STL file is then sent to the printer that uses Fused Deposition Modeling (FDM) technology to produce the orthosis or prosthesis. This phase also includes choosing the right material for the type of the device. The final phase concerns the post-processing of the device through mechanical methods: sanding, abrading, vibrating and machining (Figure 5). The objective of post-processing is to make the orthosis or prosthesis as soft and comfortable as possible (Milan et al., 2019).

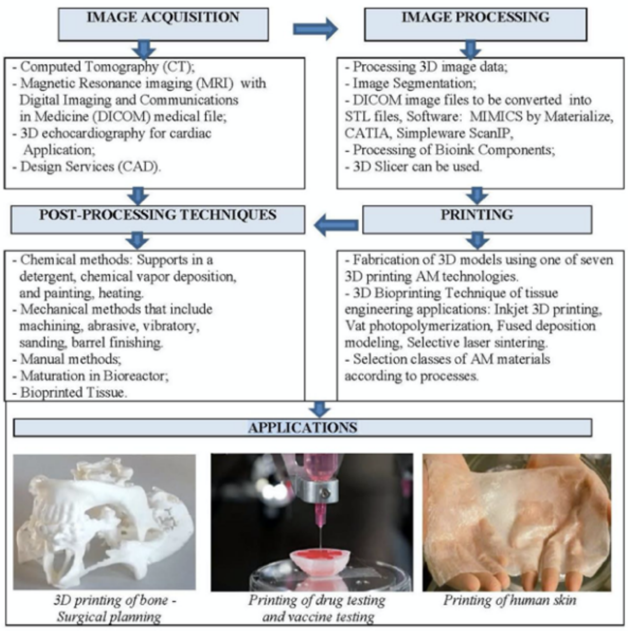


Figure 5: Basic Step of 3D medical models using 3D printing and 3D bioprinting

FDM technology is the method used to create the 3D printed orthosis and prosthesis, by depositing melted thermoplastic polymer through a filament form (Figures 6 & 7). Various types of materials can be used, including ABS plastics, polyamides, polycarbonates, polyethylene, polypropylene and melted wax (Milan et al., 2019).

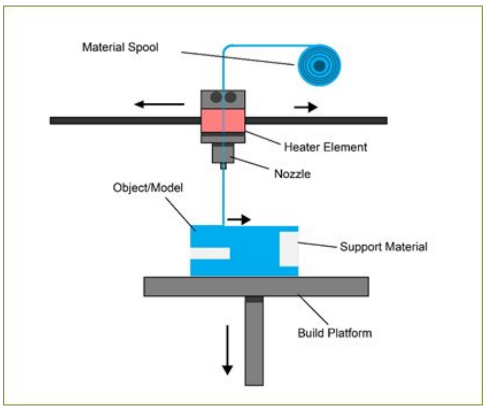


Figure 6: Fused Deposition Modeling System

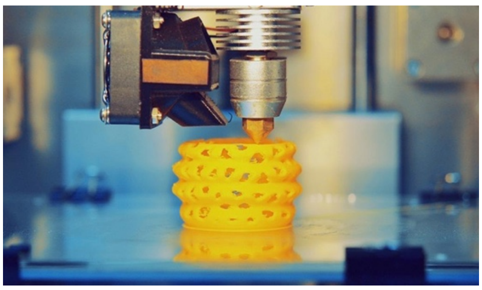


Figure 7: 3D Printed Product through Fused Deposition Modeling

2.3.2 The advantages and limitations compared to non 3D printed orthosis and prosthesis

Over the years, the use of 3D printing technology for the production of orthosis and prosthesis has proven its benefits to patients. In order to analyze its effectiveness, relevant parameters have been studied: manufacturing time, weight of the device, fit to the body shape, and certain user-centered parameters such as comfort and aesthetics. The results show that its fast and high-precision design can be easily customized and meets the requirements of custom-made orthosis and prosthesis. Moreover, it does not include an assembly process because of its ability to produce from a single piece, and then provide faster availability compared to traditional versions (ten Kate et al., 2017). Thanks to the freedom of design and the material used, 3D printing allows the creation of aerated devices that reduce skin irritation. It also makes the devices lighter than traditional devices. In addition, the materials used are biocompatible, waterproof and recyclable. These features prove the effectiveness of 3D printed orthosis and prosthesis compared to traditional ones, and make them more convenient to facilitate the patient's daily life (Fitzpatrick et al., 2017).

However, the technology also has some drawbacks to consider regarding orthosis and prosthesis. Firstly, orthoses printed in 3D are more valuable for secondary cast, because of the printing time. Secondly, there is a need to improve rapid accessibility for the initial use of the orthosis stabilization in case of fracture. The effectiveness of the device may also be affected by material shrinkage, parameters errors of the printers, CAD files or post-processing methods. Fourthly, the device is limited to the size of the printer, which restricts the creation of very large orthoses and prostheses. In addition, 3D printers can use a limited amount of material compared to traditional manufacturing (ten Kate et al., 2017).

2.3.3 Business model evolution

The digital transformation of 3D printed orthosis and prosthesis contributes to the transformation of the medical industry by acting on two different dimensions: process and product innovation, which involves an evolution of the business model (Doctors et al., 2012). This disrupting technology implies changes in the device itself and in the manufacturing process where the various stakeholders must operate according to these changes (Figure 8) (SME MMI., 2018).

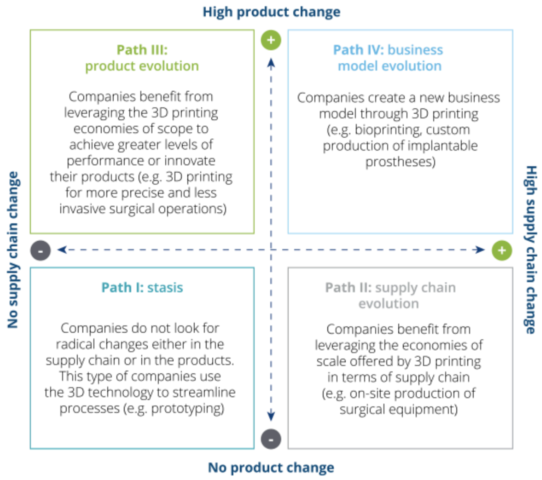


Figure 8: 3D printing Healthcare Industry Framework

3D printing technology has two common types of manufacturing in the healthcare industry. The first one refers to a "Point-of-Care Manufacturing" (POC) or "mass customization at point of use", which produces just-in-time devices at the patient's point of care, i.e. an in-house 3D printing facility. The hospitals or medical hubs involved are typically larger and can afford the investment in equipment and personnel. The second type is "mass customization near the place of use", i.e. when hospitals or medical hubs work with a traditional 3D printing manufacturer for production (Doctors et al., 2012).

Generally, 3D printing manufacturers offer two types of solutions for orthosis and prosthesis. The first is an "end-to-end" solution. This type of manufacturing refers to "mass customization near the place of use". It can be described in three steps: the manufacturer first provides a software to the orthotist for the scanning and modeling part; then, the CAD files are sent to the manufacturer and the modeling is reworked by developers to obtain the desired outcomes; lastly, the orthosis or prosthesis is printed in 3D on the manufacturer's premises and sent to the patient or medical hubs. This solution is usually more valuable for complex shapes or the development of a new design for specific pathologies (SME MMI., 2018).

The second type of solutions provided for by 3D printing manufacturer is supporting hospitals that have their own facility (POC) by providing a "Software as a Service" (SaaS) solution. This involves selling a software service for the scanning and modeling process to hospitals or medical hubs, and complementing POC projects with the manufacturer's expertise. This solution is best suited for the production of standard models of orthoses and prostheses that require a small degree of customization, such as a forearm splint in case of fracture. Both solutions imply a partnership between 3D printing manufacturers and medical hubs or hospitals. Where surgeons, orthotists and manufacturers establish a close relationship to develop patient-specific design (SME MMI., 2018).

Hospitals that set-up an in-house 3D printing facility to produce orthosis and prosthesis benefit from faster turnaround by eliminating shipping time. Devices can be controlled on-site, hence facilitating quality control and providing regulatory feedback. Moreover, POC allows for a combination of expertise, leading to greater interdisciplinary collaboration and better outcomes. This pool of knowledge and skills can lead to innovative solutions for patients and the creation of new types of orthosis and prosthesis for specific pathologies. It is expected that the manufacture of POCs will be a growing trend due to technological improvements enabling the easuer use of more sophisticated software and printers (SME MMI., 2018).

2.4 Benchmark of 3D printing in a similar industry: the orthodontic industry

In order to understand the potential value of commercializing 3D printed orthoses and prostheses, a benchmark comparative analysis is made with the orthodontic industry, which shares the common characteristics of complex custom products.

The orthodontic industry has been transformed by the development of 3D printing for specific dental alignment uses. Orthodontic technology has been commonly used since 1999, as a result of Invisalign. Initially a brand name, Invisalign has also developed its own technology that allows the manufacture of custom-made dental appliances that are unique for each patient (Figure 9). Using intra-oral scanning and a computer-assisted software that creates dentition simulations, Invisalign produces 3D printed teething molds that are made of biocompatible polyurethane material, that properly realign the patient's teeth, and that have the ability to handle complex cases. It offers a therapeutic treatment similar to that of traditional braces, but it is transparent, removable and more comfortable. It changes the patient's smile without disturbing his or her life (Kaye et al., 2016).

Invisalign has sold more than 4 million treatments in over 90 countries worldwide since its introduction on the market. It produces more than 200 000 alignment molds every day. In addition, the technology is constantly improving due to significant investments in Research and Development that are increasing its common use by doctors (Figure 10) (Morton et al., 2017).

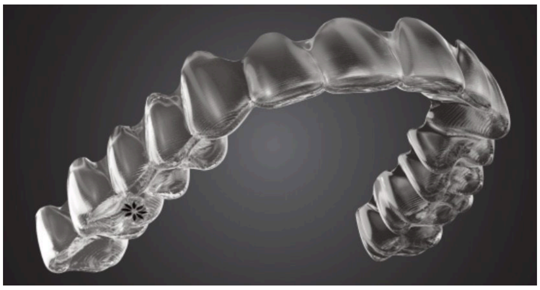


Figure 9: Invisalign Dental Brace

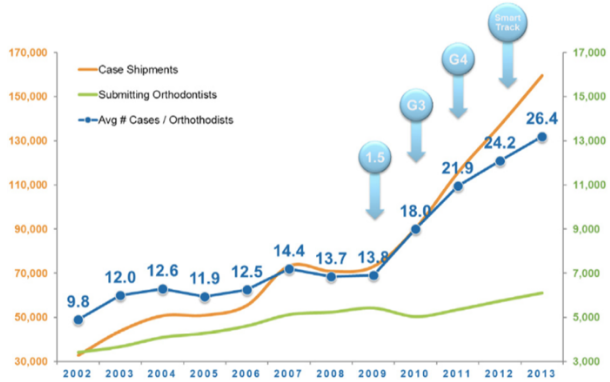


Figure 10: Growth in treatments with the Invisalign System

This example shows that 3D printing can be successfully commercialized for the use of customized and complex products. Furthermore, it is now a mature technology in the orthodontic industry, and it proves that patient-focused innovation can overcome the barriers and potential resistance of traditional dental methods of alignments (Lee Ventola, 2014).

3. Methodology

3.1 Research design

Despite the great opportunities for 3D printing technology, uncertainties and speculation about its future developments remain. The dissertation aims to answer three related fundamental research questions. In the literature review, it is proven that 3D printed orthosis and prosthesis have specific advantages over the traditional ones. Information from the literature review, conducted interviews, and additional reports, will be gathered to answer the first research question: "*To what extent does 3D printing technology enhance post-surgery treatments of orthosis and prosthesis when compared to traditional techniques?*".

3D printed orthosis and prosthesis are still in the development phase in Belgium. This means that the gathering of exact facts and quantitative results is still too early. Therefore, a qualitative approach was chosen to estimate the impact questioned in the second research question: "*What is the potential value of applying 3D printing to these post-surgery treatments on the Belgian market?*". In order to answer this question, a quantitative method will be used to measure the value, based on qualitative components. First of all, by choosing the right parameters from the interviews, literature review and additional reports, as well as their frequency. Second, the parameters will be assessed using a method of scaling from 1 to 5 of agreement. Additionally, the weight of each type of stakeholder will be established according to their importance and involvement in the subject. The two combined will be multiplied to visualize the outcomes.

The third research question, "*How can it be effectively implemented throughout this market?*", will be based on a Delphi method stemming from interviews with different stakeholders, as well as the results of the previous research questions. The Delphi method is a prediction method used for project management or economic prediction, based on expert interviews that are linked together to make a reliable future prediction (Jiang et al., 2017). The objective is to close the gap by predicting possible scenarios within 5 to 10 years, which assists in long-term strategic planning for hospitals and 3D printing manufacturers. Researchers can use this possible scenario as a starting point for further research on the development of the technology in the specific field of orthosis and prosthesis.

3.2 Data collection

The information that will be mentioned in the discussion part of the dissertation will draw on different types of data collection: interviews, literature review and additional reports.
The data are subdivided into two classifications, primary data and secondary data.
The primary data comes from the interviews. The objective is to interview the different stakeholders involved in order to have the most accurate insight possible of the topic (Table 1). These actors include orthopedic surgeons and orthotists, on the grounds of their medical expertise, as well as their knowledge and experience of 3D printing technology. They also include 3D printing manufacturers because they are the main players in the implementation of the technology. Finally, the regulators are included too, as they set the rules that cannot be circumvented by the technology. Most of the information will come from the primary data. Interviews will be semi-structured, with a certain amount of freedom to obtain spontaneous information from the interviewees.
Secondary data are the information collected from the literature review as well as insights from additional reports.

Table 1: Experts Interviews

Interview	Name	Position	Company/Hospital	Range of revenue
Interview A	Gadhy El Koury	Orthotist	Institute of Neurosciences, University Hospital of Saint Luc	➢ Revenue 2018: 536 000 000 €
Interview B	David Mazy	Orthopedic surgeons	CHIREC Hospital	➢ Revenue 2018: 503 000 000 €
Interview C	Thomas Schubert	Orthopedic surgeons	University Hospital of Saint Luc	➢ Revenue 2018: 536 000 000 €
Interview D	Robert Elbaum	Orthopedic surgeons, president of the orthopedic surgeons	CHIREC Hospital	➢ Revenue 2018: 503 000 000 €
Interview E	Louis-Philippe Broze	CEO & Co-founder	Spentys	➢ Fund raising 2 650 000 ➢ Cash In 2019: 200 000 €
Interview F	Non-Mentioned	Representative of the orthopedic department	INAMI	➢ 2019 budget for healthcare: 26.518.320.000 €

4. Discussion and Analysis

Before digging into the discussion part, it is necessary to clarify the types of orthopedic support in order to align and understand the following paragraphs. With respect to prostheses, the focus is on external prostheses for missing limbs (Figure 11). For the orthoses, there are two types of cases requiring orthopedic support. The first is for cases of injury or fracture and is referred to as "post-traumatic". This is a common case in children and it involves pediatric orthopaedics. In this case, the immobilization of a limb is traditionally done by a cast. They are generally made of plaster, resin or thermoformable material (Figures 12 &13). The second case concerns "congenital pathologies". A congenital disease is a pathology that affects a person from birth. It may be an inherited disease, although the origin of the congenital disease is not automatically genetic. Indeed, a congenital disease can be transmitted by one of the parents. It can also be contracted during pregnancy. In this case, it is a so-called acquired congenital disease (passportsanté, 2019) (Figures 14 & 15).

Figure 11: Traditional Prosthesis of Inferior Limb

Figure 12: Traditional Cast

Figure 13: Thermoformable cast of a Forearm

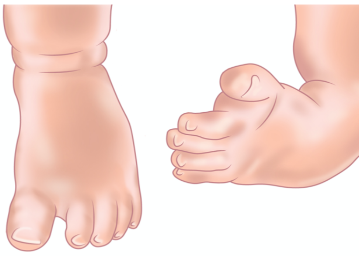


Figure 14: Clubfoot Pathology

Figure 15: Traditional Orthosis for Clubfoot Pathology

4.1 Advantages compared to traditional orthoses and prostheses

The first point to consider when launching a new technology in the medical industry is the added value for the patient in terms of medical treatment. If this can be proven, then other parameters are observed to consider potential adoption of the technology. The objective of the following section 4.1 is to answer the first research question: "To what extent does 3D printing technology enhance orthopedic treatments of orthosis and prosthesis when compared to traditional techniques?".

4.1.1 Therapeutic impact

In the case of 3D printing for the orthopedic industry, regarding "post traumatic" treatment, standard models of orthoses are usually required. For these standard models (see Figures 12 & 13), studies are still at too early a stage to state that 3D printed orthoses have a better therapeutic added value on the patient compared to traditional orthoses. However, tests undertaken on patients show that patient satisfaction, comfort, and perceived function are similar, or even superior, in the 3D printed orthosis (Appendix 1) under those specific conditions (Graham et al., 2018; Interview C).

1. The 3D scan must be done perfectly to be sufficiently accurate. This means that no movement is allowed and it requires the right angle of the scanned limb.
2. There is a prerequisite to have disciplined patients because it requires a dedication to wear a 3D orthosis that is not fixed. A good profile is, for example, a compliant young person who likes the technology and is receptive to it. A bad profile would be an elderly person with dementia.

Regarding the use of the technology for congenital pathologies, complex cases are involved, such as Jaccoud's hand or Clubfoot pathologies (Figures 16 & 17), for which the standard models do not match. A customized orthosis is necessary for each patient as the pathology will bring different types of angles and trauma to the limbs concerned. The possible customization through high-precision 3D printing is then necessary for complex pathologies. The 3D orthosis is considered to have a strong potential in this type of situation, specific to the anatomical characteristics of the patient (Interviews A,D,E).

Figure 16: Jaccoud's Hand Pathology

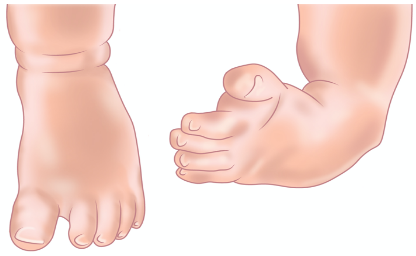


Figure 17: Clubfoot Pathology

Even though the orthopedic industry has thought of the ideal orthosis, it was never realized. 3D printing technology makes it possible to approach this ideal and meet the required characteristics. Both the device itself and the technology have specific advantages over traditional devices in terms of therapeutic impact (Appendix 2). They are enumerated as follows (Interviews A,B,C,D).

1. The device is more ventilated, which brings less risk of skin irritation (Appendix 3).

2. There is a possibility of cutaneous visibility with the feature of making openings during 3D modeling, for example around a wound or scar, allowing daily care if it seems necessary (Figure 18).
3. The 3D scanner is non-irradiating to the patient compared to the commonly used scanner, CT, which can develop cancer in case of high exposure.
4. The 3D orthosis is "radiotransparent" and facilitates the examination of the patient and the detection of anomalies (Figure 19).

Table 2: Quantitative Analysis of the Therapeutic Advantages of the 3D Technology

Therapeutic Impact	Degree of therapeutic importance	Frequency of the information	Source of the information	Total level of importance
Ventilation	3	3	3	3x3x3 = 27
Skin visibility	4	3	3	4x3x3 = 36
Non irradiating	2	2	2	2x2x2 = 8
RX transparency	2	1	2	2x1x2 = 4
	1 – 4 scale therapeutic benefits 1 Side benefit 2 Moderate benefit 3 Critical benefit 4 Huge benefit	1 - 3 scale of the frequency of the information 1 Low 2 Moderate 3 High	1- 3 scale relevance of the information 1 Secondary data 2 Primary data 3 Both	

Figure 18: Customized Openings for Wound or Scarce

Figure 19: RX Transparency: Cast VS 3D Orthosis

When looking at the previous paragraph, the therapeutic aspect of 3D printing in the orthopedic industry has proven to be similar under specific conditions for standard models of orthoses. Moreover, it confirms that there are advantages to using the technology in the case of specific congenital pathologies requiring a high degree of customization. Finally, the device and the technology itself have distinct advantages that are mentioned above. Ventilation and skin visibility appear to be the most impactful (Table 2). It is then worth analyzing the other parameters of adoption in order to examine the overall added value of 3D technology for the different stakeholders involved.

4.1.2 Social impact

Once the therapeutic impact of wearing an orthosis or prosthesis is achieved, quality of life becomes the major selection criterion. These devices have a real impact on the patient's social life. It is an uncomfortable device that interferes with daily activities such as showering, writing, cooking, etc. Overall, children are the main customers for orthoses and casts, and 3D printed orthoses will give them the opportunity to live more easily. Additionally, the social aspect is linked to the therapeutic aspect since the comfort of the device will have an impact on the resilience of the treatment. If the patient does not approve of the orthosis, or if it is too uncomfortable, it is more likely that the patient will not wear it as he should do, and will then lose the therapeutic effectiveness of the treatment. The major quality of life impacts of a 3D orthosis compared to a traditional orthosis are as follows (Graham et al., 2018; Interviews B,C,D,E).

1. The weight of the 3D orthosis and prosthesis is lower, and therefore more comfortable to wear.
2. The 3D orthosis is more ventilated and allows the skin to breathe more easily, which reduces odor due to less confinement.
3. The 3D orthopedic supports are waterproof, which eases patients' life and enables them to enjoy certain pleasures, such as taking a proper shower, cooking or swimming, which would not be possible with a traditional orthosis or cast for example.
4. It is recyclable. At the end of the treatment, the orthosis must be returned to recycle it and reduce plastic waste without compromising patient care. Furthermore, it is in line with the values of the current generation with regards to the issue of waste.
5. The many possibilities for customization also improve the aesthetics of the device thanks to its organic shape that reduces barriers to wearing it.

Table 3: Quantitative Analysis of the Comfort Advantages of the 3D Technology

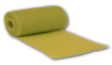
Comfort Impact	Degree of comfort importance	Frequency of the information	Source of the information	Total level of importance
Weight	4	3	3	4x3x3 = 36
Less smell	4	3	3	4x3x3 = 36
Waterproof	4	3	3	4x3x3 = 36
Recyclable	3	2	3	3x2x3 = 18
Aesthetics	2	1	2	2x1x2 = 4

1 – 4 scale comfort benefits	1 - 3 scale of the frequency of the information	1- 3 scale relevance of the information
1 Side benefit	1 Low	1 Secondary data
2 Moderate benefit	2 Moderate	2 Primary data
3 Critical benefit	3 High	3 Both
4 Huge benefit		

4.1.3 Disadvantages and improvements

In the following paragraph, the three main limitations of the technology for orthopedic immobilization devices will be mentioned. 3D printing technology for orthopedic supports is in a transitional phase on the Belgian market. It has already been seen above that it brings many advantages in the treatment of patients. Nevertheless, the technology still needs some improvements in order to be commercialized. These improvements are now considered to be disadvantages compared to traditional methods. The first and most important one is the printing time (Table 4): it takes too much time to produce an instantaneous device, which is a necessity in some medical cases such as fractures. Moreover, the technology must save time for the orthopedic surgeon and orthotist, otherwise they will reduce their work efficiency and have a negative impact on the patient's treatment. Looking at the table 4, it is seen in the third column that the orthotist gain in operational flexibility due to a decrease of physical care of the patient.

Table 4: Time Production Comparison of the Different Types of Forearm Orthoses

Type of Forearm Orthosis	Time of Production	Time of Medical Core with the patient
Plaster 	30min (production directly on the patient)	30min (laying)+ 15min (drying + verification) + 15min (remove) Total = 1h
Synthetic (polyurethane resin) 	25min (production directly on the patient)	25min (laying) + 2min (verification) + 10min (remove) Total = 37min
Thermoplastic 	45min (production directly on the patient)	45min (laying) + 2 min (verification) Total = 47min
3D printed 	9h (production is done independently from the patient)	5min (scanning) + 5min (modelling) + 2min (verification) Total = 12min

The second disadvantage is the printing failure that can occur and which then requires the device to be reprinted. This results in a waste of material and time. Lastly, the software for the scanning and modeling process still needs some improvements. The reliability of the scan is not 100% guaranteed, it may lack precision, which can cause design errors and, in some cases, be harmful to the patient (Interviews A,C).

Table 5: Quantitative Analysis of the Disadvantages of the 3D Technology

Disadvantage Impact	Degree of disadvantage importance	Frequency of the information	Source of the information	Total level of importance
Production Time	4	3	3	4x3x3 = 36
Printing errors	3	3	2	3x3x2 = 18
Scan reliability	3	3	2	3x3x2 = 18

1 – 4 scale disadvantage

1 Side disadvantage
2 Moderate disadvantage
3 Critical disadvantage
4 Huge disadvantage

1 - 3 scale of the frequency of the information

1 Low
2 Moderate
3 High

1- 3 scale relevance of the information

1 Secondary data
2 Primary data
3 Both

The ability to overcome these barriers will be critical to the potential commercialization of 3D printed orthosis and prosthesis. In the meantime, it is anticipated that technological advances will allow for a significant reduction in printing time in the near future, as well as continuous software improvements (Interviews A,B,C,E).

To summarize part 4.1 of the dissertation and answer the first research question "To what extent does 3D printing technology enhance orthopedic treatments of orthosis and prosthesis when compared to traditional techniques?", it appears that the therapeutic aspect and social aspects are interlinked. However, the therapeutic benefits come first in order to analyze whether the adoption of the technology is worthwhile. It appears that the most important therapeutic advantage is visibility of the skin, followed by ventilation. In terms of social impact, weight and odor are the most influential with regards to adoption. Lastly, the most critical disadvantage is production time (Table 6).

Table 6: Summary of Advantages & Disadvantages and their Importance of Impact of 3D Printing Technology for Orthopedic Supports

Therapeutic Impact	Degree of therapeutic importance	Frequency of the information	Source of the information	Total level of importance
Ventilation	3	3	3	3x3x3 = 27
Skin visibility	4	3	3	4x3x3 = 36
Non irradiating	2	2	2	2x2x2 = 8
RX transparency	2	1	2	2x1x2 = 4
Comfort Impact	**Degree of comfort importance**	**Frequency of the information**	**Source of the information**	**Total level of importance**
Weight	4	3	3	4x3x3 = 36
Less smell	4	3	3	4x3x3 = 36
Waterproof	4	3	3	4x3x3 = 36
Recyclable	3	2	3	3x2x3 = 18
Aesthetics	2	1	2	2x1x2 = 4
Disadvantage Impact	**Degree of disadvantage importance**	**Frequency of the information**	**Source of the information**	**Total level of importance**
Production Time	4	3	3	4x3x3 = 36
Printing errors	3	3	2	3x3x2 = 18
Scan reliability	3	3	2	3x3x2 = 18
	1 – 4 scale level of agreement 1 Side benefit/disadv 2 Moderate benefit/disadv 3 Critical benefit/disadv 4 Huge benefit/disadv	1 - 3 scale of the frequency of the information 1 Low 2 Moderate 3 High	1- 3 scale relevance of the information 1 Secondary data 2 Primary data 3 Both	

Most important factors of impact

4.2 Potential Value of Applying 3D Printing

The objective of the following section 4.2 is to answer the second research question: "What is the potential value of applying 3D printing to these orthopedic treatments on the Belgian market?". Before assessing the potential value of diffusion, different aspects must be understood, including some background information about the organizational structure and the people involved in the orthopedic devices process. The digital enablers of the digital transformation, as well as the role of 3D manufacturers, will also be considered.

4.2.1 Background information

The process of delivering an orthosis or prosthesis in Belgium will be explained in the following paragraph in order to understand the cross collaboration, the current business model and the organizational aspect of traditional orthopedic supports.
First of all, when a patient requires an orthosis or prosthesis, he or she must be examined by an orthopedic surgeon. The surgeon examines the injured or missing limb and, using his or her expertise, decides whether an orthosis or prosthesis is needed. If so, the surgeon prescribes the necessary device and the prescription is given to the orthotist who is responsible for the production of the device, the setting-up, and the follow-up of the patient. The people involved in the process are thus the orthopedic surgeons, the orthotist and the patient (Interviews B,D).

In terms of costs and prices, in Belgium, the prices of devices are set by the INAMI and are referring to codes (National Institute of Health and Disability Insurance) (Appendix 4; Interview F). The codes are 100% reimbursed by the patient's health insurance. In Belgium, it is compulsory for every citizen to subscribe to a health insurance. The totality of the reimbursement goes to the orthotist. In some cases, the orthotist may also overcharge a user fee of maximum 10% of the INAMI code that has to be paid by the patient and which is not reimbursed (Interviews B,D,E).

4.2.2 Digital enablers

The implementation of a new technology in any industry implies changes where certain parameters must be adapted or must adapt themselves to this new technology. The successful implementation of 3D printing technology in the orthopedic industry will depend on the ability of digital enablers to alleviate barriers to adoption. The greatest challenge is usually the willingness to adopt the technology, and not the technology itself.
In Belgium, the digital enablers involved in the implementation of 3D printing in the orthopedic industry are list below.
Firstly, 3D printing manufacturers have a major role to play in convincing and educating surgeons and orthotists to adopt the technology and smoothly implement a new type of production. Cultural and organizational change is needed to successfully support the technology, where those involved must be receptive to 3D printing and open to working through a digital process. Moreover, the ecosystem of partners is changing with the arrival of new 3D printing

manufacturers and brings about modifications in terms of cross collaboration between the surgeon, the orthotist and the 3D manufacturer.

Secondly, in order to be successfully adopted, the incentives of the new technology must outweigh the ones of traditional orthoses and prostheses, medically speaking, but also in terms of time and cost for the orthotist and the surgeon.

Thirdly, the technology must be mature and precise enough to be widely used by the medical core and commercialized. Moreover, IT support and technical maintenance must be available in case of printer or software malfunction.

Fourthly, in order to comply with national rules on the pricing and reimbursement systems of orthosis and prosthesis, regulators must adapt it to 3D printing, which is not yet the case, due to the early phase of implementation.

4.2.3 3D Printing Manufacturer: Spentys Case

As previously seen, 3D printing manufacturers play a major role in the diffusion of the technology. To illustrate this role, the example of the stakeholder Spentys will be presented. It is a Belgian start-up, created in 2017, which produces 3D printed orthopedic immobilization devices. Their mission is to bring the value of mass customization to the orthopedic environment. They have developed a 3-step solution centralized in a software package: 3D scanning, 3D modeling and 3D printing (Appendix 5). Their current business model is based on an “end to end” solution. For the first step, they educate orthotists to use their 3D scanning in the hospital (Appendix 6). The scan is sent directly to the Spentys team, which takes care of the 3D modeling and printing. Spentys is in an early stage of commercialization, they are doing numerous tests in collaboration with orthotists and orthopedic surgeons to obtain approval of the technology from a medical care point of view (Interview E).

The choice of Spentys to represent a manufacturer of 3D orthopedic devices in this dissertation was made carefully by looking at the competition. Spentys’ main competitors in Belgium are Materialise and Twikit (Appendix 7). Materialise is active in many industries, including the healthcare sector. They specialize in anatomical modeling for surgical preparation. This enables surgeons to gain insight and time for a specific surgery, which is valuable for both the patient and the surgeon (Materialise, 2019). Twikit mainly operates in two different industries: the automotive industry and the healthcare industry. As Spentys, they also focus their business model on orthosis and prosthesis. However, they only cover the 3D software aspect; they do not offer a 3D scanning and printing solution. This means that they do not collaborate with the medical core to develop a specific design, but let them do it by themselves (Twikit, 2019).

Spentys is the only firm in Belgium to focus its core business on 3D printed orthosis and prosthesis, and to cover a solution for the whole value chain of the device. Moreover, it aims to commercialize it in hospitals and to develop a specific design that does not yet exist (Appendix 8). On the one hand, their goal is to combine this new technology with traditional techniques that are complementary to each other. On the other hand, they intend to replace old-fashioned techniques where 3D brings advantages to the devices (Appendices 9 & 10; Interview E).

These 3D manufacturers are disrupting the established organizational process. By entering the loop, they are asking orthotists to change the way they work. First of all, the orthotist must use a 3D scan and be trained to do so. Second, with the "end to end" business model, the orthotist is no longer responsible for the production of the device. Economically speaking, the reimbursement of the device by the health insurance is then divided, since the production and the laying of the splint is done by two different entities, namely the 3D manufacturers and the orthotist (Interviews D,E). The major problem that Spentys faces is that the orthotist is used to get full reimbursement with the traditional technique because he also takes care of the production. Therefore, Spentys has to find a way to convince and prove that it is economically advantageous for the orthotist to use 3D printing technology, which is not the case with their "end to end" solution. As mentioned earlier, the economic factor is a major parameter of adoption (Interview B). In order to do this, Spentys plans to adapt its business model and add a "SaaS" option by January 2020 (Interview E).

4.2.4 Assessing the value of implementation

Once the organizational structure of orthopedic immobilization devices is understood, as well as how the sector is being disrupted by the arrival of 3D manufacturers, it is necessary to discern the willingness to adopt by the different stakeholders involved. A frequency analysis was created by translating the qualitative components into quantitative data to assess the value of the technology and its diffusion. All respondents were asked to respond to their level of agreement on a scale from 1 to 5 with respect to the five main potential barriers to large-scale diffusion of the technology. These barriers were based on 5 criteria for adoption: uncertainty, complexity, economic importance, novelty, and the need of the technology for orthopedic supports. They are listed as follows.

1. Lack of regulation of the 3D production process for orthopedic supports
2. Lack of knowledge and skills in 3D printing and its software for the production of orthopedic supports
3. Uncertainties about the required investment and economic return
4. Uncertainties about the maturity of the technology (performance of the material and available hardware)
5. Uncertainties about the need of the technology for orthopedic supports

The weight of importance from the stakeholder groups towards the diffusion of the technology have been decided as follow. In this early phase of implementation, orthopedic surgeons have an important decisional power. As they are the first medical core involved in the treatment of a patient, if they are favorable to the 3D printing technology, they are likely to send their patients to orthotists using the technology. Then the orthopedic surgeons have a strong negotiation power over the orthotists the adopt the 3D technology if those ones want to keep their collaboration with the surgeons. In this reason, the weight of importance for the implementation of the tech is 30% for orthopedic surgeons, 20% for orthotists, 10% for regulators and 40% for 3D manufacturers.

Table 7: Potential barriers to the diffusion of the technology and its values

Degree of agreement Scale: 1 -5

1: Low

2

3: Moderate

4

5: High

	Orthopedic surgeons	Orthotists	Regulators	3D manufacturers	Total barrier importance
Lack of regulations on the 3D production process for orthopedic supports	2	3	2	2	(2x0.3)+(3x0.2)+(2x0.1)+(2x0.4)= 2.2
Lack of knowledge and skills toward 3D printing and its software for the production of orthopedic support	4	2	2	1	(4x0.3)+(2x0.2)+(2x0.1)+(1x0.4)= 2.2
Uncertainties toward the investment required and the economic return	1	4	3	3	(1x0.3)+(4x0.2)+(3x0.1)+(3x0.4)= 2.6
Uncertainties towards the maturity of the technology (performance of material and material available)	4	3	2	2	(4x0.3)+(3x0.2)+(2x0.1)+(2x0.4)= 2.8
Uncertainties towards the necessity of the technology for orthopedic supports	3	1	2	1	(3x0.3)+(1x0.2)+(2x0.1)+(1x0.4)= 1.7
Weight of importance for each stakeholders in the implementation of the 3D tech	30%	20%	10%	40%	

As can be seen from the analysis in Table 7, uncertainty about the need of the technology for orthopedic supports is the least critical barrier with a 1.7 degree of importance. This means that all four types of experts involved are assessing the medical care potential of 3D orthopedic supports.

The lack of regulation is also not considered a significant barrier to adoption with a degree of importance of 2.2, as it the second least important one. The diffusion of the technology is still in the development phase, but it appears that the INAMI is willing to cooperate and create pricing codes for 3D orthopedic supports if the technology can prove its therapeutic impact. Nonetheless, it turns out that the appropriate pricing codes will be set once the technology is widely disseminated. Otherwise, the INAMI does not consider this new pricing code to be necessary (Interview E).

The main stakeholders involved in the production of orthopedic supports are orthotists and 3D manufacturers. Both categories fall between low and moderate in terms of the lack of knowledge and skills of 3D printers and the required software. This shows that the complexity of the technology is not recognized as an important fear of adoption with a 2.2 degree of importance.

Nevertheless, while it seems possible to overcome three of the barriers, two critical criteria remain constraints to widespread diffusion: the economic aspect and the maturity of the technology.

Starting with the economic impact. With a degree of importance of 2.6 of uncertainties towards the investment required and the economic returns, it is a high barrier of adoption.
As the technology is still in an early phase of diffusion for orthopedic immobilization supports, there is not yet evidence of economic return. Moreover, it has been seen that the business model of 3D manufacturers refers to an “end to end” solution which includes an economic disadvantage for the orthotists. This means that with the current “end to end” situation there is no incentives for the orthotist to jump in the 3D printing business industry for orthopedic immobilizer devices.

The last criteria to take into consideration is maturity of the technology. With a degree of importance of 2.8, the fact that the technology is not mature enough can have direct deleterious effect on the patient. Therefore, it is logical that the medical core, orthopedic surgeons and orthotists, consider this criterion as a significant barrier to adoption. However, technological progress will greatly reduce this uncertainty. Thanks to intense collaboration between engineers, 3D manufacturers and the medical core, printers and software will continue to improve in terms of production time, accuracy and product quality, all of which are now considered as disadvantages (Interviews A,B,C,E). By delivering a drastic technological evolution, the degree of agreement is likely to switch in the opposite direction. To give an example of advanced technology for production time criteria, 3D manufacturers are testing the production of 3D cast made of resin in less than 2 hours (Appendix 11). If these casts are medically certified, this will have a considerable impact on the expansion of the technology in the orthopedic immobilization supports industry. The focus on casts in the pediatric department is a wise choice. Children have grown up in an environment that is more prone to injury or fracture. These small fractures are the most common ones that require a cast. It thus represents a huge market for the 3D printing industry (Interview E).

As discussed throughout section 4.4.4, the assessed value for large-scale diffusion of 3D printing technology for orthopedic supports is promising, despite some critical and some less significant barriers still to be overcome. However, all of them are taken into consideration by the 3D manufacturer.

4.3 Successful implementation

On the basis of the primary and secondary data collected in the dissertation, a possible scenario is created to answer the third research question: "How can it be effectively implemented throughout this market?". This is done by focusing on the business model, the collaboration between the main stakeholders and the opportunities of the technology.

4.3.2 Full package solution

Once comfort and therapeutic effects have been proven, it is necessary to review the financial strategy. As the technology is still at an early stage of commercialization, it cannot yet prove its economic viability with real figures. Hence, a financial hypothesis is made that, if it can be demonstrated, there is a real potential for 3D orthopedic devices to be commonly used.

The hypothesis is: "By providing a full package solution with "end to end" and "SaaS", the 3D manufacturer covers the entire value chain of orthopedic immobilization devices and is financially advantageous for orthotists and 3D manufacturers."

In order to respond to the above hypothesis, 3D manufacturers must adapt their business model by introducing a "SaaS" (Software as a Service) solution, in addition to the "end to end" solution. The two business models will have different purposes. The "end to end" is necessary for complex cases of congenital pathologies, where an important customization of the device is required. The reason behind this is that collaboration between orthopedic surgeons, the orthotist and the 3D manufacturer is necessary for the design of complex shapes. In this case, the pricing strategy does not change, and reimbursement is shared between the 3D manufacturer who produces the device and the orthotist (Interview E). This business model is an effective approach to convince the medical core of the technology and gain visibility before introducing the SaaS model. It links the medical and emotional aspects to treat complicated pathologies, which is an incentive for them to use it (Interview E). However, the 3D printing manufacturer cannot stay alive solely by modeling and producing devices for complex cases. The number of these specific cases is too small for an entire business to rely on this model. From an economic point of view, it is not viable (Interview C).

The second business model, "SaaS", will involve the production of orthopedic immobilization devices at the place of use (with reference to the literature review: POC manufacturing). The SaaS will focus on standard model devices requiring a small amount of customization, primarily for post-traumatic treatments. In order for 3D manufacturers to implement the SaaS strategy, hospitals or orthotists hubs must have an in-house 3D printer. To overcome the high investment hurdle for hospitals or the orthotist department in purchasing 3D printers, the 3D manufacturer can offer a package that includes the rental of 3D printers. This will change the pricing strategy from the "end to end" solution. Since production will take place at the point of care (the hospital or orthotist hub), the full reimbursement goes to the orthotist, which is similar to the pricing strategy of traditional methods. In return, the orthotist hub will pay a monthly fixed fee to the 3D manufacturer for the "SaaS", the rental of 3D printers, the educational tool for proper use of the technology and the maintenance service. Additionally, the hub will pay a variable fee to the 3D manufacturer based on the number of orthoses made per month (Interview E).

By providing a full package solution with the “end to end” and the “SaaS”, the 3D manufacturer covers both types of orthoses mentioned in this dissertation, i.e. the complex ones that require a high degree of customization, and the standard ones that can be customized in mass. Moreover, with the “end to end” solution, the manufacturer is also able to produce individual external prostheses (Figure 20). If 3D manufacturers are able to successfully introduce the “SaaS” strategy, they will fulfill their mission to bring the value of mass customization to the orthopedic environment.

Figure 20: External Forarm Prosthesis by Spentys

4.3.2 Cross Collaboration

The entry of the 3D manufacturer, a new stakeholder in the orthopedic immobilization industry, is not without its challenges. It disrupts the way orthotists operate, which generates resistance to change. However, there was unanimous agreement among those interviewed that, culturally speaking, the adoption of this new technology is only a matter of time or generational change (Interviews A,B,C,D).

The key to a successful implementation involves smooth cross collaboration between the 3D manufacturer, the orthotist and the orthopedic surgeon. In order for them to work in synergy, the medical core must clearly understand the benefits of adopting the technology.

First of all, the introduction of a “SaaS” business model implies that orthotists have their own 3D printer facilities. It does not apply to orthopedic surgeons. Even if they have the expertise, they prefer to work in collaboration with the orthotists, as it would otherwise require additional work. They do not have the time to produce 3D orthopedic devices in-house. This means that there is no conflict of interest with those who adopt the technology (Interview C,D).

The “end to end” and “SaaS” package solution enables 3D manufacturers to cover the entire value chain of orthopedic immobilization devices and ensures economic added value for the orthotist. For the orthotist, as no physical individual is required to produce the device, it saves time and operational flexibility (Table 4; Interview E). By adopting this technology, orthotists are increasing their margins on the long term. The technology lowers the production costs once the initial investment costs have been recovered. Moreover, the fixed costs of salaries are decreasing due to a greater operational flexibility and a smaller amount of physical orthotists. (Interview E)

4.3.3 The Technology as an Opportunity

The diffusion of a new technology in an industry has an intriguing and exciting aspect. This is the reason why the storytelling around the new technology is a powerful tool for persuasion. The 3D manufacturer can play on the innovation factor that is directly linked to the reputation of a hospital or an orthotist hub. If hospitals have an in-house facility and produce 3D printed devices, it is a favorable tool of persuasion to attract new patients, as new technologies attract the new generation of patients (Interview B).

The storytelling can also revolve around the green trend. With the new generation’s growing awareness of environmental issues, the recyclability factor of 3D printed orthopedic devices is a powerful tool for persuasion. Manufacturers can play on this added value: the product is even more attractive if it is recyclable (Interviews B,E).

Another type of opportunity is to use other aspects of 3D printing technology to create advantages. The material itself can be used as a force for the comfort and therapeutic impact of the patient. Firstly, 3D printers allow the materials to be mixed; bi or tri materials can be blended together to create articulated orthoses. This pluri-material technique makes it possible to combine flexible parts of the device with other parts requiring total immobility. This characteristic has a direct therapeutic impact.

Secondly, 3D printers can be used to create devices made of resorbable material (PVA filament) that can be useful for orthopedic devices. It can be used in two types of cases. In the first case, the patient removes the orthosis by himself by immersing it in water when the treatment is done.

This facilitates the organizational process and does not require the patient to return to the hospital to remove the orthosis. Resorbable devices for this type of case are not yet operational, but are being considered for future improvement (Interview C). In the second case, 3D printers can make the scaffolding of the 3D product resorbable, which requires the 3D product to be immersed in water after printing to remove the scaffolding by itself. This feature makes the production process easier and saves time. As technology continues to advance, 3D manufacturers will add new attributes to orthopedic devices that will give them more and more bargaining power to sell them (Interview C).

A foreseeable scenario within the next five years would be to implement a full package offer containing an "end to end" and "SaaS" solution in order to cover all types of orthoses and external prostheses. Moreover, the 3D manufacturer, the orthotist and the orthopedic surgeon must work in synergy and the benefits of adoption for all three players must be well defined and understood. Finally, the technology itself must be used as an implementation opportunity because of its constant technological advances. The storytelling around the trend of innovation must be played out and the technical aspects of the technology must be used to make it an advantage. That is, the specific use of materials or structural possibilities during the modeling phase to gain flexibility (figure 21).

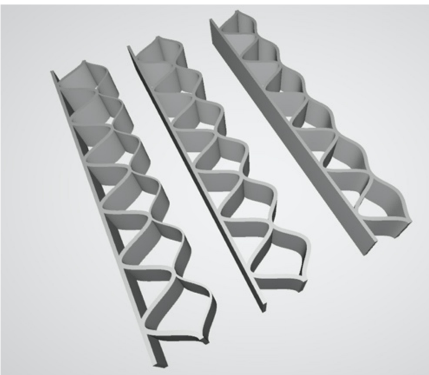


Figure 21: Flexible Structure

5. Conclusion and limitations

5.1 Conclusion

This dissertation endeavored to present the advantages of 3D printed orthopedic immobilization devices, their limitations and their opportunity for implementation on the Belgian market.
The biggest challenge of this technology is to enter an already well-established and well-functioning industry. The evolution of 3D technology in the orthopedic industry can be compared to the diffusion of the LED lamp. Initially, no one believed that the LED lamp could replace Thomas Edison's light bulb, since the bulb was lightening perfectly and there was no reason to switch to another technique. However, it was then realized that the LED could have the same light intensity as the light bulb while saving energy and being economically advantageous (Interview C).

First of all, concrete clinical studies are underway to prove the non-inferiority of 3D printed devices compared to traditional orthoses and prostheses. In the long term, given the technological advancements, the objective is to prove therapeutic superiority. Nonetheless, it has been found that the social life of the patient is positively impacted by the technology. It enhances comfort and facilitates daily tasks compared to traditional orthoses, which is directly related to the therapeutic effectiveness of the technology.
Secondly, for a successful implementation, the most suitable business model for the 3D manufacturer is the combination of an "end to end" and a "SaaS" solution, moving from a product-based logic to a service logic for standard models that require a small customization. This business model has an economic added value for the 3D manufacturer, as well as for the orthotist, and meets the technology's mission of mass customization.
By demonstrating that the technology is not medically deleterious for the patient and that, financially speaking, it is advantageous compared to traditional orthoses and prostheses for the main stakeholders involved, it will then likely take a prominent place in the orthopedic market.

Although the technology may still be flawed in terms of production time and reliability of scanning, researchers are constantly improving the performance of printers, materials and software, which ensures medical advances and successful implementation of the technology. Further industrial collaboration, additional clinical studies, and regulatory guidelines will help 3D manufacturing become the standard of care in Belgian hospitals.

5.2 Limitations

The research is not without its limitations. Whilst the quantitative analysis provided key insights, the fact that these figures are derived from the translation of qualitative components remains a weakness in the analysis that was subsequently carried out. The inclusion of additional statistical data could have improved the accuracy of the research.

Furthermore, the early phase of implementation of 3D technology on the orthopaedic market in Belgium is not yet generating economic results. The dissertation mainly based its results hypothesis on the lessons and insights learned from the interviews to analyse the financial benefits.

Although scientific studies are still underway to prove the therapeutic effectiveness of the technology for orthopaedic immobilization devices, access was not available to all of these studies. This could have been more useful and accurate for this particular point.

Further research should be undertaken to gain deeper insights and more accurate information in economic and therapeutic terms. However, the objective of this dissertation was to provide a general overview of the implementation of 3D technology for orthopaedic immobilization devices, including the advantages and the most suitable business model.

Despite the limitations, it is hoped that this dissertation will inspire further studies on this inspiring topic that can affect us all.

5.3 Final notes

"With 3D printing, we can actually create structures that are more intricate than any other manufacturing technology – or, in fact are impossible to build in any other way."

Lisa Harouni, *Co-Founder and CEO of Digital Forming*

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7. Appendices

1. Study results: the AM orthosis design, a feasible approach

PUBL-008	
Abstract	Analysis and comparison of wrist splint designs using the finite e
Authors(s)	Cazon A, Kelly S, Paterson AM, Bibb RJ, Campbell RI.
Source	Proc Inst Mech Eng H
Year	2017
Search term	S1
Database	D1
Summary	
Objective of the study/article	Rheumatoid arthritis (RA) is a chronic disease affecting the joints. Treatment can include immobilisation of the affected joint with a custom-fitting splint, which are typically fabricated by hand from Low Temperature Thermoplastic (LTT), but the approach poses several limitations. This study focused on the evaluation, by Finite Element Analysis (FEA), of Additive Manufacturing (AM) techniques for wrist splints in order to improve upon the typical
Patient group	
Materials and methods	An AM splint, specifically designed to be built using Objet Connex multi-material technology and a virtual model of a typical splint, digitised from a real patient-specific splint using 3D scanning, were modelled in Computer-Aided Design software. Forty FEA simulations were performed in Flexion-Extension and Radial-
Results	Simulations have shown that for low severity loads, the AM splint has 25%, 76% and 27% less displacement in the main loading direction than the typical splint in Flexion, Extension and Radial respectively, while Ulnar values were 75% lower in the traditional splint. For higher severity loads, the Flexion and Extension movements resulted in deflections that were 24% and 60% respectively lower in the AM splint. However, for higher severity loading the Radial defection values were very similar in both splints and Ulnar movement deflection was higher in the AM splint. A physical prototype of the AM splint was also manufactured and was tested under normal conditions to validate the FEA data. Results from static tests showed maximum displacements of
Summary/Conclusion	According to these results, the present research argues that, from a technical point of view, the AM splint design stands at the same or even better level of performance in displacements and stress values in comparison to the typical LTT approach and is therefore a feasible approach to splint design and manufacture.
Analysis	
Safety	
State-of-art	the AM splint design stands at the same or even better level of performance in displacements and stress values in comparison to the typical LTT approach and is therefore a feasible approach to splint design and manufacture.
Side-effects	

2. Study of 3D orthosis characteristics comparing to traditional ones.

PUBL-003

Abstract	Design of an Orthopedic Product by Using Additive Manufacturir
Authors(s)	Blaya F, Pedro PS, Silva JL, D'Amato R, Heras ES, Juanes JA.
Source	J Med Syst
Year	2018
Search term	S1
Database	D1
Summary	
Objective of the study/article	In this study a splint model printed in 3D, that replaces the deficiencies of the cast maintaining its virtues, has been proposed.
Patient group	
Materials and methods	The proposed methodology is based on three-dimensional digitalization techniques and 3D modeling with reverse engineering software. The work integrates different scientific disciplines to achieve its main goal: to improve life quality of the patient. In addition, the splint has been designed based on the principles of sustainable development. The design of splint is made of Polycarbonate by technique of Additive Manufacturing with
Results	In this preliminary study the final result is a prototype of the 3D printed arm splint in a reduced scale by using PLA as material.
Summary/Conclusion	The achievements in this work have been the study, design, prototyping and 3D printing with the technique of AM of an orthopedic arm immobilization product. This has allowed the improvement of some characteristics of traditional splints as: Water resistance that improves personal hygiene. Cost reduction due to the choice of used material. Recyclable product Lightness The pleasant and novel aesthetics An orthopedic product for immobilization that allows visual control of the skin and anticipation in the application of physiotherapeutic treatments during the immobilization period A biocompatible splint, that does not irritate the skin and that favors the ventilation of the skin. The future lines that could be followed from this idea would be: Printing of the real splint by using Polycarbonate. A PLA prototype has been realized that serves to verify the solidity of the design and to be able to show it in a much closer and palpable way. Its good characteristics could be observed in practice by printing the splint with Polycarbonate, the material for which the splint has been created. Creation of a software that is responsible for carrying out
Analysis	
Safety	very low risk for irritation thanks to material choice and contact su
State-of-art	The splint was manufactured with FDM. The material used was PLA (biocompatible and recyclable). Aesthetic and functional openings, its organic shape and rubber button as closure system.
Side-effects	Additively manufactured splints can reduce the risk of pressure syndromes induced by a traditional cast

3. Study results: Custom-Made Orthoses have fewer skin complication

PUBL-032

Abstract	Custom-Made Finger Orthoses Have Fewer Skin Complications
Authors(s)	Witherow EJ, Peiris CL.
Source	Arch Phys Med Rehabil
Year	2015
Search term	S2a
Database	D1
Summary	
Objective of the study/article	To investigate which orthosis results in (1) fewer complications; (2) the least extensor lag; and (3) the highest rates of treatment success according to the Abouna and Brown criteria for soft tissue mallet injury in adults.
Patient group	
Materials and methods	Data Sources: Electronic databases AMED, CINAHL, Embase, MEDLINE, PubMed, OTseeker, and PEDro were searched from the earliest available date until September 16, 2014. Study Selection: Controlled trials evaluating orthosis type in the conservative management of mallet injury were included. Database searching yielded 1024 potential studies, of which 7 met inclusion criteria with a total of 491 participants. Data Extraction: Data were extracted using an author-designed extraction form by one reviewer, and accuracy was assessed by a second reviewer. The PEDro scale was used to assess methodological quality.
Results	Results were pooled using a random-effects model with inverse variance methods. Dichotomous outcomes are expressed as risk ratios (RRs) and 95% confidence intervals (CIs) and continuous outcomes as standardized mean differences and 95% CIs. There is moderate quality evidence that prefabricated orthoses had 3 times the risk of developing skin complications as compared with all other orthoses (RR, 3.17; 95% CI, 1.19-8.43; I^2=47%) and nearly 7 times the risk of developing skin complications as compared with custom-made thermoplastic orthoses (RR, 6.72; 95% CI, 1.59-28.46; I^2=0%). Treatment outcomes were found to be similar for treatment success when prefabricated orthoses were compared with custom-made orthoses (RR, .99; 95% CI, 0.80-1.22; I^2=39%; very low quality evidence), as well as for extensor lag when custom-made thermoplastic orthoses were compared with other orthoses (standardized mean difference, .03; 95% CI, -.29 to .36; I^2=0%; moderate quality evidence).
Summary/Conclusion	Prefabricated orthoses were found to increase the risk of developing skin complications as compared with custom-made orthoses, but there were no differences in treatment success, failure, or extensor lag.
Analysis	
Safety	Less risk to develop skin complications with custom-made orthoses
State-of-art	

4. Pricing codes set by the INAMI

"A.R. 29.1.1993" (en vigueur 1.2.1993)
"Groupe principal IV : Poignet :

Topographie :"
"A.R. 29.1.1993" (en vigueur 1.2.1993) + "A.R. 28.3.1995" (en vigueur 1.4.1995)
"(CIV1) Du milieu du métacarpe au 1/3 proximal de l'articulation du poignet."

"A.R. 29.1.1993" (en vigueur 1.2.1993) + "A.R. 9.9.1993" (en vigueur 23.10.1993)
"(CIV2) Du milieu du métacarpe au milieu de l'avant-bras, mesuré à partir du pli du coude."

"A.R. 29.1.1993" (en vigueur 1.2.1993) + "A.R. 18.10.2013" (en vigueur 1.12.2013)
"Préfab :"

	649412	649423	*Supprimée par A.R. 21.7.2014 (en vigueur 1.10.2014)*			

"A.R. 29.1.1993" (en vigueur 1.2.1993) + "A.R. 18.10.2013" (en vigueur 1.12.2013)

"	649434	649445	Bandage du poignet fortement restricteur de mouvement avec renforcement dur (CIV2)	T	34,86	"

"A.R. 29.1.1993" (en vigueur 1.2.1993)
"Groupe principal V : doigt - main - poignet et avant-bras :

Topographie :
(CV1) De l'extrémité des doigts aux deux tiers proximaux de l'avant-bras. La longueur de l'avant-bras est mesurée depuis la fente du poignet jusqu'au pli du coude."

"A.R. 29.1.1993" (en vigueur 1.2.1993) + "A.R. 18.10.2013" (en vigueur 1.12.2013)
"Préfab :

649456	649460	Orthèse dynamique du doigt, de la main, du poignet et de l'avant-bras, type Cock-up, pour les doigts prise individuellement ou en bloc	T	65,37	
649471	649482	Orthèse dynamique combinée du doigt, de la main, du poignet et de l'avant-bras, type Oppenheimer, pour flexion ou extension	T	74,09	
649493	649504	Attelle postopératoire de la main, type Swanson	T	224,88	
649515	649526	Attelle de déviation ulnaire	T	54,48	"

"A.R. 29.1.1993" (en vigueur 1.2.1993)
"Groupe principal VI : Main, poignet et avant-bras :

Topographie :
(CVI1) De l'articulation métacarpophalangienne aux deux tiers proximaux de l'avant-bras. La longueur de l'avant-bras est mesurée depuis la fente du poignet jusqu'au pli du coude."

"A.R. 29.1.1993" (en vigueur 1.2.1993) + "A.R. 18.10.2013" (en vigueur 1.12.2013)
"Préfab :
Orthèse de la main, du poignet et de l'avant-bras :

649530	649541	Orthèse dynamique, type Cock-up splint	T	37,04	
649552	649563	Attelle statique de flexion ou d'extension du poignet	T	41,40	"

"A.R. 29.1.1993" (en vigueur 1.2.1993)
"Groupe principal VII : Poignet et avant-bras :

Topographie :
(CVII1) De l'articulation métacarpienne aux deux tiers proximaux de l'avant-bras."

"A.R. 28.3.1995" (en vigueur 1.4.1995)
"(CVII2) De l'articulation métacarpienne, au tiers proximal de l'avant-bras."

"A.R. 28.3.1995" (en vigueur 1.4.1995) + "A.R. 18.10.2013" (en vigueur 1.12.2013)
"Sur mesure :

649574	649585	Segment du poignet et de l'avant-bras CVII1	T	141,60	
653494	653505	Segment du poignet et de l'avant-bras CVII2	T	109,4	
		Préfab :			
649596	649600	Attelle dynamique, type Oppenheimer splint	T	56,66	
649611	649622	Orthèse statique	T	39,22	
		I.M.F. :			
649633	649644	Segment du poignet et de l'avant-bras CVII1	T	45,23	
653516	653520	Segment du poignet et de l'avant-bras CVII2	T	33,10	"

"A.R. 29.1.1993" (en vigueur 1.2.1993)
"Groupe principal VIII : Coude :

Topographie :
(CVIII1) De la moitié de l'avant-bras à mi-bras. Les points de mesure sont les plis du poignet, du coude et de l'aisselle."

"A.R. 29.1.1993" (en vigueur 1.2.1993) + "A.R. 18.10.2013" (en vigueur 1.12.2013)
"Préfab :
Orthèse du coude :

	649655	649666	Orthèse du coude avec système de charnière (CVIII1)	T	187,40	
	649670	649681	Bandage pour tennis-elbow en matière non élastique	T	21,79	"
	649692	649703	*Supprimée par A.R. 21.7.2014 (en vigueur 1.10.2014)*			
			"A.R. 29.1.1993" (en vigueur 1.2.1993) + "A.R. 18.10.2013" (en vigueur 1.12.2013)			
"	649714	649725	Bandage d'anti-hyperextension (CVIII1)	T	56,66	"

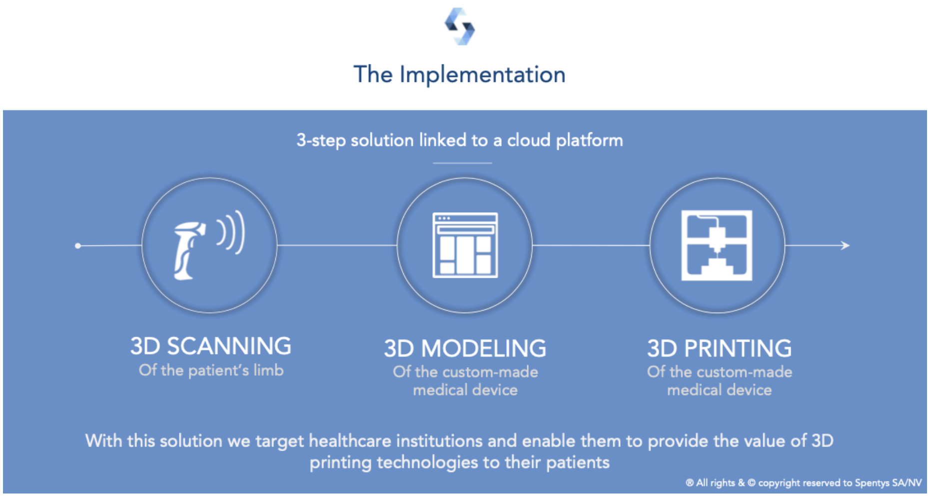
"A.R. 29.1.1993" (en vigueur 1.2.1993)
"Groupe principal IX : Bras :

Topographie :
(CIX1) De l'articulation du coude aux deux tiers proximaux du bras. Les points de mesure sont les plis du coude et de l'aisselle."

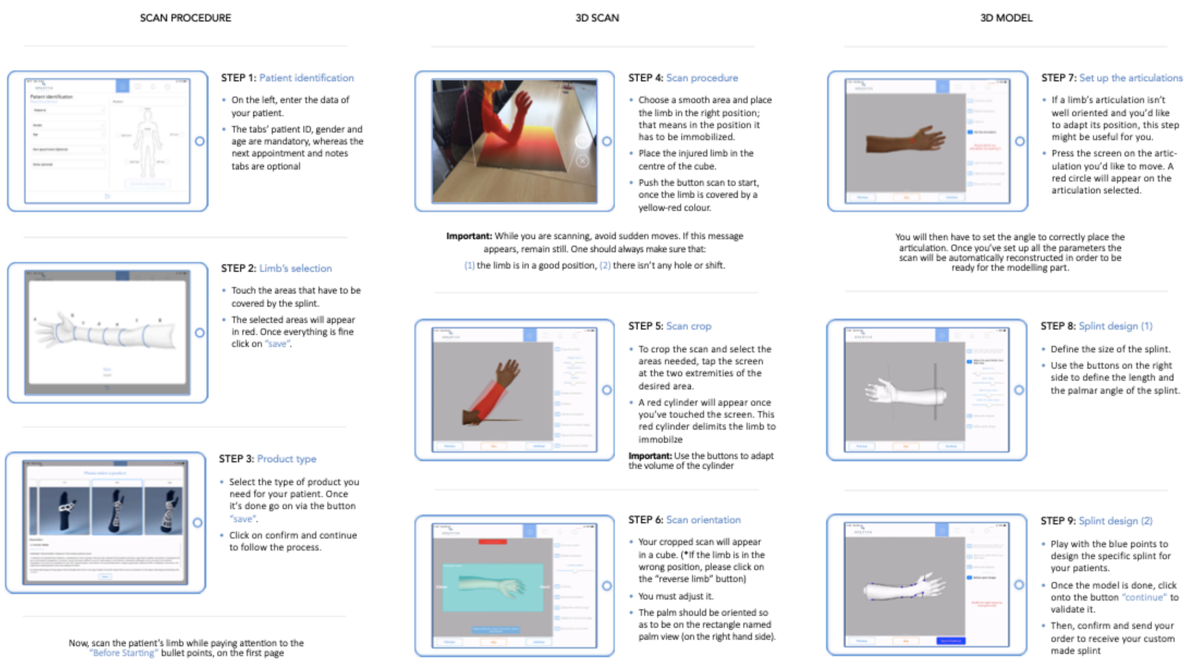
"A.R. 29.1.1993" (en vigueur 1.2.1993) + "A.R. 18.10.2013" (en vigueur 1.12.2013)
"Sur mesure :

649736	649740	Segment-bras	T	141,60

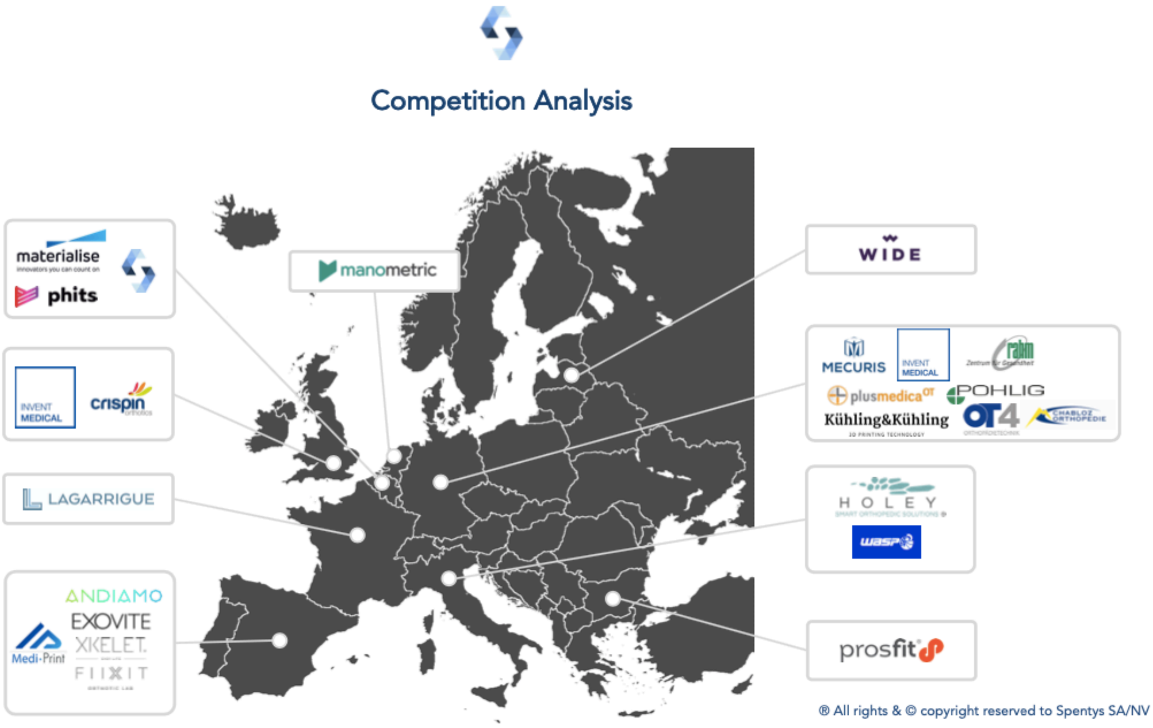
5. Implementation of the 3 steps solutions of Spentys



6. Instruction of use of the 3D Spentys scan



7. Competition Analysis on the European market



8. Main competitors of 3D printed orthoses and prostheses manufacturers in the world

Main Competition

Who?	Country	Solution for the whole value chain?	Adaptable Fit?	Interactive solution?	Machine Learning?	Price approach?	Versatility?
	BE	*Covers the whole value chain*	V	V	V	LOW	All body limbs
EXOVITE	SPAIN	*Focus on the 3D scanning and 3D modelling*	*Rigid materials*	-	-	HIGH	Forearm only
Medi-Print	MEX.	*Focus on the 3D printing*	*Rigid materials*	-	-	HIGH	Forearm only
XKELET	SPAIN	*Focus on the 3D modelling*	*Rigid materials*	+	In progress	HIGH	Forearm
ACTIVARMOR	U.S	*Focus on the 3D printing*	*Rigid materials*	-	-	HIGH	Forearm + hands
INVENT MEDICAL	CZECH.	*Cover the whole value chain*	*Rigid and flexible*	Limited	In progress	HIGH	Soles + Baby helmet + Face mask
ManoMetric	NETH.	*Focus on the 3D scanning*	*Flexible materials*	Limited	-	HIGH	Hand only
WASP	ITALY	*3D printer manufacturer*	/	/	-	HIGH	Forearm + Corset + Prosthesis

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9. Pros & Cons towards the comfort parameters of the traditional techniques

Plaster

\+ Cheap
Easily moulded
More comfortable fit
Much smoother

− Poor resistance to water
Low strength to weight ratio
Exothermic reaction (45-50 °C)

Synthetic

\+ Lightweight
Waterproof

− Strong
Radiolucent
Stiff = difficult to mold

Thermoplastic

\+ Lightweight
Waterproof

− Hot water to meld it
Sites Sizes
Cost
Learning curve

Common problem in the removal procedure:
- Saw
- Noise
- Dust
- Burn risk

10. Comparative table of the substitute of 3D printed orthosis

Substitutes

Type of substitute	Description	Aerated	Water-proof	Hygienic	Light	Adaptable	Custom-made	Reimburs-ement Price	Production Price	Learning curve
Prefab Splint	Prefabricated splint with tissus and metal parts.	X	X	X	LIMITED	LIMITED	X	+- 73,64€	From +- 25 € To +- 60€	LOW
Thermo-settable splint And Synthetic splint	Thermoplastic material. Can be modified with water tanks at a T° of 60°C.	X	LIMITED	LIMITED	✓	X	LIMITED	131,33€	From +- 70 € To +- 155€	HIGH

11. 3D cast prototype made by Spentys in collaboration with Soliquid

12. Interviews

A. Orthotist Gadhy El Koury - Institute of Neurosciences, University Hospital of Saint Luc – *Brussels, Belgium* (30/10/2019)

Focussing on external orthoses and prostheses. The question is, in Belgium, how is the situation and how can it be on long term.
<u>Ghady:</u>
Must be careful when mention that 3D printed orthoses and prostheses have an added value on the patient. → Define clearly the parameters because medically speaking, it is not proven that 3D printed orthoses repair better injuries than traditional ones because no proper evaluations.
Subjective from the patient and depends of the injuries from the surgeons.

<u>Medical parameters and gadget effect</u>
Parameters evaluated so far: comfort, aesthetics has advantages over traditional ones.
If it is well scanned and molded, it has then an advantage looking on a social aspect, however still struggling on a 100% clear scan.
The gadget effect, tell a story (of 3D) appealing for choosing the 3D.
Medically speaking: 3D for complex cases is very useful, when standard sizes don't match → 3D is necessary in this case. Customization of specific pathologies
The gadget effect: For the standard size → not medically necessary because the difference is minimal or non, comparing to traditional ones. To sell in this category: play around the story of 3D printing.
3D materials better or not? Polypropylene and thermoformable: same feelings of plastic on the skin, biocompatible. So yes because more comfort, less irritation, less smell, less roteness.
Tech mature enough to commercialize it? The orthoses are not mature enough regarding the flexibility of the materials, scan has still too many errors, adv of not being irradiant but then not 100% exact.

<u>Dc.Ghady own opinion regarding tech</u>: Favorable to explorate what can be beneficial for the patient.
Parameters to check: added value for the patient and added value for the surgeons in terms of time, space and money for society and hospital (cost reduction and time reduction, gain space).
3D printing we can still not say if these parameters are applicable for the surgeons because the time to print is still too long but believe that the future technological advance of 3D printing will dramatically reduce the time of production.

<u>End to end solution and SaaS</u>: Clearly it is better to produce internally at the hospital because no need to anticipate, can be print on the moment. → The scan is done directly of the right limb. Less inconvenient for the patient, no need for displacement (back and forth) of the patient to pick the orthoses or prostheses as it is done directly.
In Belgium, no internal 3D production in hospital so far.

<u>Economic</u>: so far, the surgeons do not pay for the orthoses, the patient does and gets refund. The question is who get the surplus? Example for a 3D printed orthosis: an orthosis for the hand cost 15€ to produce, sell it at 80€ (price set by INAMI), the manufacturer gets the entire surplus.
However, if it is internally done, then the surplus would go for the surgeons/hospitals. (They must be convinced that they will earn more than it costs.
Economically speaking for surgeons: hard to predict now that they earn more money than trad ones. However, the internal infr. Could give them an opportunity to earn more. (interesting in the negotiation, proof the surgeons that they will earn more money)

<u>Cultural change</u>: three types:

1) We have always done like this why should we change (old generation)
2) Nice a new product we have to adopt
3) Middle attitude, wait to see how it goes on the market (Better suits for surgeons which first criteria: comfort of the surgeons economically speaking but also time reduction)

Bandagistes are important for the after-sale services

Barriers: the change most important one, changing his habits is complicated, (it's like asking someone to stop drinking coffee). If it's proven that it has adv. It just takes time to adopt it. Sometimes it is not only time but a real change of generation to adopt a new tech

Internal infrastructure: who decide? Orthopedic service

Communication between the surgeons: cost X, gain Y. However too few discussions and unilateral. Discuss together and analyze the receptivity. Not mandatory that every surgeon uses 3D printing that's why it's important to check the receptivity of everyone before installation of internal 3D printing facility. In order to make the printer profitable need a certain amount of surgeons receptive to use it.

The role of the manufacturer → Internal infra: proof that is profitable. 1st parameter is money. Manufacturer as Spentys has a great role to play to convince hospital to go internally because for them the SaaS service is more profitable on the long term.

Future scenario:
How is it gonna be in 5years: it will evaluate but is it gonna be 3D printing or something else?

B. Doctor David Mazy – Orthopedic surgeon at CHIREC Hospital- *Brussels, Belgium* (10/11/2019)

Barriers and limitations
Time of the production → however it is obvious that it will be shortened with the technological advance in the near future.
Finance: not the biggest problem to overcome, at some point it will be realized that will earn more than it cost
Intermediary: need less intermediaries, organizational barrier
→ Once these three barriers have been overcome, easily to commercialize

Advantages and Opportunities
3D printing is future in the medical industry at every level
Must be proven that the therapeutic efficacy is as good as the traditional splints then look at the quality of life to check if the impact on the patient is the same.
Expertise of Dc Mazy: same results for the wound but in the case of disciplined patient because asks dedication.
Good profile: receptive young people who like the tech aspect
Social aspect: wearing a plaster has real impact on the social life and the 3D printed splints and orthoses give the opportunity to live more easily. Major impact on quality of life: less heavy, more aerated, don't smell, go into the water, cook
Storytelling around the innovation aspect: new tech attract new patient generation. It a hospital use it, it must be said
Recyclable (40% of the product): People will bring back their orthosis if they know about the fact that is recyclable, if awareness has been raised → again storytelling around this, it is a trend: the green trend, eco trend. Positive point, even more attractive when you know it is recyclable
Use different type of materials: specific percentage of materials to give more flexibility
The plaster will always stay in immediate post trauma but will be combine with the 3D orthoses/splints

Be careful to not look only at the cost because other important parameters:
Product itself better for the quality of life of the patient
Trendy effect
Give a new and exclusive image for the hospitals

Economically speaking
Surgeons thinks first what's best for the patient (should always be the priority), however will use it if economically benefiting for them.

SaaS & End to End solution
Less intermediary, less cost→ having its own internal facility in hospitals, better for the hospitals. Printer at consultation point, no need for intermediaries. The revenue goes to the hospitals/surgeons.
If it is proven that it will save money/earn money, it will be appealing for the hospital.

Culturally speaking
Old surgeons have their routine don't want to change their method → not receptive
Young surgeons → Receptive, have long term vision, keen to learn new tech and more interested
Question of generation change, time and acceptation

Future scenarios
In 10 years, everybody will benefit from 3D plaster at the emergency. The technology will make it able to print a splint in 15-30min → Test phase right now
Right now, 3D splints and prosthesis are still a test phase however looking at the barriers of today it is lucky that in the 10 years 3D printed splints will be a commonplace.

C. Doctor Thomas Schubert – Orthopedic surgeon, University Hospital of Saint Luc – *Brussels, Belgium* (18/11/2019)

3D orthosis and prosthesis are in a translation phase, it is interesting to evaluate the right parameters to demonstrate if it can be commercialized. Every tech has a path: it goes from testing to being widely used if successful. 3D printing in the medical industry has huge potential (already in use or in translation or in test phase)

Barriers and limitations
Must be careful that the therapeutic effect is the same. Regarding the doctor the plaster, still more stability than 3D orthosis (must be proven that it has the same recovery impact and not deleterious). the precision comparing to a plaster is not advance enough. How to demonstrate that every splint or prosthesis are secure enough as there are all different → How to be sure that there are no conception errors. (Security of the patient). Comparing to trad ones they underwent testing
Traditional ones: instantaneous service on the patient still not the case with 3D printed orthoses
Replace a standard and well established treatment of plaster that works well
Patient must be compliant

Advantages and Opportunities
Use other aspect of the 3D printing to create advantage. Use the material as a force to create a real advantage for the comfort of the patient but also for therapeutic impact.
→ Bi or tri material can be combined together to create articulated orthosis (flexibility at some place and immobility at others)
→ Resorbable material: Eg 1: the patient can leave it out the orthosis by itself when the treatment is done by immersing it in water : PVA filament. Eg 2: Make the scaffolding of the 3D product resorbable, immerse the product when 3D printed to leave out the scaffolding by itself.
Added value on the comfort: proven: aerated parameter is also link to medical treatment (eg: a kid playing on the beach the sand can enter and leave out the orthoses)
Recyclable: It can be systematized easily because the patient usually have to consult the doctor at the end of the treatment where the orthosis can be given back to be recyclable.

Economically speaking
INAMI set the prices of the orthoses and prostheses
Part of the price is paid by the patient, the other by the health insurance to the orthotist. Orthopedic surgeons make money on the patient consultations.

SaaS & End to End solution
End to end the refund of the orthosis or prosthesis goes to the manufacturer, barrier of adoption for the orthotist who does not make money anymore.
With SaaS, the refund is still going to the orthotist and the manufacturer ask a small percentage of it.
→ SaaS seems a better option but must prove that it is economically beneficial for the orthotist and surgeons.

Culturally speaking
Orthopedic surgeons are interested by 3D printing because they work through 3D everyday through 3D surgery. Generally speaking, only a niche of the doctors find it interesting.

Future scenarios
Must demonstrate that medically no deleterious and financially speaking it has advantage over the traditional orthoses and prostheses.

1. link together comfort (already proven that it is better) and therapeutic (must be proven similar or advantages) impact link together
2. Link together time (must proof it saves time) and finance (cost of the product for 3D printers, education and maintenance)

→ If both categories are proven to be beneficial over the traditional ones then don't see why it shouldn't be commercialized. It has a future
Exponential curve of the tech must be careful of the fast expansion

On long term, 3D printing manufacturer cannot stay alive just through modelization of complex cases (because too few to earn money just through those, comparing to standard model)
Comparing with the led → The evolution of the tech, nobody believed that the led could replace the bulb of Thomas Edisson because the bulb worked perfectly why should we need something different? When it has been realized that the LED could light enough/similar comparing to bulb and was saving energy then money.

D. Doctor Robert Elbaum – Orthopedic surgeon, president of the orthopedic surgeons committee at CHIREC Hospital- *Brussels, Belgium* (19/11/2019)

Kids are more keen to get fracture link to their way of living and wear a cast. An environment where the kids are more subject to fall down etc. Small fracture that is one of the fracture most common → Huge market for the 3D. Two to four weeks of recovery. Focus on orthoses in the pediatric department.

Ideal in post trauma for 3D device: the few days following the injured limb because in emergency more favorable to put pre-fabricated immobilization orthosis that let the limb breath.

Every device system must go through an orthotist

Would be ideal to have a 3D printer in the office

Contact Pascal Rase – Orthopedia firm – corps enseignant
Contact Nathalie Geerts – Ortheis

Ent to end: the manufacturer gets the refund but has an agreement with the orthotist because the manufacturer does not have the right to medically treat the patient. Then the 3D orthosis will be placed by the orthotist.

What would be the best scenario regarding the organizational process: orthotist have inhouse 3D printers and are educated to do the scan and modelization, pay a fee to the 3D printing manufacturers to benefit from the software scan and modelization. Interesting to produce on site.

Reimburse from the health insurance to the orthotist: 100% refund.

Prospective studies to proof the therapeutic impact: necessary. The results of the study at Chirec are not out yet. Ask the article and see if it can be included in the dissertation. Mentioned: Submitted for publication (first articles that mention the first studies and the results).

Comfort is link to medical and therapeutic impact. Because comfort have an impact on the treatment and the resilience of the treatment. If the patient does not approve the orthoses or it is too uncomfortable, bigger chance that the patient will not wear it as he should. Waterproof is not only about comfort but medical too. Example a cast that does not resist to water → Loose the medical efficacy

The surgeon gets the money of the act of immobilization and the consultation → in emergency a cast is needed on the moment. No financial gain from the orthopedic devices.

On the long term: interesting for the INAMI to establish 3D codes

SaaS: required a tariff code for in house 3D printing for the surgeons. However, the surgeons prefer to work in collaboration with the orthotist because no time to produce in house 3D devices. Asking them additional work.

Important customization for complex case: not proven to have an optimal system at the immobilization level. Limited factor: bring sufficient correction during the modelization phase.

Disadvantage: The precision of the orthoses and the closing system. Not yet in the commercialization phase. It must be totally adapted to the cutaneous surface, shape, morphology. The cast can do it but with the secondary inconvenient → Bigger risk of infections.

In the near future: Will take a prominent place if the facility are in house.

3D manufacturer must get the exclusivity and patent their products and work in the synergy with the orthotist and orthopedic surgeons.

E. Louis-Philippe Broze - CEO of Spentys - *Brussels, Belgium* (21/11/2019)

Actual business model “end to end” is suitable for small group of orthotists because they do not produce themselves the orthoses and prostheses. However, the main target is bigger group of orthotists.
Small orthotists represent 40% of the market.

Why the orthotists are favorable to 3D:

1. Gain in operational flexibility
2. Decrease the price and then increase their margins (no need for a physical person to produce the devices, gain in time) → Cost of production on the long term is cheaper. The investment cost is important the fixed cost decreases.

Development of Spentys for 2020 – 2 axes
<u>Chronic axis</u>: for complex cases
Also divided in two axes. 1st one production is done at Spentys (Good way to convince to use the technology, gain in visibility and then introduce the SaaS model)
2nd one: give the solution / SaaS where the hospitals have 3D printer facility. No leasing offers, hospitals pay a fee for the materials, platform, Software of 3D modeling, Software of certification.
The
<u>Traumatic axis</u>. Construction of the business case with 5 pilot cases by printing cast in less than 2 hours. The materials used are resin that solidified with light. DLP method with the Atum3D printers. Resin is costly.
Business model: leasing of the 3D printers (2) in hospitals. Hospitals pay a monthly fee for the entire packages.
Actual pricing situation: Don’t know yet the pricing. Know it’s gonna be a monthly fee + a variable fee regarding the amount of orthoses made per month. (look at the refund code and decide on the percentage of it)

Personal conviction: The 3D orthoses represent a gain of comfort and quality of life. Spentys is entering a scientific procedure to proof this conviction. Otherwise they don’t have any credibility. → Clinical studies are in progress to proof first the non-inferiority comparing to traditional orthoses. The long term objective is to proof the superiority.
Clinical studies in progress in Bâle, in the Netherlands, in Belgium (In 5 different hospitals).

<u>Spentys in the future</u> is not just orthosis prosthesis and cast, the objective is to become a platform to do many different customizable thing (implants, organs, cutting guide). Enable a mass customization of orthopedic devices and other medical devices.

The comfort is link to the medical impact.
Why is it more <u>aesthetics</u>: more organic, lighter, more aerated, more beautiful.
<u>Disadvantage</u>: Time of production first major one for the post traumatic axis. Error of printers. Reliability of the scan.
Disrupt the way of working of the medical core. → Which generate resistance to change.

Competitors: analysis documents
Actual pricing: INAMI code is 100% refund by the health insurance, the orthotist can additionally ask (overcharge) a user fee of at most 10% of the INAMI code that must be paid by the patient and is not refund.

<u>Estimation</u>: how long is it to produce a traditional forearm orthosis. Not done the calculation yet

Play on the fact that material can bring a real advantage: resorbable or pluri-material. Find new characteristic to the device to sell it. Start already working on the flexi material, also play on the structure to gain in flexibility.

F. Non mentioned – employee at INAMI – responsible for orthoses and prostheses – *Brussels, Belgium* (06/12/2019)

The health minister has an annual budget for the public health. She/He decides the amount for orthopedic immobilizer devices. The INAMI set the refund codes on the basis of those budgets. The main role of the INAMI is to be the mediator between the different stakeholder involved. They are supposed to be neutral.
They gather the stakeholder around a table and through the consultation look at the different parameters and decide to agree on new regulation or not.
For the orthopedic industry the stakeholders involved are:

1. Patient
2. Service provider - Orthotist and Orthopedic surgeon
3. Health Insurance – Mutuel
4. Public Health representative
5. Device supplier/manufacturer

Regarding the 3D printing technology: for the moment there is no specific codes for 3D printed orthoses or prostheses. The devices are categorized between "Pre-fabriqué" = "Pre-made" and "sur-mesure" = "made to mesure"
→ The 3D orthoses and prostheses find themsleves in those two categories. It means that it can already be commercialized if the devices got the EU certification regarding the biocompatibility and are aligned with the INAMI nomenclature. It is then not a barrier for the diffusion of the tech on the Belgian market.

The 3D tech in the orthopedic industry can be compare with the hearing aids

The European Union set medical requirements in terms of 3D materials in order to have a traceability of the product. This can be a barrier of diffusion or the decrease the amount of manufacturer on the market. Hard to get the certification

Possibility to contact the organisme professionnel: union professionnel belge des technologies orthopedic: 022517578
Thomas Moor