

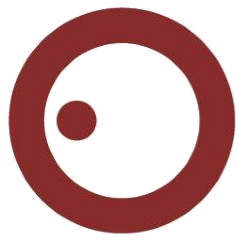


Sustainable optimization of the manufacturing of prostheses and orthoses through
CAD/CAM technology for low-income communities in Ecuador

Master in Product Design Engineering

Diego Fernando Teran Pazmiño

Leiria, December 2025



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escola superior de tecnologia e gestão
instituto politécnico de leiria

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Dissertation carried out under the supervision of Professor Henrique de Amorim Almeida
co-directed by Professor Célia Patrício Valente de Oliveira

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DEDICATION

"Learning is discovering that something is possible." – Fritz Perls

I dedicate this thesis to my parents, who have been my pillar and unwavering support at every step of my journey. To life itself, for teaching me that patience, consistency, and perseverance are the foundations of every achievement, and for always reminding me that no effort made with dedication is in vain. To my friends, for sharing joys, challenges, and long conversations that made every difficult moment more supportable.

To my teachers and mentors, thank you for instilling in me curiosity and passion for learning, for inspiring me to overcome my own limits, and for showing me that knowledge has the power to transform lives. This thesis reflects his influence and is proof that perseverance, passion, and dedication are forces capable of opening paths where none seemed to exist.

May this work also serve as a reminder that "I can't" is just a thought; the limits we believe are impossible often exist only in our minds, but with determination, effort, and perseverance, they can be overcome. More than a personal achievement, this thesis is a tribute to all those who taught me that learning is truly LIVING, and that dreams are built with passion, because every idea we hold in our minds has the power to change the world.

ABSTRACT

This dissertation addresses the challenges faced by low-income communities in Ecuador in accessing prostheses and orthoses, due to high acquisition costs and long manufacturing and delivery times. Conventional fabrication methods often require labor-intensive processes and imported materials, resulting in devices that are economically inaccessible for a large portion of the population.

The main objective of this dissertation is to evaluate the technical and economic feasibility of producing customized prostheses and orthoses through CAD/CAM technologies and additive manufacturing, using recyclable and low-cost polymeric materials. The proposed approach integrates 3D body scanning, digital modeling, mesh optimization, and parametric design tools to create patient-specific devices with reduced production time and material waste.

The methodology includes the use of structured-light 3D scanning to capture anatomical data, mesh processing using MeshLab, solid modeling and customization in Autodesk Fusion 360, and the exploration of lightweight parametric structures. In addition, a cost simulation based on realistic economic parameters from Ecuador is performed to estimate unit production costs and potential selling prices.

The results demonstrate that the proposed digital workflow can significantly reduce manufacturing time and costs when compared to traditional methods, while maintaining functional and ergonomic requirements. This dissertation highlights the potential of additive manufacturing as a sustainable and socially impactful solution to improve healthcare accessibility and promote circular economy principles in low-resource contexts

Keywords: 3D printing, sustainable design, healthcare accessibility, low-income communities, CAD/CAM technologies.

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LIST OF ABBREVIATIONS AND ACRONYMS

Acronym	Meaning
ABS	Acrylonitrile Butadiene Styrene
ABC	Activity – Based Costing
ASTM	American Society for Testing and Materials
CAD	Computer-Aided Design
CAM	Computer-Aided Manufacturing
CAE	Computer-Aided Engineering
CT	Computed Tomography
DIN	Deutsches Institut für Normung (German Institute for Standardization)
DPL	Diffusion production line
EO	Elbow Orthosis
EBM	Electron Beam Melting
EVA	Ethylene Vinyl Acetate
FDM	Fused Deposition Modeling
FEA	Finite Element Analysis
FRP	Fiber Reinforced Polymer
HDPE	High-Density Polyethylene
HIPS	High Impact Polystyrene
HO	Hand Orthosis
ISO	International Organization for Standardization
LDPE	Low-Density Polyethylene
LSO	Lumbosacral Orthosis
MRI	Magnetic Resonance Imaging
PA	Polyamide
PAEK	Polyaryletherketone
PB	Polybutylene
PCL	Polycaprolactone
PC	Polycarbonate
PE	Polyethylene
PEEK	Polyether Ether Ketone
PEI	Polyetherimide
PET	Polyethylene Terephthalate
PLA	Polylactic Acid
PVA	Polyvinyl Alcohol
S-EO	Shoulder – Elbow Orthoses

SLA	Stereolithography
SLS	Selective Laser Sintering
TLSO	Thoracolumbosacral Orthosis
TPE	Thermoplastic Elastomer
TPU	Thermoplastic Polyurethane
UV	Ultraviolet
WHO	World Health Organization
W-HO	Wrist-hand orthoses
CLLAIM	Creating Knowledge and Skills in Additive Manufacturing
WEF	World Economic Forum

1 INTRODUCTION

In Ecuador, people with limited resources face significant barriers in accessing medical orthoses. Among the most critical obstacles are long waiting times and high acquisition costs, which reduce the quality of life of those in need. This research proposes a technical and financial solution to improve the orthosis manufacturing process by incorporating advanced Computer-Aided design and manufacturing (CAD/CAM), 3D printing, and recycled materials. The ultimate goal is to reduce delivery times and provide more affordable and sustainable medical devices.

The main objective of this dissertation is to assess the economic feasibility of producing 3D-printed prostheses and orthoses using recycled materials in Ecuador. To achieve this, the dissertation is structured into several sub-objectives. Chapter 2 reviews the design and development processes of orthoses, examines the materials used in medical 3D printing, and analyzes the key stages of fabrication.

Chapter 3 explores the initial investments required to establish a 3D prosthesis production system, including equipment, scanning technologies, software, and operating costs. Additionally, it presents a financial analysis that evaluates the dissertation viability under different cost and demand scenarios.

Finally, Chapter 4 estimates the economic and social impact of the proposed system, identifying potential beneficiaries and its contribution to the circular economy in Ecuador. The study also highlights the capacity of the dissertation to generate a sustainable production model that benefits vulnerable communities while reducing environmental impact.

2 LITERATURE REVIEW

2.1 Orthoses and Prostheses

Orthoses and prostheses are essential medical devices in the field of rehabilitation and orthopedics, each fulfilling specific functions that are crucial to the patient's well-being. Prostheses are artificial limbs that replace a missing body part, whether due to amputations, congenital malformations, or some type of degenerative disease. The main objective of prostheses is to restore the functionality and aesthetics of the lost limb, facilitating the performance of daily activities and significantly improving the patient's quality of life Zepeda, (2023).

On the other hand, orthoses are external medical devices that are designed to modify, correct, and improve the specific conditions of each patient's case; in this case to improve the structural and functional conditions of the neuromuscular and skeletal system. Unlike a prosthesis that replaces a part of the body, the orthosis focuses on enhancing, stabilizing and rehabilitating existing body segments that present some functional limitation, injury or deformity since the main objective is to maintain, restore or improve a specific part of the body by providing better biomechanical support, reducing pain and controlling movement PrimeCare LLC (2023).

Innovations and technological developments in areas such as additive manufacturing, also designated as 3D printing, have radically transformed the design and production of orthoses, as these devices can now be customized with millimetric precision, adapting perfectly to the individual's anatomy of each patient figure 1.

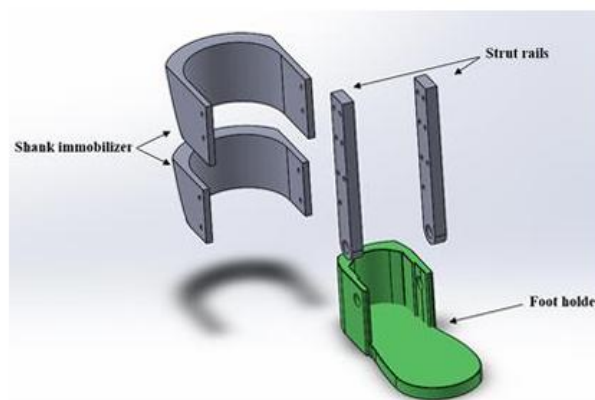


Figure 1 . Design of 3D foot ankle orthosis (Source: N Negru, 2019, Figure 8).

Orthoses are external devices that play an important role in medical rehabilitation since, with the design of these structures, they can modify the functional characteristics of the musculoskeletal systems and neuromuscular functions; but they must comply with certain specific characteristics since the orthosis will depend on the function of the anatomical region on which they act and their different mechanisms of action. This classification will allow us to personalize its use to adapt to the specific needs of each patient, thus achieving greater efficiency in rehabilitation.

2.1.1 Classification of orthoses

The classification of orthoses is comprehensive and covers multiple aspects since we can consider factors such as their functionality, duration of use and the area of the body to which they can be applied table 1. With this classification, specialists can select and design the most appropriate orthoses for the specific needs of each patient.

Table 1 . Criteria for classification of an orthosis (Own elaboration based on Ocello & Lovotti, 2020,).

Classification Criterion	Type of Orthosis	Description
Functionality	Stabilizing	Immobilize a body part
	Functional	Allow controlled movement
	Corrective	Correct skeletal deformities
	Protective	Prevent injuries
Duration of use	Temporary	For short-term disorders
	Definitive	For permanent disabilities
Body Area	Upper Limb	Arm, elbow, wrist, hand, fingers, shoulder
	Lower Limb	Knee, ankle, foot, hip
	Spine	Spinal, cervical
	Others	Facial, cranial

2.1.2 Upper limb orthoses

Upper limb orthoses, as their name suggests, are intended for the upper limb and are divided into passive splints and dynamic splints. The passive or non-articulated ones are designed to immobilize the anatomical segments in order to prevent deformities or correct them in early stages, and are commonly used in cases of trauma, rheumatic diseases, and post-surgical processes. Dynamic splints allow or assist certain movements by means of mechanical or electronic systems in such a way that they facilitate muscle strengthening and

rehabilitation of patients with weakened muscles. In recent years, these splints have included small electrical generators that stimulate muscle contractions, which optimizes a prompt and functional recovery of the patient. In figure 2 we can see on the left side a passive splint and on the right side a dynamic splint. Additionally, within this category we can also find: Hand Orthosis (HO), Wrist – Hand Orthosis (W-HO) , Elbow Orthoses (EO), Shoulder – Elbow Orthoses (S-EO).

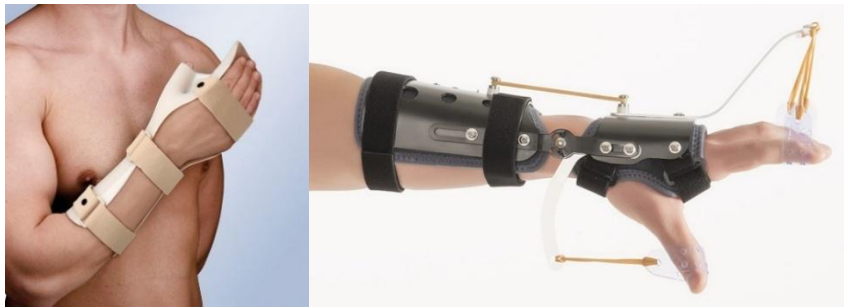


Figure 2 . Passive and dynamic splints (Source: SANICOR, 2024, Figure: DS01/05).

2.1.3 Lower limb orthoses

Lower limb orthoses cover a wide range of devices designed to restore or improve lifestyles, prevent deformities, and assist patients in their recovery. Within this category, functional or dynamic orthoses are aimed at improving the biomechanics of gait (optimizing joint alignment and load distribution) of patient figure 3. Finally, the main mechanism of corrective orthoses is based on a three-point force system that applies controlled pressure in specific areas allowing the correction of structural malformations.



Figure 3 . Antiequin orthosis (Source: Orliman S.L.U., 2024, Figure TP-2102D).

2.1.4 Spinal Orthoses

Spinal orthoses are designed to provide support, immobilization, or correction of the spine, adapting to the specific needs of each patient. In the case of cervical spine, these are divided into flexible collars, semi-rigid and rigid supports. Soft collars, such as the Philadelphia model, are suitable for treating minor injuries, such as whiplash, providing comfort and analgesia Spanish Society of orthopedic surgery and traumatology , (2023). On the other hand, Thoracic-Lumbosacral Orthosis (TLSO) and Lumbosacral (LSO) are classified as rigid, flexible, and corrective depending on the degree of support required. Rigid orthoses, such as Taylor orthoses figure 4, are designed to limit certain types of harmful movements and stabilize the spine helping in the recovery of injuries or pathologies.

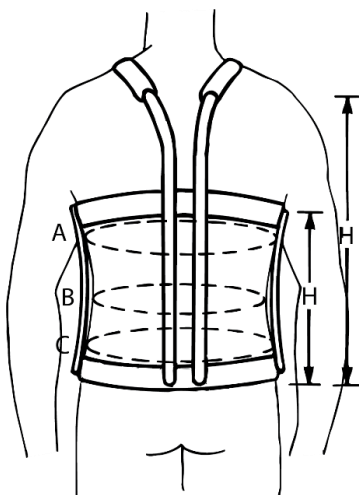


Figure 4 . Taylor Orthoses (Source: Becker Orthopedic, 2024, Figure 107-C).

2.1.5 International norms and standards for orthosis design

Orthotics represent a fundamental tool in the treatment of physical disabilities and functional limitations, as these devices are designed to improve the quality of life of those who use them. That is why it is important to have an adequate regulatory framework to ensure the functionality, safety, and accessibility of these devices. In this sense international organizations such as the International Organization for Standardization (ISO) and the World Health Organization (WHO) have played a key role in defining the global standards applicable to the design and manufacture of these devices.

The development of ortho prosthetic devices such as orthoses are linked to international standards especially by ISO. Among these regulations are the ISO 8549-1 regulations that

standardize terminology and improve technical interoperability and ISO 10328:2016, that regulates structural tests to ensure the durability and safety of these products Health Product Policy and Standards , (2017). These standards are designed to ensure that orthoses are able to withstand the stresses and functional demands of daily use while always preserving the physical integrity of the user. Additionally, WHO reinforces these guidelines with strategies focused on social inclusion and accessibility, aligning them with the Sustainable Development Goals and the Convention on the Rights of Persons with Disabilities Health Product Policy and Standards, (2017).

These prosthesis-specific regulations, there are general standards applicable to the design of medical devices. ISO 13485:2016 regulates quality management systems in the manufacture of medical devices, ensuring controlled and safe processes ISO, (2016). ISO 14971:2019 establishes a framework for risk management, ensuring that devices are evaluated and optimized prior to production ISO, (2019)

In terms of biocompatibility, ISO 10993:2021 regulates biological compatibility testing of the materials used, minimizing risks to patients ISO, (2021). On the other hand, ISO/ASTM 52900:2021 provides guidelines for additive manufacturing 3D printing, which is particularly relevant in the development of customized prostheses ISO, (2021). Finally, ISO 11607:2019 regulates packaging methods for sterile medical devices, ensuring their integrity until use ISO, (2023).

Table 2 . Structural tests required by ISO 10328 to certify complete orthoses and prostheses, partial prostheses, and individual components (Source: International organization for standardization, 2016, Table 2).

Test sample	Princip al structu ral tests	Supplementary Structural tests			
		Torsi on test	Fo ot test	Knee flexi on stops tests	Kne e lock test
Complete transfemoral prosthesis	x	x	x	x	o
Complete transfemoral prosthesis without foot unit	x	x	x	x	o
Partial structure including knee unit but not foot unit	x	x		x	o
Partial structure including knee unit and foot unit	x	x	x	x	o
Foot unit only	x		x		
Partial structure including foot unit but not knee unit (transtibial prosthesis)	x	x	x	x	
Partial structure without knee unit and without foot unit	x				

NOTE: x= test required, o= test required if feature is present

The design and construction of orthoses involve not only technical, but also ethical and economic considerations, since it is essential to use cost-effective materials, especially in low-income countries, without compromising the quality and safety of the device. These materials must meet standards that guarantee their sustainability and performance in various contexts. Similarly, the reuse of components can be a viable option as long as quality controls are carried out to prevent risks to the user. These regulations also require rigorous clinical and structural testing before the device enters the market to ensure that it meets the required functional and safety specifications International organization for standardization, (2016).

Complying with international and local regulations not only improves the quality of the product to be delivered, but also has a positive impact on the accessibility and equity of health services since facilitating access to functional orthotic devices for people with physical disabilities promotes their autonomy and participation in society in a way that aligns with the principles of inclusion and equity established by the WHO and reinforces the importance of addressing economic and social barriers Health Product Policy and Standards , (2017).

In summary, these international standards led by ISO and WHO provide an essential framework for the design, construction, and regulation of orthoses. Their application not only ensures the safety and functionality of orthoses but also promotes social inclusion and equity in access to healthcare services.

Table 3 . ISO standards applicable to medical device design (Own elaboration based on ISO standards ISO 8549-1:2020, ISO 10328:2016, ISO 13485:2016, ISO 14971:2019, ISO 10993:2021, ISO/ASTM 52900:2021, ISO 11607:2019)

Standard	Description	Application in Medical Device Design
ISO 8549-1:2020	Defines the terminology for prosthetics and orthotics.	Ensures standardized language in the industry.
ISO 10328:2016	Establishes structural requirements and testing for limb prostheses.	Ensures the strength and durability of prosthetics.
ISO 13485:2016	Defines the quality management system requirements for medical devices.	Ensures that the design and production processes meet quality standards.

ISO 14971:2019	Provides a framework for risk management in medical devices.	Enables risk evaluation and mitigation in the design of implantable devices.
ISO 10993:2021	Regulates biocompatibility testing for medical devices.	Verifies that materials used in prosthetics and other devices are non-toxic.
ISO/ASTM 52900:2021	Defines additive manufacturing (3D printing) standards.	Regulates the 3D printing of customized prosthetics, ensuring quality and precision.
ISO 11607:2019	Regulates packaging for sterile medical devices.	Ensures safe storage and transportation of prosthetics and implantable devices.

2.2 Process for Designing and Manufacturing Orthoses

Orthotics are essential medical devices that provide support, correction, and assistance to people with musculoskeletal disabilities. Over the years, the design and fabrication of these devices have evolved significantly, especially with technologies such as additive manufacturing, material extrusion and fused filament fabrication. These types of technologies offer major advantages in terms of customization, cost reduction and accessibility compared to traditional fabrication methods Michalec, et al (2024).

For example, ankle-foot orthoses have benefited from customization through digital scanning and additive manufacturing. The orthoses provide controlled flexibility to restore more controlled and natural patient mobility as they are commonly fabricated using selective laser sintering or fused deposition modeling techniques. These methods allow for improved fitness, comfort and mechanical properties compared to prefabricated solutions and although there are still challenges in optimizing design and material selection it is still a better option in terms of custom orthotic fabrication Rogati, et al (2022).

Another example is hand orthoses since this type of orthosis requires a high degree of customization due to the structural complexity of the human hand, traditional methods such as thermoforming and manual modeling usually involve higher costs and long production times. Unlike 3D printing, this allows a more automated production of modular

orthoses adapted to each patient's case, thus improving the patient's rehabilitation results without compromising accessibility or efficiency Michalec,et al (2024).

It begins with an evaluation of the patients where their medical and functional needs are identified. This first stage is very important to ensure that the orthosis is properly adapted to the user's body and meets the requirements of the patient. Once this is done, with the aid of 3D scanning techniques anatomical patient data are collected that will serve as the basis for developing a digital computer model.

Once the digital model data is obtained, the 3D model is designed and edited in Computer-Aided design CAD software. This model is then prepared for 3D printing to optimize production time. After 3D printing, post-processing and final fitting processes are carried out to ensure that the orthosis meets the patient's needs and expectations. The following sections detail the steps involved in this process Hale, ed at (2020).

2.2.1 Clinical evaluation of the patient

In order to create a customized 3D orthosis, we first start with a clinical evaluation of the patient as this is crucial to ensure that the final device meets the appropriate anatomical and functional requirements so that the patient can perform his or her activities normally and without any discomfort. The evaluation includes a series of steps that allow accurate and complete data on the patient's condition to be obtained.

First, a detailed medical history is taken where information is gathered about the patient's previous medical conditions, including chronic diseases, surgeries, allergies, or current treatments figure 5 . This analysis allows the identification of relevant factors that

may influence the design and use of the orthosis and also notes the specific needs that the patient requires such as improvements in mobility, correction of deformities or pain relief.

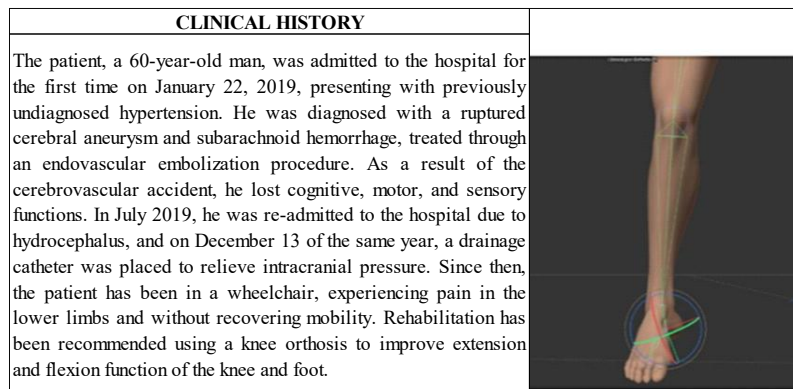


Figure 5 . Clinical evaluation for customs orthotics (Source: Lema Delgado , 2024, Figure 20).

In some cases, tools such as imaging studies X-rays, computed tomography or magnetic resonance imaging are also provided, since these techniques provide more detailed information about the bone structure and tissues that are often affected and can be crucial for the three-dimensional modeling; this, together with the previous clinical history, helps to determine the technical and specific characteristics that the device should have to meet a wider range of established therapeutic objectives Castillo González, et al (2022). Nowadays there is a step that has become very important when making an orthosis and it is 3D scanning, a technology that allows us to accurately capture the anatomical surface of the patient and generate a three-dimensional digital model that will work as a base guide for the modeling figure 6.

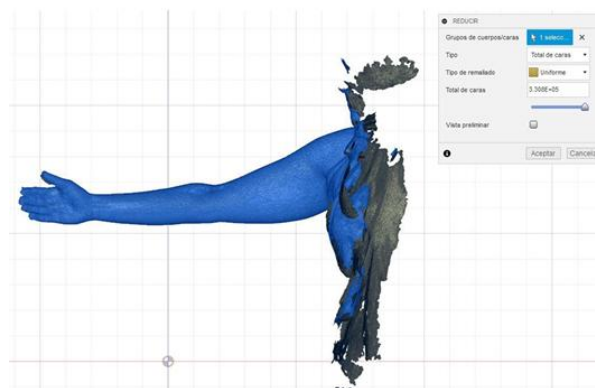


Figure 6 . Prosthetic Customization with Fusion 360 (Source: Angun, 2024, Figure 33).

Finally, in addition to the physical aspects, it is also recommended to carry out a psychosocial follow-up to understand the emotional and social behavior of the patient, since factors such as motivation, the environment where the patient lives and expectations regarding the use of an orthosis can influence the adaptation and efficacy of the device with the patient.

A study conducted by the Spanish Society of Senology and Breast Pathology compared the use of compression orthosis versus traditional dressings figure 7 in 198 patients undergoing breast cancer surgery (Cantero Rodríguez, et al (2018)). The results showed that the group using orthosis experienced improvements in physical function, social function, emotional role, and mental health. Patients reported greater aesthetic satisfaction and overall comfort. Additionally, postoperative pain was reduced after seven days compared to those who received traditional dressing.

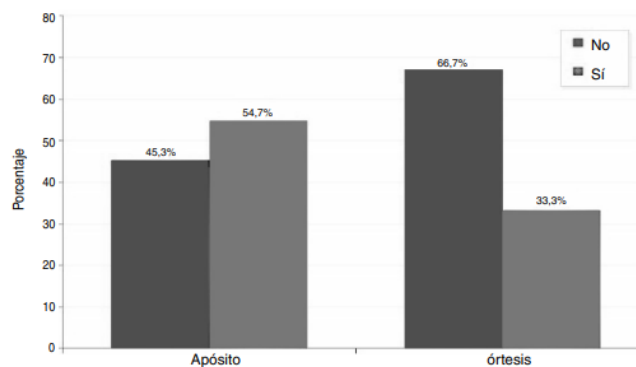


Figure 7 . Comparison between dressing and orthosis according to emotional problems in daily tasks (Source: Cantero Rodríguez, et al., 2018, Figure 4).

In conclusion, the design and manufacture of orthoses have had remarkable progress thanks to the integration of various technologies. This modern approach allows a more precise customization, adapting to the unique anatomy of each patient. In addition, the digitalization of the patient optimizes production time and reduces material waste, ensuring greater efficiency and effectiveness in the design of orthoses. Several studies, such as Cantero Rodríguez, et al. (2018) and Angun (2024), have demonstrated that customized orthoses not only enhance patients' quality of life but also contribute to their emotional stability by improving comfort and functionality.

2.2.2 Body Scanning

3D scanning has revolutionized multiple disciplines, making it possible to capture three-dimensional shapes with a precision never before achieved. This technology, based on non-invasive methods such as photogrammetry and advanced computer vision techniques, has transformed the way in which products are designed and customized to meet the needs of each patient, from clothing to medical devices.

Its growing adoption in sectors such as fashion and medicine shows its practical value and positive impact in terms of efficiency and accuracy Ekaterina Strunevich, (2020). Body scanning technology not only allows measuring the whole body, but also specific parts such as the feet or the head, facilitating the customization of products such as shoes, clothing, or orthopedic insoles figure 8. By integrating advanced tools such as computer vision to create digital models, machine learning and artificial intelligence, mobile scanners generate detailed three-dimensional models of the human body from images captured with common devices such as smartphones or tablets, these models are not only accurate but also allow the product to have an optimal fit for the characteristics of each individual.

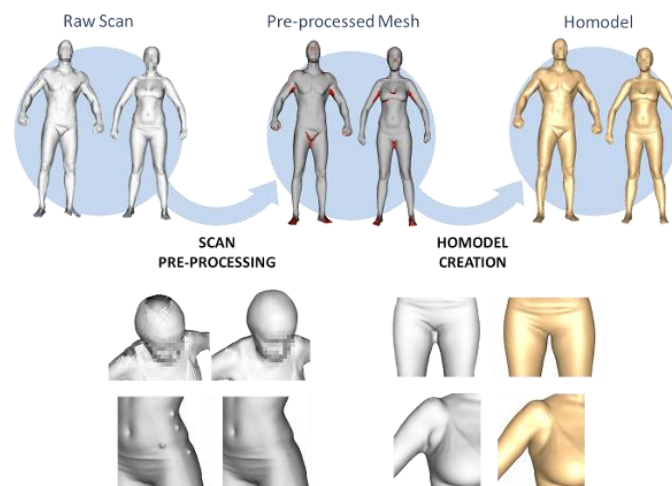


Figure 8 . 3D body scanning (Source: Image taken from 3D Scans to avatars, Anthropometry Research Group, 2016).

One of the main benefits of mobile body scanning lies in improved accuracy of measurements, overcoming the limitations of traditional natural methods by not only speeding up the patient customization process, but also reducing the time and complexity in the production of each brace. The most recent studies have shown that mobile scanners can

provide results that are just as accurate as measurements taken by professional technicians using traditional techniques Brooke Smith, (2022).

However, despite these advantages, the large-scale adoption of 3D scanning faces challenges such as the need to refine algorithms to capture bodies with non-standard postures or complex use cases. There are also inherent limitations, such as the inability to analyze internal structures of the human body, an area where technologies such as X-rays, Computer tomography (CT) and magnetic resonance imaging (MRI) remain indispensable Pascua & Garcia Flores (2024).

Even so, the power of these tools is complementary and even more so when combined with 3D printing and augmented reality technologies. 3D printing has emerged as an important technological strategy in the manufacturing process of medical devices, one of them the creation of prostheses and orthoses due to the ability to produce much more customized designs and adapted to the patient.

Traditionally these prostheses are made in plaster or foam molds, foam boxes or plaster impressions figure 9 where the affected part of the patient is placed, and the mold captures the environment and then add the liquid plaster and create the solid mold of the patient Walker, et al (2023).



Figure 9. Traditional method of plaster impression (Source: Mehmood, Abd Razak, Gholizadeh, & Chung, 2018, Figure 2).

2.2.3 Types of medical scans on a patient

In the field of medicine, various scanning technologies are used to image the human body, allowing healthcare professionals to diagnose, plan treatments and perform procedures more accurately. Each tool has its limitations and advantages that make it useful in different medical contexts. According to Haleem and Javaid (2018), the most common tools for scanning the human body are X-ray, computed tomography (CT), magnetic resonance imaging (MRI), ultrasound and 3D scanning. Each of these technologies offers a unique approach to study the human body whether it is to detect disease, plan surgical procedures or perform three-dimensional computer modeling Islamia (2018). Table 4 describes their strengths, weaknesses, and medical applications.

Table 4 . Medical Scanning Technology Comparison Chart (Own elaboration based on : Haleem & Javaid, 2018)

Technology	Description	Strengths	Weaknesses	Medical Applications
X-Ray	Uses radiation to create images, capturing the difference in density of the materials	Fast, easy to use, good for dense bones	Does not provide details of soft tissues, radiation	Bone diagnostics, dentistry, fractures, pulmonary diseases
CT (Computed Tomography)	Uses X-rays moving in an arc to capture high-resolution images	Provides internal details at multiple density levels	Radiation exposure, not ideal for soft tissues	Diagnosis of brain, lungs, heart, bones, and internal organs
MRI (Magnetic Resonance Imaging)	Uses magnetic field and radiofrequency to obtain detailed images of internal tissues	No radiation, excellent for soft tissues	Expensive, not suitable for patients with metal implants	Diagnosis of brain, soft tissues, tumors, internal organ injuries
Ultrasound	Uses sound waves to create internal images, without ionizing radiation	Safe, non-invasive, non-radiation, real time	Lower resolution than other technologies	Diagnosis of cardiac conditions, biopsy guidance, internal organ analysis

3D Scanning	Captures three-dimensional data to create 3D models	Provides details of the external surface	Does not provide internal images depend on scan quality	Surgical planning, prosthetic design, anatomical models for surgery, and education.
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2.3 CAD and Numerical Tools for the Design of Medical Devices

Computer-Aided design (CAD) has revolutionized the creation of medical devices, especially in the area of customization of orthotics and prosthetics, where precision and fitness are crucial. According to Gibson, et al (2015), the use of CAD in additive manufacturing allows for greater flexibility in design, enabling engineers to create highly accurate digital models that can be easily modified to suit individual patient needs. This customization capability is as designs must conform to the anatomical specifications of the patient.

In addition, Computer-Aided design facilitates the transition of design processes into digital manufacturing, such as 3D printing and 3D scanning, a technology that has been closely integrated into the medical device design process. The use of CAD tools allows not only the creation of detailed three-dimensional models, but also the ability to perform virtual simulations and testing of designs, which reduces the need for physical prototypes and speeds up the development process Gibson, et al (2015).

2.3.1 Numerical Tools for Medical Device Design

Numerical tools, such as finite element simulation (FEA), are fundamental in the analysis and validation of designs created in CAD . These tools allow engineers to analyze the response of materials and structures under different loading and stress conditions, simulating behaviors that can be difficult to evaluate in a physical environment Belal Al-Tam (2023) .According to Gibson, et al (2015). Finite element simulation is essential to simulate the behavior of materials under various loading conditions, which is crucial to ensure that medical devices are functional and safe. This type of analysis makes it possible to predict how devices will behave in real situations, improving the quality of the final design and reducing risks in use.

In fact, numerical tools make it possible to optimize designs by predicting device performance prior to manufacturing, reducing the need for costly and time-consuming

physical prototypes. Structural optimization can improve the use of materials, minimizing the weight of prostheses without compromising their strength ȚÎȚU & Bianca (2024). According Gibson, et al (2015). This optimization of designs using numerical tools is crucial when looking to make lighter and cheaper medical devices, which in turn can reduce production costs and make them more affordable.

2.3.2 Integration of CAD and Numerical Simulation in Medical Device Design

Integrating CAD with numerical tools, such as FEA, creates an efficient workflow in which designers can iteratively adjust and test digital models. This combination of design and simulation is essential in the additive manufacturing of medical devices, as it enables continuous optimization throughout the design process. In the case of orthotics, for example, designers can create a CAD model, simulate how it will react to biomechanical forces, and then adjust the design based on the simulation results Valdes Aguirre (2024).

This iterative approach not only improves the accuracy of designs but also speeds up the development process by reducing the number of physical prototypes required. In addition, finite element simulation allows virtual testing of devices under different conditions of use, which helps to identify potential failures prior to manufacturing. For example, according to Cirello, et al (2024), demonstrated that the use of CAD software combined with FEA simulations allowed the structural behavior of an orthosis to be evaluated prior to fabrication as the orthosis was modeled in CAD and then a simulation was performed to analyze the stress distribution under biomechanical loads.

This allowed the design to be optimized prior to 3D printing, reducing the need for physical testing and improving development efficiency. In addition, the results of the numerical simulation allowed the evaluation of different materials and geometric configurations for the orthosis, which facilitated the selection of an optimal structure in terms of strength and comfort for the user Cirello, et al (2024).

2.3.3 Specific Tools and Software Used

For the development of these medical devices (orthoses), several tools that integrate Computer Aided Design (CAD) and numerical simulation are used, some outstanding and well-known programs are SolidWorks, Autodesk Fusion 360, ANSYS and CATIA.

- **Fusion 360**

Fusion 360, developed by Autodesk is a CAD, CAM and CAE design software that enables comprehensive modeling and simulation of medical devices. The program's ability to perform stress and deformation analysis makes it a key useful tool in the development of custom orthoses Autodesk Inc (2025). In addition, its integration with 3D printing facilitates rapid prototyping, which reduces costs and development times.

- **SolidWorks , CATIA and Abaqus**

SolidWorks is a widely used software in the biomedical industry due to its accurate parametric modeling and advanced simulation tools SolidWorks Corporation (2025) .It allows structural mechanics analysis, load simulation and topological optimization to improve the performance of prostheses and orthoses. Its intuitive interface and compatibility with other simulation programs make it ideal for biomedical engineers.

CATIA is an advanced tool used in the design of highly complex products, including medical devices. Its modeling engine allows the creation of complex surfaces, which is essential for developing customized prostheses based on the patient's anatomy SolidWorks Corporation (2025). In addition, it offers integration with simulation tools, which facilitates design validation prior to manufacturing.

Abaqus, developed by Dassault Systemes, is an advanced simulation software used to evaluate the mechanical response of materials in prosthetics and orthotics. Its ability to perform contact and biomechanical simulations makes it ideal for the development of customized medical devices SolidWorks Corporation, (2025).

- **ANSYS**

ANSYS is one of the leading finite element simulations (FEA) tools in industry. It is used to evaluate the mechanical and thermal behavior of medical devices under different loading conditions ANSYS Inc (2025) In the case of orthoses, it allows the stress distribution and deformation of materials to be analyzed, ensuring that the design is safe and efficient prior to production.

- **Mimics**

Mimics, developed by Materialize, is a software specialized in processing medical images, such as computed tomography (CT) and magnetic resonance imaging (MRI). It

allows these data to be converted into three-dimensional models that can be used for the manufacture of custom orthoses through 3D printing Materialise, (2025). Its application is key in the customization of medical devices based on the exact morphology of the patient.

- **FreeCAD and OpenSCAD**

FreeCAD is open-source software that offers 3D parametric modeling tools. Although not as powerful as commercial solutions, it is an affordable alternative for designers and engineers looking to develop orthotic models without incurring high costs FreeCAD (2025). OpenSCAD is a programming-based modeling software, allowing the creation of highly customized designs through scripting. It is useful for developing mathematically accurate models of orthoses and prostheses OpenSCAD, (2025).

Table 5 . Summary of Tools and Software for Orthotics Design (Source: Created by the author with data from Autodesk Inc (2025), SolidWorks Corporation (2025), FreeCAD (2025), ANSYS Inc (2025), Materialise (2025), OpenSCA (2025)

Software	Description	Monthly Cost	Annual Cost	Availability	Applications in Orthotics
Fusion 360	Integrated into CAD, CAM, and CAE software	€60 (personal plan with limited features available for free)	€495/year (standard plan). Discounts are available for students and educators	Commercial	3D modeling and simulation for custom orthoses
SolidWorks	Advanced parametric modeling tool	Not available monthly (only perpetual licenses)	€4,000 (perpetual license), Annual maintenance €1,000	Commercial	Detailed design and structural analysis of orthotics
CATIA	Advanced modeling and simulation platform	Not available monthly (only perpetual licenses)	€10,000 (perpetual license), Annual maintenance €2,000	Commercial	Development of complex orthotics with design validation
ANSYS	Finite Element Analysis (FEA) software	€500/month (basic plan)	€5,000/year (standard plan)	Commercial	Evaluation of mechanical behavior of orthotics under load conditions
Abaqus	Advanced simulation platform for materials and structures	€500/month (basic plan)	€4,000/year (basic plan)	Commercial	Simulation of stress and optimization of orthotic designs

Mimics	Software specializes in medical image processing	Not available monthly	€10,000/year (standard plan)	Commercial	Conversion of medical images into 3D models for custom orthotics
FreeCAD	Open-Source CAD software	Free	Free	Open source	Parametric 3D modeling is suitable for orthotics design
OpenSCAD	3D modeling tool based on scripting.	Free	Free	Open source	Creation of precise 3D models through programming

2.4 Materials for Medical Devices

The advancement of technology in the design and construction of orthotic devices has been profoundly influenced by the selection and development of suitable materials. These innovations are directly related to the incorporation of digital 3D modeling and simulation as an essential tool in the customization, production, and improvement of these devices. The ability of materials to meet the structural, functional, and aesthetic demands of orthotic and prosthetic devices is critical to ensure clinical effectiveness and user acceptance as materials used in orthotics encompass plastics, metals, composite fibers, leather, and a variety of synthetic and natural fabrics. Each material is selected based on key properties such as strength, flexibility, weight, durability, and interaction with the user's skin. In this context, advances in 3D modeling and computer simulation have facilitated the evaluation and prediction of these properties, allowing for greater accuracy in custom design Edelstein, (2002).

2.4.1 Selection of Materials and Properties

Plastics, particularly thermoplastics, are in widespread use because of their ability to be molded and reshaped by heat. These include polyethylene, polypropylene, and copolymers, which are valued for their impact resistance, light weight, and malleability. A typical example is the use of polyethylene for the construction of ankle and foot orthoses where its flexibility ensures comfort while its rigidity provides the necessary support. In the digital design process, these plastics can be simulated to analyze deformation and strength prior to fabrication, optimizing both design and material consumption. The combination of composite materials, such as carbon fiber integrated into plastics, are designed to meet

specific needs. They combine light weight with extraordinary structural strength, making them essential in devices intended to withstand high loads or undergo repetitive cycling, such as orthopedic knees. Advances in 3D printing have enabled these composites to be incorporated directly into customized devices with complex geometric configurations that would be impossible to produce using traditional methods Pereira (2018).

2.4.2 Plastics

The hardness of plastic materials is measured and classified according to the American society for testing and materials (ASTM) in the standard D2240, a widely used standard for determining the resistance of plastics, elastomers, and rubbers to deformation.

This standard establishes an accurate and universal method for measuring hardness using Shore scales, which facilitates comparison between materials and ensures consistency in technical specifications American Society for Testing and Materials (2021).

The implementation of this standard is crucial in the plastics selection process, as it allows the stiffness or flexibility of a material to be evaluated and classified according to the needs of each application. For example, hardness directly influences factors such as wear resistance, impact absorption and the ability to withstand deformation under load Bennis (2023).

The most common scales defined by ASTM D2240 are:

- Shore A: Indicated for soft and flexible materials, such as rubbers and elastomers, with values ranging from 0 (very soft) to 100 (very hard).
- Shore D: Oriented to stiffer and harder materials, covering a wider hardness range, also from 0 to 100.

Thanks to this standard, it is possible to make an informed choice of the most suitable plastic for a specific application, ensuring that it meets the required functional and mechanical requirements. The following table 6 shows examples of plastics classified according to their Shore hardness and their main applications Bennis (2023).

Table 6 . Guide to Choosing Hardness Testers: Typical Applications (Source:American Society for Testing and Materials, 2021, Table: X1.1)

Type (Scale)	Typical examples of tested materials	Hardening meter (Typical uses)
A	Soft vulcanized rubber, natural rubber, nitriles, thermoplastic elastomers, flexible and thermoset polyacrylics, wax, felt and leathers ("EHS Shore Durometer Hardness Tester Unit - Mikrometry instruments limited")	20-90A
B	"Moderately hard rubber, thermoplastic elastomers, paper products and fibrous materials" ("Wallace Hardness Testers Data Sheet - Wallace Instruments")	Above 90 A, below 20 D
C	Medium hard rubber, thermoplastic elastomers, medium hard plastics, and thermoplastics	Above 90 B, below 20 D
D	Hard rubber, thermoplastic elastomers, harder plastics, and rigid thermoplastics	Above 90A
DO	Moderately hard rubber, thermoplastic elastomers, and very dense textile windings	Above 90 C, below 20 D
M	Thin, irregularly shaped samples of rubber, thermoplastic elastomer, and plastic	20-85A
O	Soft rubber, thermoplastic elastomers, very soft plastics and thermoplastics, medium density textile windings ("Instruction manual digital shore hardness tester") ("Instruction manual digital shore hardness tester")	Below 20 DO
OO	"Extremely soft rubber, thermoplastic elastomers, sponge, extremely soft plastics and thermoplastics, Foams, low-density textile windings, human and animal tissue" ("Analog Duromete Type OO for Very Soft rubber - MRC-Lab")	Below 20 O
CF	Composite foam materials, such as safety cushions for rides, vehicle seats, dashboards, headrests, armrests, and door panels	See test method F1957

In addition to manufacturing processes, plastic materials play a key role, offering a wide variety of properties to suit diverse applications. For example, acrylonitrile butadiene styrene (ABS) is a popular thermoplastic in 3D printing, especially in fused filament fabrication (FDM) technology, thanks to its durability, light weight, and ability to withstand impact. Its printing temperature ranges from 230 °C to 260 °C, and although it is not biodegradable, it is reusable and allows glossy finishes and chemical welding with acetone.

On the other hand, polylactic acid (PLA), derived from renewable resources such as corn starch, is biodegradable, easy to handle, and requires lower printing temperatures (190

°C to 230 °C), although it is less resistant than acrylonitrile butadiene styrene (ABS). Advanced materials such as nylon, used in selective laser sintering (SLS) and fused filament fabrication (FDM) processes, stand out for their strength and durability, while acrylonitrile styrene acrylate (ASA), similar to acrylonitrile butadiene styrene (ABS), offer greater UV resistance. Other materials, such as polyethylene terephthalate (PET), are semi-rigid, tough, recyclable, and safe for food contact figure 12 (Bennis, 2023).

In more demanding applications, polycarbonate (PC) withstands temperatures up to 150 °C, and high-performance thermoplastics, such as polyaryletherketone (PAEK) and polyetherimide (PEI), stand out for their thermal and mechanical properties. For specific dissertation, there are innovative options such as Laywood, a hybrid of wood and polymer; flexible thermoplastic elastomer (TPE) materials, ideal for deformable objects; and carbon fiber-reinforced filaments, which combine lightness with high stiffness.

Table 7. List of tables of the diverse types of plastics and their characteristics. (Source: Prusa, 2020, Table: 1)

Material	Printing with enclosure	Dry box recommended	Hardened nozzle required	Nozzle temperature (°C)	Bed temperature (°C)	Printable on textured sheet	Printable on smooth PEI sheet	Printable on satin sheet	Printable on PP sheet	Soluble with common solvents
PLA	No	-	No	185-235	50-60	☑	☑	☑	X	X
PETG	No	No	No	215-270	70-90	☑	☑	☑	X	X
PETG HT	No	No	No	270	110	☑	☑ (with glue stick)	☑	X	X
ASA	Yes (recommended)	No	No	220-275	90-110	☑ (with glue stick)	☑ (with glue stick)	☑	X	X
ABS	Yes (recommended)	No	No	230-255	95-110	☑ (with glue stick)	☑ (with glue stick)	☑	X	X
PC (Polycarbonate)	Yes (recommended)	No	No	270-275	100-115	☑ (with glue stick)	☑ (with glue stick)	☑	X	X
CPE	No	Yes	No	275	90-110	X	☑ (with	☑	X	X

							glue stick)			
PVA / BVOH	No	Yes	No	195-215	60	☑	☑	☑	X	☑
HIPS	No	No	No	225-255	100-110	☑	☑	☑	X	☑
PP (Polypropylene)	-	No	No	220-245	70-100	X	☑ (with PP tape)	☑	☑	X
Flex	No	Yes	No	220-260	40-85	☑	☑ (with glue stick)	☑	X	X

Also essential are soluble materials such as high impact polystyrene (HIPS), Polyvinyl alcohol (PVA) and ethylene vinyl alcohol copolymer (BVOH), used as print substrates that dissolve easily, and photosensitive resins, used in stereolithography (SLA) and diffusion production line (DPL) technologies, which stand out for their precision and strength. Finally, polyamide powders for SLS provide biocompatibility and an important level of detail, closing a range of options that covers basic to the most technical applications in additive manufacturing Bennis (2023).

2.4.3 Composite materials

A composite material is a combination of two or more materials with different physical and chemical properties that, when joined together, create a new material with improved characteristics, such as greater strength, lightness, and resistance to electricity. Throughout history, several types of composites have been developed, such as the composite bows of the Mongols in 1200 A.D, and with the Industrial Revolution, synthetic resins emerged that allowed the creation of plastics such as Bakelite.

The 1930s were crucial for the advancement of composites with the introduction of fiberglass and the development of fiber-reinforced polymers (FRP). Composites can be classified into several categories, including ceramic matrix composites, metal matrix composites, reinforced concrete, and fiberglass The Welding Institute (2024).

The reinforcements in these materials can take various forms, such as fibers, flakes or particles, with fibers being the most commonly used due to their high aspect ratio between

length and diameter, which allows for better interaction between the matrix and fibers, as well as easier processing and fabrication of parts with different techniques table 8.

The advantages of these materials include their high strength-to-weight ratio, corrosion resistance and design flexibility, allowing them to be used in various industries such as automotive, aerospace and construction. Thanks to their customizable properties, composite materials are ideal for applications that require superior performance and efficiency.

Table 8 . Fiber composites: Properties of some polymers (Source: Ngo, 2020, Table 2).

Type	Polymer	Density (g/cm ³)	Elongation (%)	Tensile Strength (MPa)	Young's Modulus (GPa)
Thermoplastic	Acrylonitrile styrene acrylate (ASA)	1.0–1.1	30	43.5	2.2
	Acrylonitrile butadiene styrene (ABS)	1.0–1.1	270	47	2.1
	Cross-linked polyethylene (PE)	0.9	350	18	0.5
	Ethylene vinyl acetate (EVA)	0.9–1.0	750	17	0.02
	High-density polyethylene (HDPE)	0.9–1.0	150	32.0–38.2	1.3
	High-impact polystyrene (HIPS)	1	2.5	42	2.1
	Low-density polyethylene (LDPE)	0.9	400	10.0–11.6	0.2–0.3
	Nylon 6 (PA 6)	1.1	60	81.4	2.8
	Nylon 66 (PA 66)	1.1	60	82.7	2.8
	Perfluoroalkoxy (vinyl ether)	2.15	260.0–300.0	28.0–31.0	0.50–0.60
	Polybutylene (PB)	0.95	220–300	29.0–35.0	0.29–0.30
	Polylactic acid (PLA)	1.2–1.3	2.1–30.7	5.9–72.0	1.1–3.6
	Polycarbonate (PC)	1.2	200	69	2.3
	Polycaprolactone (PCL)	1.1	700	16.0–23.0	0.4

2.4.4 Ceramics

Ceramic materials are a class of inorganic, non-metallic solids that possess unique characteristics derived from their chemical bonds, ionic and covalent. These properties include high hardness, thermal and chemical resistance, and excellent electrical insulating

qualities. However, their natural brittleness limits certain applications, making them a specialized choice in various industries Boch & Niepce (2007).

Among them, silicate-based ceramics are composed of silicon and oxygen compounds, such as quartz. Traditionally used in tableware, bricks, and glass, these materials continue to evolve thanks to innovations in manufacturing processes. In addition to silicates, there are non-silicate ceramics, which are designed for specialized applications. These include carbides, such as silicon carbide (SiC), known for its exceptional hardness and heat resistance, and nitrides, like aluminum nitride (AlN), valued for their excellent thermal conductivity and electrical insulating properties Boch & Niepce (2007).

Other important ceramic materials include advanced oxides like alumina (Al_2O_3) and zirconia (ZrO_2), which play a crucial role in technical applications due to their mechanical and thermal resistance. Additionally, glasses and enamels, though not always classified as ceramics, share many equivalent properties and are widely used in electronics, optics, and construction.

Ceramic materials exhibit key properties that make them indispensable in various applications. Their hardness and wear resistance surpass most metals, making them ideal for cutting tools and protective coatings. They demonstrate high-temperature resistance, retaining structural integrity under extreme conditions, such as in turbines and aerospace coatings Boch & Niepce (2007). With low electrical conductivity, ceramics serve as excellent insulators in components like capacitors. However, their brittleness, characterized by minimal impact and tensile strength, limits their use in applications requiring high toughness. Additionally, their chemical stability ensures resistance to corrosion and chemical attacks, making them suitable for harsh industrial environments.

Ceramic materials are typically produced through a process that combines powdered mineral raw materials, such as clays or metal oxides. These powders are refined and mixed to achieve a uniform composition during the powder preparation stage. The material is then shaped into specific forms through forming techniques, such as pressing, casting, or extrusion. Finally, the shaped material undergoes sintering, a high-temperature heat treatment that promotes the densification of the material by binding particles together, consolidating its structure, and enhancing its properties.

The applications of ceramics, which leverage the unique characteristics achieved through this process, are outlined in the following table 9.

Table 9 . Applications of ceramics materials across various industries (Own elaboration based on: Boch & Niepce, 2007).

Category	Main Applications	Specific Examples
Construction	Structural and decorative materials.	Ceramic tiles, bricks, earthenware, glass for windows and impact-resistant facades.
Electronics	Components for storage, insulation, and electrical transmission.	Capacitors, substrates for integrated circuits, temperature sensors, varistors, piezoelectric devices.
Medicine	Biocompatible implants and prosthetics, materials for surgical tools.	Orthopedic prostheses made of zirconia or alumina, dental implants, ceramic surgical coatings.
Aerospace Industry	Lightweight materials, resistant to heat and corrosion.	Thermal coatings for turbines, structural materials for spacecraft.
Automotive Industry	High-performance components resistant to friction and heat.	Ceramic brakes, catalytic converters in exhaust systems, spark plugs.
Chemical Industry	Corrosion-resistant coatings, advanced filters.	Containers for aggressive chemicals, ceramic membranes for gas and liquid filtration.
Energy	Energy storage and conversion.	Fuel cells, solid-state batteries, ceramic coatings for solar panels.
Defense and Security	Ballistic materials and lightweight armor.	Bulletproof vests with boron carbide plates, armor for military vehicles.
Art and Decoration	Aesthetic products with technical properties.	Porcelain tableware, sculptures, decorative enamels.
Cutting and Machining	High-hardness, wear-resistant tools.	Cutting tools made of silicon nitride, silicon carbide discs.

2.4.5 Metals

In additive manufacturing, metallic materials play a key role due to their unique properties, which directly influence their behavior during the additive manufacturing process. From microstructure formation to final mechanical properties, each type of metal has characteristics that must be considered. Factors such as scanning speed, layer thickness and melting strategies are determining factors to ensure the quality and performance of the parts produced in table 10.

Table 10 . Process Parameters and Metal Types (Own elaboration based on: Yakout, Elbestawi, & Veldhuis, 2018).

Material	Characteristics	Impact of Additive Manufacturing
Titanium Alloys (TiAl6V4)	High strength-to-weight ratio, corrosion resistance.	Internal porosity and residual stresses significantly affect tensile strength and fatigue. SLM parameters, such as scanning strategies, influence microstructure and mechanical properties.
Aluminum Alloys (AlSi10Mg and AlSi12)	Lightweight with good mechanical properties, used in industrial and manufacturing applications.	Microstructure affects strength, elongation, and fatigue behavior. Porosity and internal particles limit fatigue strength compared to wrought materials.
Stainless Steel 316L	Common material in Additive Manufacturing processes, known for high corrosion resistance.	Grain size, scan speed, and layer thickness influence density and mechanical properties. Controlling these parameters is crucial for improving surface finish and mechanical performance.

2.4.6 Materials for medical applications

Advances in the manufacturing process have led to the development and diversification of the materials used in the medical part, in applications such as orthoses or prostheses, their development has not only improved their functionality but has also raised new challenges and opportunities for sustainability and recycling with respect to materials and their manufacturing processes.

The selection of materials is not only based on mechanical properties but also on their biocompatibility, a fundamental aspect for medical applications. A recent study published in *The International Journal of Lightweight Materials and Manufacturing* states that a finite element study can be conducted to optimize the selection of materials for prostheses and orthoses, improving both environmental impact and recyclability in 3D-printed medical components Patel (2024).

Table 11 presents the main materials used in medical applications, specifically in the manufacture of orthoses and prostheses. This selection of materials includes types such as thermoplastic, high-performance thermoplastics, composite material, ceramics, metals. In this way, the importance of selecting appropriate materials to optimize the performance of prostheses and orthoses since the material selected depends on factors such as mechanical properties, weight, durability, and compatibility with the chosen manufacturing process.

Table 11 . Materials used in medical 3D printing (Own elaboration based on: P. Patel, 2024).

Material	Type	Medical Applications	Properties	Recyclability
PLA (Polylactic Acid)	Thermoplastic	Orthoses, prostheses, surgical guides	Biocompatible, biodegradable, easy to print	High
ABS (Acrylonitrile Butadiene Styrene)	Thermoplastic	Medical prototypes, prosthetic components	Durability, impact resistance	Medium
Nylon (PA 11, PA 12)	Thermoplastic	Orthoses, flexible prostheses	Flexibility, fatigue resistance	Medium
TPU (Thermoplastic Polyurethane)	Thermoplastic elastomer	Flexible orthoses, prosthetic components	Elasticity, durability	Medium
PEEK (Polyether ether ketone)	High-performance thermoplastic	Implants, medical devices	Biocompatible, chemical, and thermal resistance	Low
Biocompatible resins	Photopolymer	Surgical guides, anatomical models	Precision, biocompatibility	Low
Carbon fiber composites	Composite material	High-performance prostheses	High strength, low weight	Low
Titanium	Metal	Dental and orthopedic implants	Biocompatible, corrosion-resistant	High
PCL (Polycaprolactone)	Thermoplastic	Tissue engineering scaffolds	Biodegradable, biocompatible	High
Hydroxyapatite	Ceramic	Bone implants, coatings	Biocompatible, osteoconductive	Medium

2.5 Types of manufacturing processes for orthoses

Additive manufacturing processes have revolutionized the manufacturing industry by enabling the creation of three-dimensional objects through the successive addition of layers of material. This approach contrasts with traditional subtractive manufacturing methods, where material is removed from a blank part to obtain the desired shape, according to DIN EN ISO/ASTM 52900:2022-03, which sets out the general principles, fundamentals and terminology related to additive manufacturing The International Organization for Standardization (2022). This standard provides a common basis for understanding and applying the various 3D printing technologies, ensuring consistency and quality in the processes, and resulting products.

2.5.1 Fused Deposition Modeling (FDM)

Fused Deposition Modeling (FDM) is a 3D printing technology that has revolutionized the manufacture of three-dimensional objects by enabling the creation of complex parts layer by layer through the extrusion of molten thermoplastic material figure 10. This process begins with a plastic filament, commonly ABS or PLA, which is loaded onto a spool attached to the printer.

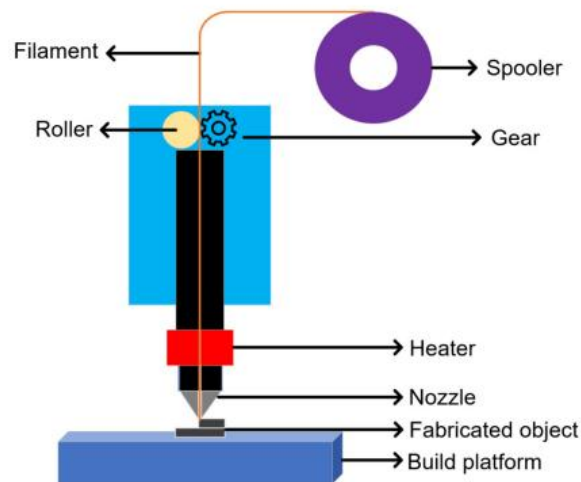


Figure 10 . Fused Deposition Modeling process (Source: Pandit, Liu, Iacono, Corti, & Hu , 2022, Figure 1).

When the digital design is initiated, the filament is conveyed to a heated extrusion head that melts it at a controlled temperature. Through a nozzle of precise diameter, the molten material is deposited in an exact digital pattern, creating thin layers that solidify quickly. Each deposited layer has a millimeter thickness, usually between 0.1 and 0.3 millimeters, allowing detailed reproduction of complex designs. The precision of the head movement, controlled by stepper motors, ensures geometrically accurate construction. As each layer is completed, the build platform lowers slightly to allow deposition of the next layer NOORANI (2005).

2.5.2 Stereolithography (SLA)

SLA (stereolithography) photopolymerization is an advanced technique in 3D printing that uses ultraviolet (UV) light to solidify a photosensitive liquid resin because in this process, a UV laser is used to cure the resin, which is composed of monomers and

oligomers that, when exposed to light, polymerize and transform into a solid material figure 11.

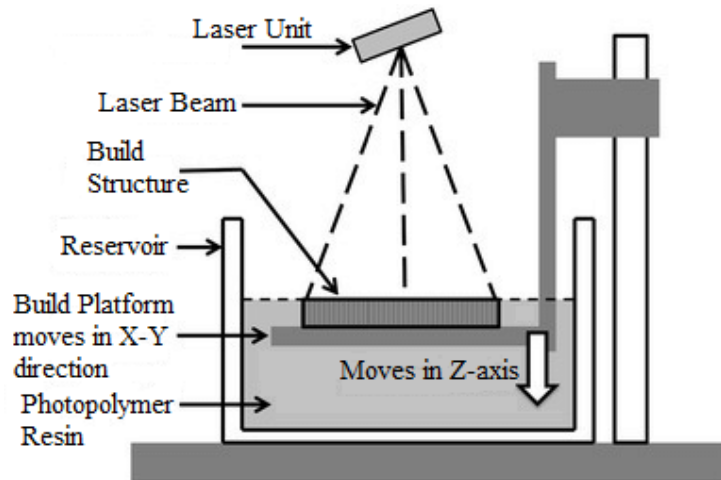


Figure 11 . Graphical representation of the basic principles of SLA technology (Source: Suresh, Reddy, Narendra, Santosh Kumar, & Balasubramanyam, 2019, Figure: 2)

The precision of the machine allows detailed patterns to be traced on the surface of the resin, following a digital 3D model. This process is repeated layer by layer, allowing the gradual construction of complex objects with high resolution. The ability to create detailed and precise shapes has made SLA one of the most widely used techniques in prototyping and the production of customized parts Muhammed, et al (2024).

2.5.3 Selective Laser Sintering (SLS)

Selective laser sintering (SLS) is an additive manufacturing technology that uses a high-power laser to sinter small particles of polymer powder to form a solid structure based on a 3D model. This technique has been a popular choice for engineers and manufacturers for decades due to its low cost per part, high productivity and established materials that make it ideal for applications ranging from rapid prototyping to small series, bridge, or custom manufacturing figure 12. Recent advances in machinery, materials and software have made SLS printing accessible to a wider range of companies, allowing more industries, once limited to advanced technology sectors, to now take advantage of these tools FormLabs, (2021).

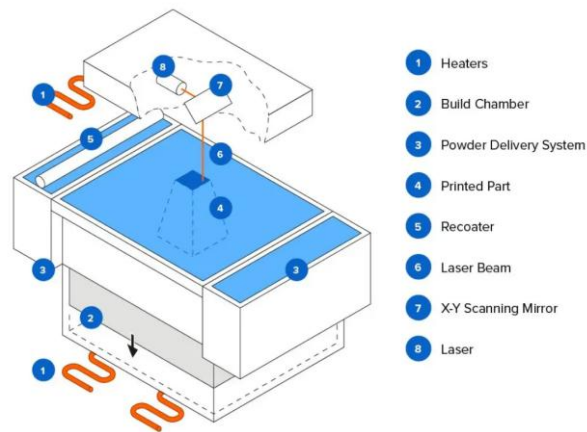


Figure 12 – Explanatory diagram of SLS technology (Source: FormLabs, 2021, Figure 1)

The SLS printing process begins with the dispersion of a thin layer of powder on a platform inside the printing chamber, which is preheated below the melting point of the material to facilitate the work of the laser. This laser scans the cross sections of the 3D model, heating the powder to its melting point and bonding the particles together to form a solid part. The unfused powder layer supports the part during printing, eliminating the need for dedicated support structures.

After each layer, the platform lowers, and the process is repeated until the part is complete. Subsequently, the printing chamber must be cooled slightly to ensure optimal mechanical properties and avoid deformation. Finally, the printed parts must be removed, separated, and cleaned of excess powder, which can be recycled. The parts can also receive additional post-processing by sandblasting or polishing FormLabs (2021).

2.5.4 Electron Beam Melting (EBM)

The Electron Beam Melting (EBM) technology figure 13 stands out for its high productivity, thanks to the use of a high-power electron beam that allows an exceptional melting capacity of the metal powder. This process is characterized by the use of an electron beam unit based on advanced electronics, with no moving parts, which ensures extremely fast and precise beam control. This enables simultaneous melting at several points without compromising surface finish, precision, or manufacturing speed AM power study, (2019).

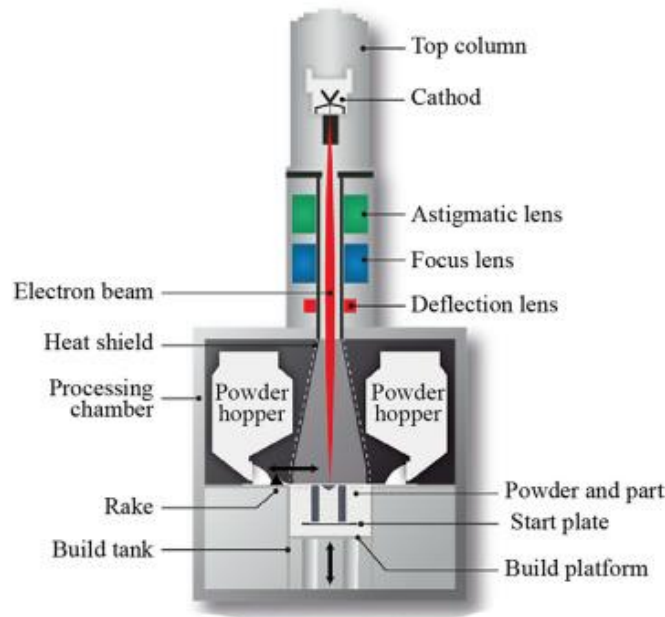


Figure 13 . Electron beam melting process (Source: Ninpetch, Kowitwarangkul, Mahathanabodee, Chalermkarannon, & Ratanadecho, 2020, Figure 3).

During the process, a layer of powder is selectively distributed, heated, and melted, repeating the cycle until the part is complete. In addition, EBM is performed in a vacuum environment, ensuring a clean and controlled environment with excellent thermal insulation. This high-temperature process not only ensures the creation of components with properties superior to castings but also offers materials with characteristics comparable to those of forgings, resulting in stress-relieved, high-performance products AM power study, (2019).

2.5.5 Relationship between materials and their manufacturing process

The relationship between the fabrication of orthotic devices is crucially influenced by the selection of materials and the manufacturing process employed. As is known, traditional materials such as thermoplastics (polypropylene, polyethylene) and laminated composites such as fiberglass or carbon fiber have dominated the market due to their high strength and ability to withstand significant loads that were mostly used for orthoses or prosthesis. However, these same materials have limitations in the manufacturing process due to the manual and traditional nature with which they were manufactured Uz Zaman & Hasan Khondoker, (2023).

In traditional processes, molding and lamination require manual and repetitive adjustments to ensure a proper fit of the part, for example in the manufacture of a prosthesis or orthosis a negative mold of the limb is created and then filled with plaster to generate a positive mold figure 14. This is adjusted manually before laminating layers of composite materials, however although this method is quite dependable and the devices made are durable, the manufacturing cost is quite high as it generates large amounts of waste and time consumption due to the iterations required for final adjustments.



Figure 14 . Conventional method for fabricating ankle-foot orthosis for a patient (Source: Mavroidis, et al., 2024, Figure 1).

In contrast, additive manufacturing or 3D printing offers an approach that reduces waste and improves design and manufacturing efficiency figure 15 . Among the materials used are polymers such as polylactic acid (PLA), acrylonitrile butadiene styrene (ABS), polyethylene terephthalate glycol (PETG) and polyamides such as (PA). According to Uz Zaman & Hasan Khondoker (2023), these materials are much easier to work with in additive manufacturing processes due to their thermoplastic characteristics and compatibility with technologies such as fused deposition modeling (FDM) or selective laser sintering (SLS).

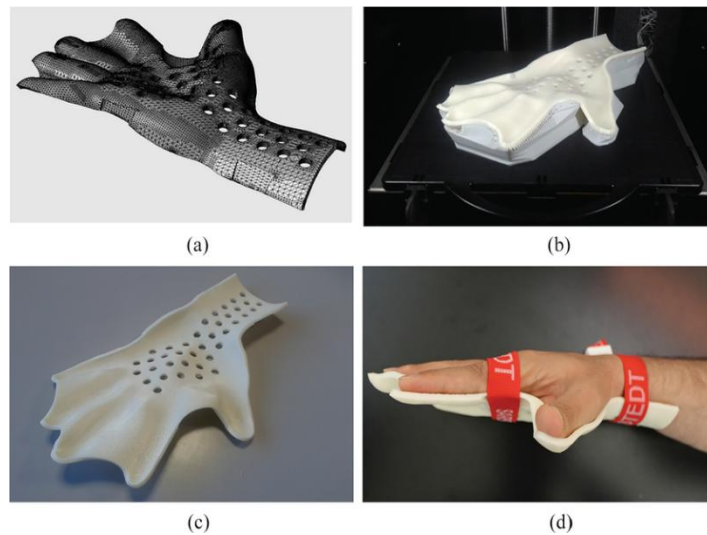


Figure 15 . Additive manufacturing stage of orthopedic hand-held devices (Source: Sharma, et al., 2019, Figure 2).

However, devices made with these additive materials face certain challenges, especially in load-bearing prostheses. Fused deposition modeling (FDM) printed products, for example, are anisotropic, which means that the strength of the material can vary depending on the orientation of the printed layers. On the other hand, technologies such as selective laser sintering (SLS) generate components with more homogeneous properties and higher strengths, although their inflated costs and restrictions on printable device size limit their mass adoption.

A promising approach is the hybrid use of technologies. For example, less structurally demanding parts, such as test sockets or cosmetic elements, can be manufactured with 3D printing. In terms of sustainability, the difference between additive manufacturing with it to the conventional method is much higher because it generates less waste and uses materials more efficiently by building layer by layer Uz Zaman & Hasan Khondoker (2023). This makes it a more viable option for small and medium-sized medical practices, particularly when the initial cost of equipment is spread out over time.

In summary, while traditional materials and processes dominate in high-load applications, additive manufacturing is advancing rapidly in the customization of lightweight devices. The adoption of processes such as additive manufacturing or 3D printing will depend on the improvement in the quality of printable materials and the development of regulatory standards that validate the safety and durability of devices manufactured using this technology table 12.

Table 12 . Traditional and modern manufacturing processes (Own elaboration based on: Uz Zaman & Hasan Khondoker, 2023)

Aspect	Traditional Processes	Additive Manufacturing (AM)
Materials Used	Polypropylene, polyethylene, Ny glass, carbon fiber, and fiberglass.	PLA, ABS, PETG, PA12, and some thermosetting composites.
Durability	High, suitable for load-bearing devices (lower-limb prostheses).	Variable depends on the technique. Limited for FDM; acceptable for SLS.
Waste Generated	High (plaster, discarded molds, trims).	Low, additive manufacturing builds layer by layer, minimizing material waste.
Production Time	Slow due to manual iterations and prolonged adjustments.	Faster, ideal for customized or low-load devices.
Cost	High due to labor intensity and composite materials.	Lower due to process simplification, though initial equipment can be costly.
Customization	Limited and based on manual molds.	High, thanks to digital design and direct manufacturing.
Mechanical Strength	Reliable tests	Challenging for load-bearing devices, especially with FDM technology.

2.6 Financial Analysis and Its Importance

It is important to perform a financial analysis of 3D printed orthotics manufacturing to know if it is affordable and sustainable. Compared to traditional methods, 3D printing has many advantages, such as lower costs, faster production and better access for people with fewer financial resources. This method allows the creation of customized orthotic devices at a lower price, making it a good option to help meet the growing demand for affordable orthoses, especially in developing countries Javaid et al (2022).

The cost of orthosis fabrication is a key factor in deciding whether 3D printing is a good alternative to traditional methods. Standard orthosis fabrication is often expensive because it requires a lot of manual labor, expensive materials, and long production times Damiao, et al (2023). In contrast, 3D printing helps reduce these costs by using affordable materials such as polylactic acid (PLA) and polyethylene terephthalate (PET), while reducing material waste. Studies show that the use of these materials and design customization can make production more efficient and cost-effective, especially in resource-constrained healthcare systems Kunwar et al (2023).

In addition to production costs, financial analysis also considers other expenses such as labor, transportation and storage. 3D printing can help reduce these costs by allowing orthoses to be manufactured locally, rather than imported from other countries. The creation of small production centers with 3D printers allows orthotic devices to be created on an as-needed basis, reducing waiting times and making them more accessible to patients Ballard, et al (2020).

2.6.1 Production Costs

The design and manufacturing process of prosthetics using 3D printing involves some cost components that must be analyzed in detail.

- **Materials:**

In additive manufacturing (AM), the most commonly used materials include polymers such as PLA (polylactic acid) and PET (polyethylene terephthalate). According to Sola and Trinchi (2023), PLA is preferred for its biodegradability and ease of printing, although its recyclability is limited to approximately two cycles before its quality decreases. On the other hand, recycled PET, derived from plastic bottles, represents a sustainable option, but requires precise control of its processing conditions to ensure adequate interlayer adhesion. In addition, they note that reinforcements such as high-density polyethylene (HDPE) and fibers have been explored to improve the mechanical properties of recycled plastics, although this may introduce challenges in printing

- **Equipment:**

The manufacturing of orthoses using 3D printing requires similar infrastructure to that used for prosthesis production, as both processes involve scanning technology, digital modeling, and additive manufacturing. Although the specifications may vary depending on the type of orthosis and its functional requirements, the costs associated with setting up such production include investment in equipment, software, materials, and other operational expenses. Below is an estimate of the costs involved in orthosis manufacturing, based on references to orthopedic manufacturing costs in 3D printing BPT Team (2025).

Table 13 . Estimated Infrastructure Costs for 3D Printed Orthosis Manufacturing (Own elaboration based on BPT Team, 2025)

Component	Cost Range (USD)
3D Printers and Printing Supplies	\$30,000 - \$100,000
Computer-Aided Design (CAD) Software	\$2,500 - \$15,000
Initial Material Inventory	\$5,000 - \$20,000
Printer Maintenance and Repairs	\$200 - \$1,000
Electricity for Operation	\$100 - \$500
Labor Costs (Design, Printing, Post-processing)	\$1,000 - \$5,000
Software Licenses	\$300 - \$1,500
Research and Development	\$500 - \$3,000
Equipment Depreciation	\$1,000 - \$10,000
Quality Control and Testing Materials	\$300 - \$2,000
Packaging and Shipping Finished Products	\$200 - \$1,000

These values are estimates and may vary depending on the region, production volume, and technology used. Since orthoses are personalized medical devices, it is essential to consider aspects such as material certification, biocompatibility testing, and clinical validation, which can increase costs. However, optimizing designs and using low-cost materials can help reduce expenses, making this technology more accessible to those in need.

- **Post-processing:**

Post-processing in additive manufacturing 3D printing of polymers can represent a significant cost, influenced by the technology used and the requirements of the final product. According to Dizon et al (2021), post-processing is divided into primary processes, such as support removal and cleaning, which are essential for all parts, and secondary processes, which improve specific properties such as aesthetics or chemical resistance.

In terms of cost, post-processing can represent a substantial part of the total expenditure. For example, in technologies such as stereolithography (SLA), the costs

associated with post-processing, including UV washing and curing, can amount to as much as 30–40% of the total production cost. This percentage is due to the need for specialized equipment and additional materials, such as resins and solvents. In contrast, fused deposition modeling (FDM) can have lower post-processing costs, around 10–20%, although this can increase if detailed surface finishes are required.

2.6.2 Economic Projections

A study conducted by Bennis (2023) analyzed the growth of the additive manufacturing market. To do this, data was collected from three key sources:

- Wohlers Report (Wohlers Associates).
- CLLAIM (Creating Knowledge and Skills in Additive Manufacturing)
- World Economic Forum (WEF)

Wohlers Report reports significant growth in the global additive manufacturing market, with an 18.3% impact on the industry Wohlers Associates (2023). This growth has been driven by developments in sectors such as healthcare, automotive and electronics. According to the report, the healthcare market in particular will experience a 16% increase in the coming years figure 16, thanks to the adoption of new technologies and advanced materials.

The World Economic Forum (WEF) has identified several key factors behind the rise of additive manufacturing. These include cost reduction, process standardization and technological innovation, which have aligned market trends with current industrial developments Word Economic Forum (2022).

The CLLAIM report also highlights the critical role of training and skills development in additive manufacturing, emphasizing the need for educational standards and certifications to ensure more effective adoption in various industries Creating Knowledge and Skills in Additive Manufacturing (2023).

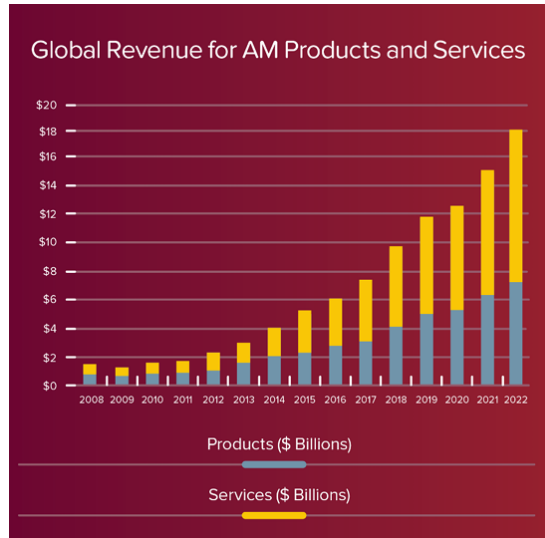


Figure 16 . Evolution of the Global Additive Manufacturing Market according to Wohlers Report (Source: Bennis, 2023, Figure 9).

2.6.3 Economic Evaluation of 3D Printing Processes for Customized Orthoses

Accurate cost estimation is essential for evaluating the economic feasibility of producing customized orthoses. The Activity-Based Costing (ABC) method is widely used to break down costs associated with each phase of the process, from 3D scanning to final delivery, assigning both direct and indirect costs to specific activities. This approach has been applied recently in discrete event simulation models for additive manufacturing Büşra and Shokrani (2025). While studies using digital twins have employed ABC to optimize cost allocation in 3D printing environments Anderson and Merwe, (2021).

2.6.4 Formulas Used and Justification

The unit cost of each orthosis is calculated using the following general formula, adapted from Ruffo and Hague (2007), which integrates all components of the manufacturing process:

$$Unit\ Cost = C_{material} + C_{energy} + C_{labor} + C_{machine}$$

This formula considers both direct and indirect costs and is widely used in recent studies to evaluate efficiency and sustainability in additive manufacturing.

Cost breakdown

- **Material Cost** ($C_{material}$)

$$C_{material} = \text{Piece weight (kg)} * \text{Filament price} \left(\frac{USD}{Kg} \right)$$

This calculation quantifies the material consumed per orthosis, which is critical for evaluating efficiency and reducing waste. The methodology was originally proposed by Ruffo & Hague (2007) and continues to be applied in modern AM studies.

- **Energy Cost** (C_{energy})

$$C_{energy} = \text{Printer power (kW)} * \text{Printing time (h)} * \text{Electricity price} \left(\frac{USD}{kWh} \right)$$

This formula estimates the energy consumed during 3D printing, which is critical for long-duration printing processes. The formula is based on the original approach of Ruffo and Hague (2007).

- **Labor Cost** (C_{labor}):

$$C_{labor} = \text{Hourly rate} \left(\frac{USD}{h} \right) * \text{Total time produce (h)}$$

This calculates the cost of personnel time across all stages of production. The ABC methodology, as proposed by Ruffo & Hague (2007), assigns costs to specific activities.

- **Machine Cost** ($C_{machinie}$):

$$C_{machinie} = \frac{\text{Equipment Cost (USD)}}{\text{Useful life (years)} * \text{Annual production (Units)}}$$

This reflects the depreciation of the printer or other equipment, distributing its cost according to useful life and production volume. Ruffo and Hague (2007) introduced this method, which has been validated in modern AM applications to analyze investment efficiency at different production scales Būşra and Shokrani , (2025).

- **Software Cost ($C_{software}$):**

$$C_{software} = \frac{\text{Annual license cost}}{\text{Annual production}}$$

This assigns the cost of CAD or 3D printing software licenses proportionally. Anderson and Merwe, (2021) applied this approach to integrate digital tools into total cost calculations in digital twin environments.

- **PC Cost (C_{PC}):**

$$C_{PC} = \frac{\text{PC price}}{\text{Useful life (years)} * \text{Annual production (Units)}}$$

This accounts for the depreciation of computers used for design and file preparation Ruffo & Hague, (2007).

- **Rent Cost (C_{rent}):**

$$C_{rent} = \frac{\text{Annual Rent}}{\text{Annual production (Units)}}$$

This distributes the cost of facilities where production occurs across all units manufactured. Based on the methodology by Ruffo and Hague (2007) and is applied in modern AM studies to account for indirect production costs Būşra and Shokrani , (2025)

Using these formulas allows all relevant variables (materials, energy, labor, machinery, and indirect costs) to be integrated into a single unit cost calculation. This

provides a realistic and practical analysis that facilitates comparison of manufacturing strategies, identification of process improvements, and informed economic decision-making in the production of customized orthoses.

2.6.5 Selling Price Estimation

In order to evaluate the economic feasibility of customized 3D-printed orthoses, it is essential to establish an appropriate method for calculating the selling price. One of the most widely adopted approaches is the cost-plus pricing method, which determines the selling price by adding a profit margin to the unit production cost.

Ruffo and Hague (2007) were among the first to formalize the use of cost-plus models in additive manufacturing economics. They demonstrated that incorporating a fixed profit margin over the calculated unit cost allows companies to guarantee profitability while maintaining competitiveness. The formula they propose can be expressed as:

$$C_{selling} = C_{unit} * (1 + M)$$

Where $C_{selling}$ represents the selling price per unit, C_{unit} is the unit cost including both direct and indirect expenses, and (M) is the desired profit margin expressed as a decimal.

For instance, Büşra and Shokrani (2025) highlight that cost-plus pricing remains one of the most practical tools for evaluating profitability in additive manufacturing, especially in low- to medium-volume production where cost variability is significant. Similarly, Anderson and Merwe (2021) argue that applying this model in the production of medical devices provides a balance between covering material and labor costs while offering an accessible final price for patients.

3 METHODOLOGY

The methodology used in this dissertation is based on a practical and somewhat experimental approach since the objective was to develop a functional, comfortable and accessible solution for the manufacture of a hand-wrist orthosis through the use of 3D scanning and printing, using recycled materials as an accessible alternative for low-income people in Ecuador. To achieve this goal, the process was divided into two parts. The first was a familiarization stage with the 3D scanning software, with the purpose of learning how to use the digital tool before applying it in a more practical way. The second phase was the practical application in which an anatomical model was scanned to design the orthosis in the modeling software and print it.

The material chosen for printing was recycled PET. This choice is based both on its technical feasibility and its local availability in Ecuador due to the existence of solid initiatives for large-scale PET recycling, such as the recycling plant in Guayaquil, as well as projects such as Origin that integrate sustainability, social inclusion and material quality criteria Enkador, (2024). At the technical level, several studies have shown that recycled PET maintains favorable mechanical properties: according to Seibert et al (2022), it retains a Young's modulus comparable to virgin PET and outperforms PETG in strength by approximately 15%.

Schneevogt et al. (2021) also reported a modulus of 2300 MPa for recycled PET filament, higher than traditional PETG of 2150 MPa. For its part, a 2024 study revealed that, by optimizing the printing parameters, recycled PET can achieve a tensile strength of up to 43 MPa, surpassing even virgin PET 38.6 MPa. All this confirms that recycled PET represents an affordable, sustainable and technically suitable alternative for the manufacture of low-impact orthotics.

3.1 Familiarization with 3D scanning software

Before applying the technology to a real case, it was necessary to practice with the 3D scanning software (EINSCAN-PRO+). This stage was fundamental since it allowed us to learn how the program works, identify its main tools and understand how to obtain a three-dimensional model from a physical object. Figure 17 describes the workflow to start with 3D Scanning.

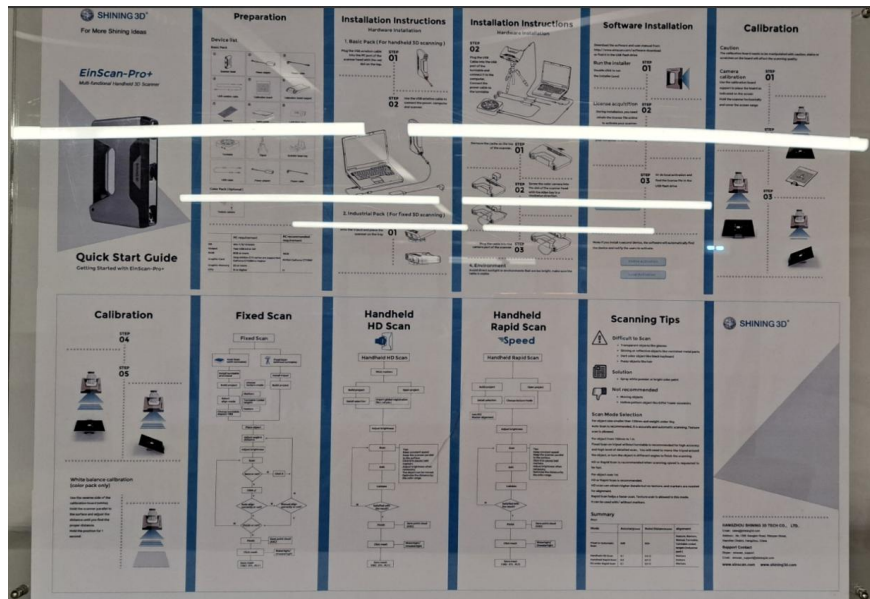


Figure 17 . Workflow with the EinScan Pro scanner (Source: Shining 3D,s.f. Photograph taken by the author)

To this end, test scans were performed with simple Figure 18 objects that were not directly related to anatomical shapes such as the hand and wrist in order to focus exclusively on mastering the scanning technique: learning how to set up the software, correctly adjust the parameters, accurately capture three-dimensional volumes, and process the generated file.



Figure 18 . Preliminary Scans with Simple Objects to Learn 3D Capture Workflow (Own elaboration)

Although the objects used in this phase were not anatomical, the tests performed allowed the identification of common errors such as shadows, shiny surfaces or lack of information in certain areas of the model, which must be corrected in order to obtain an optimal model so that an efficient and replicable workflow can be established.

3.2 3D Scanning of the patient

Once basic experience with the software was acquired, the practical application phase began. The first step was to perform the three-dimensional scanning of a wrist - hand using the same software previously practiced. The objective was to obtain a digital model in STL or similar format of the anatomical shape of the patient or the reference model. With the file generated, it was cleaned and corrected for errors to ensure its quality. Then, it was imported into Fusion 360, a Computer-Aided design software, where the complete modeling of the prosthesis was carried out. At this stage, factors such as user comfort, residual limb shape, wall thickness, ease of impression and production costs were considered.



Figure 19 . Application of 3D Scanning in Anatomical Modeling and Prosthesis Development (Own elaboration)

3.3 Mesh cleanup and optimization in MeshLab

The STL file was imported into MeshLab, an open-source software specialized in editing 3D meshes. The following actions were performed:

3.3.1 Repair surfaces errors.

- Remove duplicated faces
- Remove unreferenced vertices.
- Close holes (if needed).

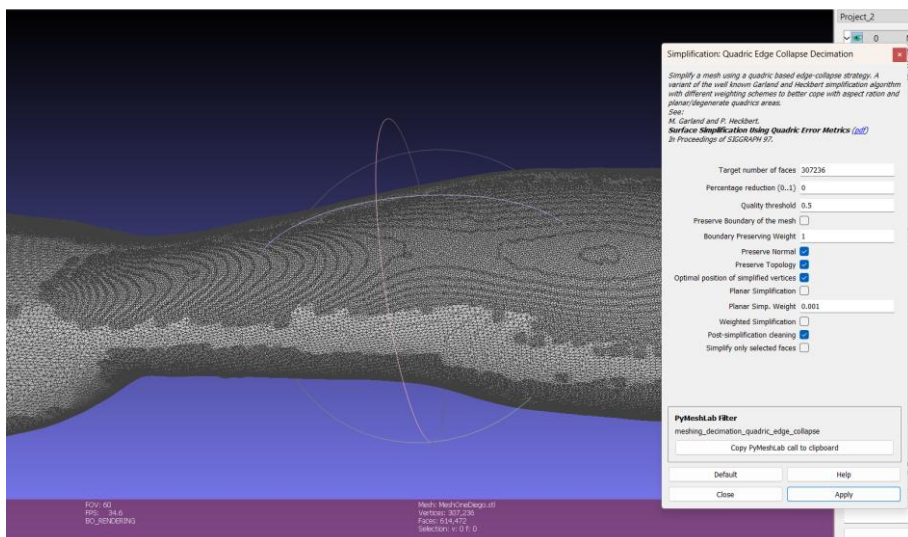
3.3.2 Triangle reduction

- This was performed by applying filters (Remeshing, Simplification, and Reconstruction) and the Quadric Edge Collapse Decimation algorithm.

To make the 3D-scanned forearm model manageable and editable in CAD software such as Fusion 360, it was necessary to simplify the original STL file. The scan, obtained from a 3D scanning application, initially contained over 307,236 triangles, which made the mesh extremely dense and computationally heavy. This high level of detail made it difficult to perform essential operations such as converting the mesh to a solid body, adding thickness, or applying advanced surface edits.

To optimize the mesh, the Quadric Edge Collapse Decimation tool in MeshLab was used. This tool reduces the number of faces by collapsing edges and vertices, while attempting to preserve the general geometry and surface details of the original scan.

Through careful adjustment of parameters, the mesh was successfully reduced to approximately 7,000 triangles, preserving the anatomical accuracy and smooth curvature of the forearm. This optimization allowed for a lightweight, editable, and structurally accurate model-ideal for continuing the orthotic design process.



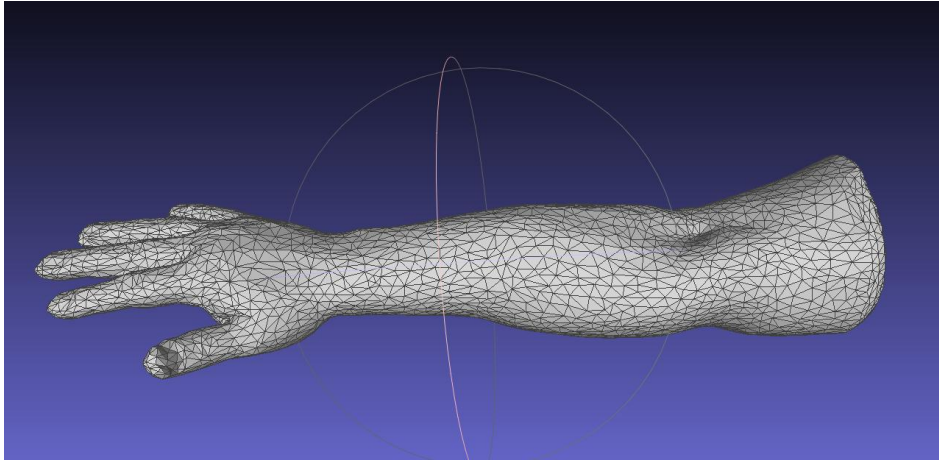


Figure 20 . Reducing 3D Scan Complexity for Efficient Modeling in Fusion 360 (Own elaboration)

These settings allowed for a significant reduction in triangle count without compromising anatomical detail. Below is a summary of the parameters used, and the recommended values applied in this study.

Table 14 . Optimization Parameters for Preserving Anatomical Detail During Mesh Decimation (Own elaboration)

Option	Function	Recommended Setting
Target number of faces	Sets the final number of triangles after simplification	5000-7000
Preserve. Normal	Maintains correct orientation of mesh faces	Enabled
Preserve Topology	Prevents important holes or features from being closed	Enabled
Optimal position of simplified vertices	Improves distribution and placement of simplified vertices	Enabled
Planar simplification	Only useful for flat surfaces; not suitable for organic shapes	Disabled
Quality threshold	Ensures good triangle quality during decimation	Default Value: 1

3.3.3 Mesh-to-Solid Conversion in Fusion 360

The simplified STL model was imported into Autodesk Fusion 360, where the mesh was converted into a solid body. This step was crucial for enabling parametric modeling operations such as extrusions, cuts, and shelling. The procedure followed was:

- In the Mesh Workspace, the tool: **Modify - Convert Mesh** was used.

- The selected conversion method was: **Faceted**

Because when converting an STL mesh into a solid body in Fusion 360, two main methods are available: Faceted and Prismatic; The faceted method preserves the original triangulated structure of the mesh, maintaining the exact geometry of the STL file. This approach is particularly suitable for organic shapes, such as human body scans where surface curvature and anatomical detail must be preserved. On the other hand, the prismatic method attempts to interpret the mesh as a solid composed of regular flat faces, similar to traditional CAD geometry. This method is not appropriate for anatomical models and is better suited for simple mechanical parts or geometric objects with clean, planar surfaces.

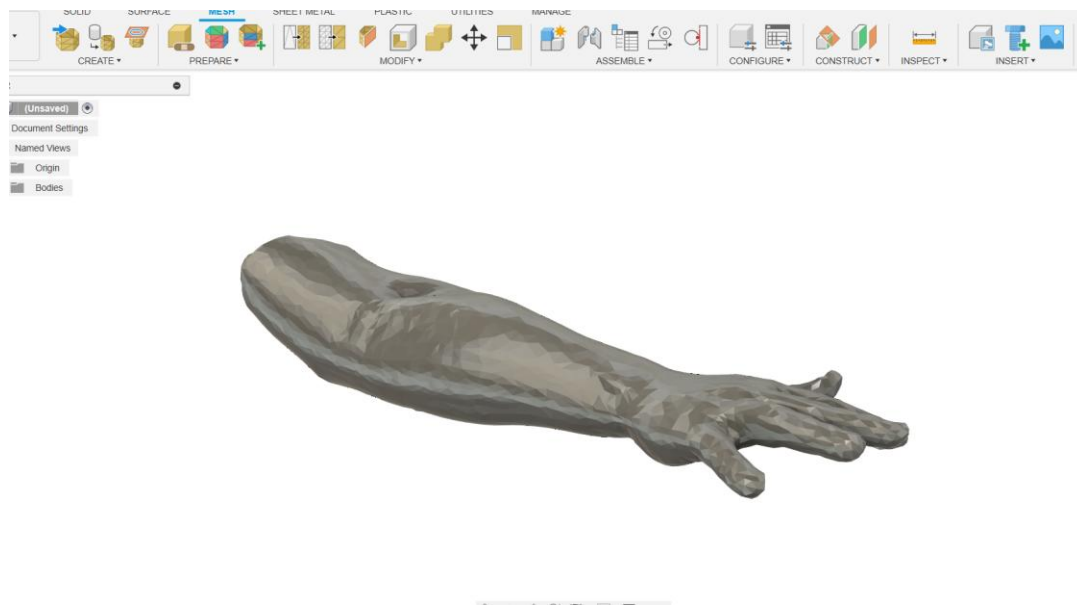


Figure 21 . Preserving Anatomical Detail through Faceted Mesh Conversion in Fusion 360 (Own elaboration)

3.4 Custom Orthosis Design

Using the converted solid, a fully customized orthosis was modeled to fit the patient's anatomy. The key modeling operations included:

- **Shell:** The solid was hollowed with a uniform wall thickness of 3 mm to ensure both comfort and structural stability.
- **Cutouts and Openings:** Sketches were drawn on external surfaces and used with the Extrude Cut tool to create ventilation holes and relieve pressure zones.

- **Split Body:** The model was divided into two halves for modular printing and better fit.

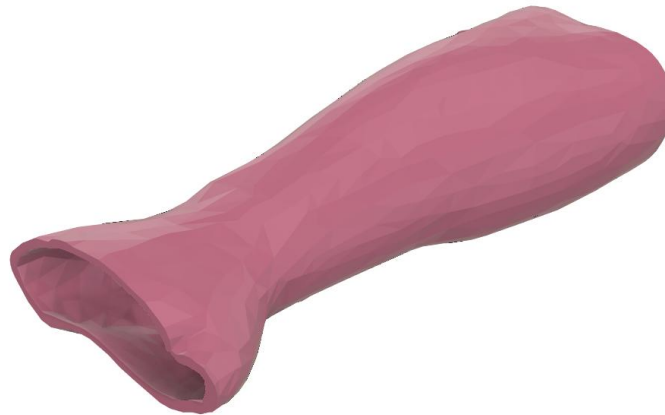
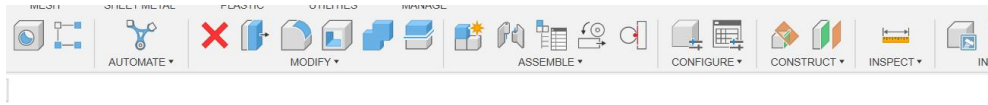


Figure 22 . Designing a Patient-Specific Orthosis with Fusion 360 (Own elaboration)

3.5 Exploration of Parametric Structures: Voronoi Pattern

To improve aesthetics, ventilation, and reduce weight, a Voronoi pattern was explored. Since Fusion 360's free version has limited generative design tools, two alternative methods were used:

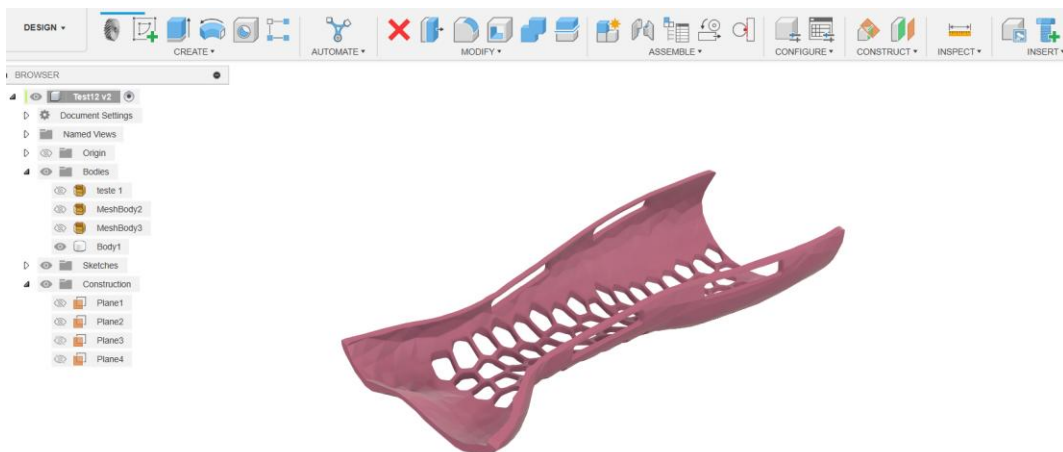


Figure 23 . Voronoi Pattern Application in Customized Orthotic Shells (Own elaboration)

3.5.1 Option A: External SVG in Fusion 360.

- A Voronoi pattern was generated online (via free tools like Patternify or Voronator) and exported as an SVG.
- This SVG was imported into Fusion 360 as a sketch and placed onto a flat surface of the orthosis.
- The tool Project to Surface (Create - Project/Include - Project to Surface) was used to project the sketch onto slightly curved areas.

3.5.2 Option B: Meshmixer Implementation.

- In Autodesk Meshmixer, the tool: Edit - Make Pattern - Dual Edges was used to generate a Voronoi-like lattice directly from the surface geometry.
- Alternatively, PNG stencil images were used and applied through the Sculpt workspace, using tools like Inflate and Draw to emboss the pattern manually.

The image clearly shows how the orthosis fits the patient's forearm and hand. The outer shell follows the natural shape of the arm and matches the 3D scan closely. This good fit gives both comfort and proper function, as the device is made for the user's specific anatomy. The pink part of the model shows the final design of the orthosis, which covers the forearm with a ventilated Voronoi pattern.

This design improves both appearance and airflow while protecting important areas like the wrist and the palm. Using digital scanning and mesh editing tools allowed a high level of customization, helping to avoid pressure points and improve comfort. The close contact between the orthosis and the scanned arm in the image shows that the digital process worked well in capturing and reproducing the patient's shape.

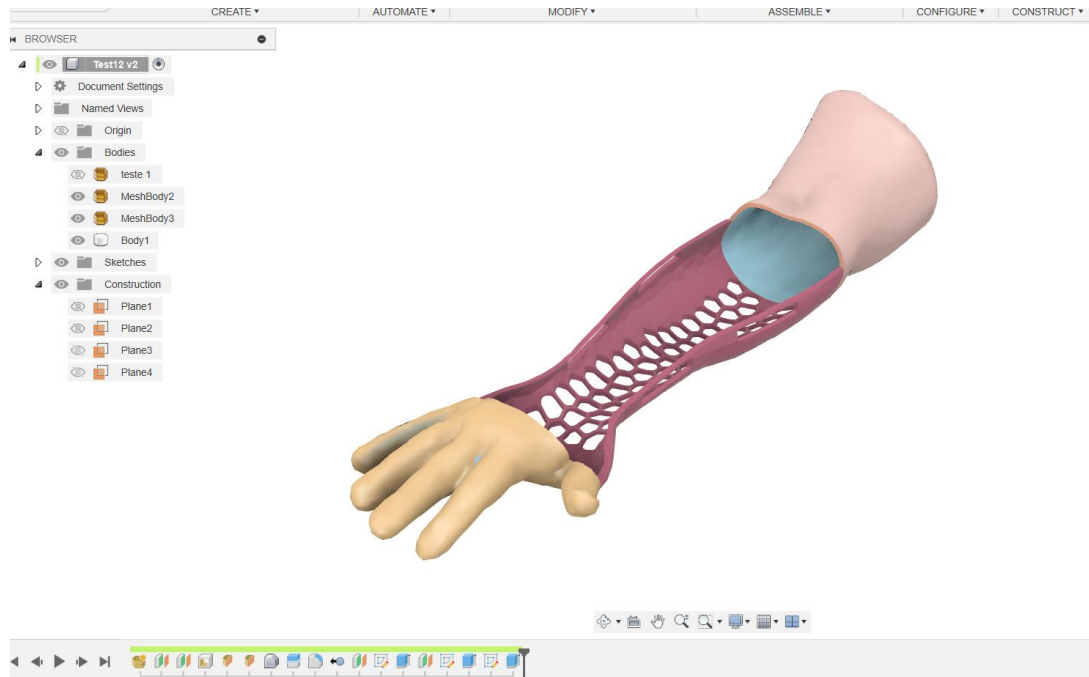


Figure 24 . Integration of Voronoi Patterns for Aesthetic and Functional Orthosis Design (Own elaboration)

3.6 Simulation Example Incorporating Realistic Parameters from Ecuador

For the cost analysis in orthosis manufacturing processes, I opted for a methodological combination that allows for the visualization of specific process activities and a more accurate quantification of the costs associated per unit produced. First, I applied the Activity-Based Costing (ABC) methodology, as it facilitates the identification and allocation of indirect costs to each activity in the orthosis manufacturing process, such as scanning, design, printing and final delivery.

In addition, I applied a mathematical approach which, according to Ruffo and Hague (2007). Enables better integration of quantifiable variables such as the volume of material used, the machine time required, and equipment depreciation. This makes it possible to obtain a detailed unit cost per piece, providing a more precise economic assessment that can be compared with existing market alternatives.

3.6.1 Direct cost

Those directly assigned to the production of the orthosis.

Main materials

- Recycled PET or PLA filament (price per kg)
- Additional components (screws, hinges, Velcro, comfort foam)
- Adhesives or coatings

Electricity

- 3D printer consumption ($\text{kWh} \times \text{electricity rate}$)
- 3D scanner consumption

Direct labor

- CAD design hours (scanning, modeling, adjustment)
- 3D printing hours (supervision)
- Post-processing hours (sanding, assembly, testing)

3D printer depreciation

- Acquisition cost \div useful life (in hours) \times hours used on the dissertation

3.6.2 Indirect cost

Software and Licenses

- Fusion 360 (if not free for students)
- MeshLab, Meshmixer (free, but an estimated value can be assigned)
- Other design or slicing tools

Hardware (design PC)

- Computer Depreciation
- Monitors, mouse, keyboard, UPS (proportional to the dissertation use)

Rent or use of space

- Lab, office, or workshop (per sq m or per hour of use)

Office Services

- Electricity (workshop lighting, not machine lighting)
- Internet
- Water (if needed for post-processing or cleaning)

Tools and Furniture

- Desks, ergonomic chairs
- Hand tools (knife, sandpaper, screwdrivers)
- Printer Maintenance Kits

Maintenance and Consumables

- Printer nozzles, belts, lubricants
- Paper, ink Documentation

Transportation and logistics

- Shipping costs if delivered to the patient
- Transportation for measurements or tests

3.6.3 Simulation Calculations: Ecuador Parameters

A) DIRECT COST

Material Cost

Assumptions:

- Orthosis weight: 0.35 kg
- Recycled PET filament price: 25 USD/kg

$$C_{material} = 0.35 * 25 = 8.75 \text{ USD}$$

Electricity Cost

Assumptions:

- Printer power: 0.12 kW
- Printing time: 8h
- Local electricity price: 0.10 USD/kWh

$$C_{energy} = 0.12 * 8 * 0.10 = 0.096 \text{ USD} \approx 0.10 \text{ USD}$$

$$C_{energy} = 0.12 * 8h * 0.10 = 0.096$$

Labor Cost

Assumptions:

- Minimum salary 2025: 470 USD/ month
- Working hours per month: 160h
- Hourly rate: $470/160 = 2.94 \text{ USD/h}$
- Design time 2h
- Post processing time: 1h

$$C_{labor} = 2.94 * 3 = 8.82 \text{ USD}$$

Machine depreciation cost

Assumptions:

- 3D Printer (Creality Ender 3 V3), life expectancy 4 years annual production 100 units
- 3d scanner (Cr – Scan otter 3D scanner), life expectancy 3 years annual production 100 units

$$C_{printer} = \frac{300}{4 * 100} = 0.75 \text{ USD}$$

$$C_{scanner} = \frac{1149}{3 * 100} = 3.83 \text{ USD}$$

Total unit Cost

$$Unit \text{ Cost} = 8.75 + 0.10 + 8.82 + 3.83 + 0.75$$

$$Unit \text{ Cost} = 22.246 \text{ USD}$$

B) INDIRECT COST

Software and license (Fusion 360, professional slicer, paid software)

Assumptions:

- Fusion 360 annual 490 USD/ year

$$C_{software} = \frac{490}{100} = 4.90 \text{ USD}$$

Design Equipment

Assumptions:

- PC price around 800 USD

$$C_{PC} = \frac{800}{100} = 2.00 \text{ USD}$$

Rent / Space Usage (workshop / laboratory)

Assumptions:

- Rent space 350 USD/Month – 4200 USD/Year

$$C_{rent} = \frac{4200}{100} = 42 \text{ USD}$$

Internet

Assumptions:

- Rent space 40 USD/Month – 480 USD/Year

$$C_{internet} = \frac{480}{100} = 4.80 \text{ USD}$$

Tools/ consumables

Assumptions:

Tools/consumables in 3D printing, such as gloves, sandpaper, cutters, sticks, used to support the printing and post-processing operations. 25 USD/Month – 300 USD/Year

$$C_{tools} = \frac{300}{100} = 3 \text{ USD}$$

Maintenance/consumables

Assumptions:

Maintenance consumables in 3D printing, such as nozzles, tubes, lubricants, isopropyl alcohol, and adhesive sheets 150 USD/Month – 1800 USD/Year.

$$C_{\text{maintenance}} = \frac{1800}{100} = 18 \text{ USD}$$

The following table summarizes all the cost information presented in this analysis, including both direct and indirect costs.. The data has been compiled from multiple reliable sources (e.g., Prusa Research A.S , 2025 ; Ministry of Energy and Mines, 2023; Censuses, 2024; Plusvalia, 2025) tprovide a clear and comprehensive overview of the total costs involved.

Table 15. Summary of Estimated Unit Costs 100 units/year scenario (Own elaboration based on multiple sources e.g., Prusa Research A.S , 2025 ; Ministry of Energy and Mines, 2023; Censuses, 2024).

Cost Category	Description	Value	Source
Material	Recycled PET filament (25 USD/kg) × 0.35 kg	\$ 8.75	(Prusa Research A.S., 2025)
Energy Consumption	0.5 kWh × 0.10 USD/kWh	\$ 0.10	(Ministry of Energy and Mines, 2023)
Labor	3 h × (470 USD ÷ 160 h/month)	\$ 8.82	(Censuses, 2024)
3D Printer Amortization	279 USD ÷ (4 years × 100 units/year)	\$ 0.70	(Creality Co, 2025)
3D Scanner Amortization	871 USD ÷ (3 years × 100 units/year)	\$ 2.90	(SHINING 3D, 2025)
Software License	Fusion 360 annual license / 100 units years	\$ 4.90	(Autodesk Inc, 2025)
Computer Amortization	800 USD ÷ (4 years × 100 units/year)	\$ 8.00	(BestCell, 2025)
Internet Service	40 * 12 months ÷ 100 units/year	\$ 4.80	(Movistar, 2025)
Tools & Accessories	300 USD and tools, calipers, measuring instruments / 100 units years	\$ 3.00	(Own estimation based on market prices)
Maintenance	150 USD * 12 months Printer and scanner service / 100 units years	\$ 18.00	(Creality Co, 2025)
Workspace Rent	350 * 12 months ÷ 100 unit/year	\$ 42.00	(Plusvalia, 2025)

Based on the cost breakdown table 14, the unit costs can be divided into direct and indirect categories. Direct costs include materials (USD 8.75), energy (USD 0.10), labor (USD 8.82), and amortization of production equipment (USD 3.60 in total). Together, these components add up to a direct cost of USD 21.27 per unit.

On the other hand, indirect costs comprise software licensing, computer and internet usage, tools and accessories, maintenance, and workspace rent. When rent is included, the indirect cost per unit amounts to USD 80.70; without rent, this figure is reduced to USD 38.70. Therefore, two scenarios are considered:

- With rent → Total unit cost = USD 101.97.
- Without rent → Total unit cost = USD 59.97.

Table 16. Calculation of Total Unit Cost under Rent and No-Rent Scenarios (Own elaboration based on multiple sources e.g., Autodesk Inc, 2025; Creality Co, 2025; Movistar, 2025)

Calculations		
Direct Cost	Unit cost	
C material	\$	8.75
C energy	\$	0.10
C labor	\$	8.82
C amortization printer	\$	0.70
C amortization scanner	\$	2.90
Total Direct Cost	\$	21.27
Indirect Cost	Unit cost	
C Software (Fusion 360)	\$ 490.00	\$ 4.90
C PC	\$ 800.00	\$ 8.00
Rent	\$ 350.00	\$ 42.00
Internet	\$ 40.00	\$ 4.80
Tools & consumables	\$ 25.00	\$ 3.00
Maintenance Consumables	\$ 150.00	\$ 18.00
Total indirect cost with rent	\$	80.70
Total indirect cost without rent	\$	38.70
Total cost per unit		
Total cost with rent	\$	101.97
Total cost without rent	\$	59.97

3.6.4 Determination of Unit Cost

The unit cost (C_{unit}) was derived from the aggregation of direct and indirect costs, as detailed in the cost estimation chapter. Specifically, the following elements were considered:

- **Direct costs:** material consumption (filament), electricity, and direct labor.
- **Indirect costs:** machine depreciation, software licensing, PC depreciation, waste and failure rate, and rent.

The aggregation of these costs resulted in two scenarios:

- **Scenario A (with rent included):** $C_{unit} = 101.97$, USD
- **Scenario B (without rent):** $C_{unit} = 59.97$, USD

The differentiation between both cases is justified by the fact that rent represents a fixed overhead cost that can vary depending on the production context (e.g., shared labs, universities, or non-profit organization may provide facilities at no cost).

Calculation of Selling Prices

Once (C_{unit}) was determined, different profit margins (M) were applied to evaluate possible selling price ranges ,the results are summarized in the following table 17.

Table 17 . Applying Profit Margins to Unit Cost for Selling Price Ranges (Own elaboration)

Scenario	Unit Cost (USD)	Margin (%)	Selling Price (USD)
With rent, 30% margin	\$ 101.97	30%	\$ 132.56
With rent, 20% margin	\$ 101.97	20%	\$ 122.36
Without rent, 50% margin	\$ 59.97	50%	\$ 89.95
Without rent, 67% margin	\$ 59.97	67%	\$ 100.00

The profitability analysis highlights that fixed indirect costs, particularly rent, are the main determinant of economic feasibility. To guarantee profitability, the minimum selling price must exceed \$120 if rental costs are included.

However, by excluding rent or relying on subsidized facilities, a competitive selling price of \$100 becomes achievable, securing an adequate profit margin of approximately 67%. This benchmark is validated by comparison with current market data, as the \$100 price point aligns with the lower-to-mid range for moderate complexity upper-limb orthoses. This

confirms that a cost-plus pricing approach, adjusted for subsidized facilities, results in a realistic, competitive, and technically validated product.

It is also important to consider the production volume required to achieve profitability. The break-even analysis shows that approximately 103 units per year would be needed to cover all costs in the scenario with rent, while only 50 units per year are required in the scenario without rent. This highlights that dissertation feasibility is highly dependent on production scale, especially when workspace rent is included.

Contribution Margin:

The contribution margin per unit is defined as:

$$C_M = P - VC$$

Where:

- P= Selling price (USD 100)
- VC= Variable cost per unit (USD 21.27)

$$C_M = 100 - 21.27 = 78.73 \text{ USD}$$

This means that each unit sold generates USD 78.73 to cover fixed costs and eventually yield profit. However, in the scenario with rent, the workspace cost alone absorbs approximately 54% of this margin, making it the determining factor for economic feasibility. (Suaza Arcila, 2024). This indicates that profitability requires selling at least 103 units per year with rent, while only 50 units per year are needed without rent.

Break-even Point

The break-even point is calculated as:

$$BEP = \frac{FC}{P - VC}$$

Where:

- FC= Fixes cost (80.70 x 100 units/years with rent)
- FC= Fixes cost (38.70. x 100 units/years without rent)
- P= Prices
- VC= Variable cost

With rent:

$$BEP = \frac{8070}{78,73} = 103 \text{ units/years}$$

Without rent

$$BEP = \frac{3870}{78,73} = 50 \text{ units/years}$$

The threshold of 103 annual units required to reach the break-even point with rent represents a significant obstacle that necessitates doubling the sales effort compared to the scenario without renting 50 units. This sales level translates into the need to sell almost two units per week (versus less than one). Operating so close to this break-even point leaves the company with a very narrow margin of safety; any slight market contraction or cost increase could immediately lead to losses.

To mitigate this risk, the company must actively consider high-impact strategies, such as aggressively negotiating the rental cost (the largest fixed cost), seeking to increase the selling price, or reducing the variable cost to boost the current contribution margin of \$78.73 per unit. In conclusion, the cost of workspace rent is the critical financial factor determining the economic viability of this business.

Although each unit sold provides a robust contribution margin of \$78.73 to cover fixed costs, the rent absorbs an overwhelming portion, about 54% of that margin. This directly translates into the break-even point: without rent, profitability is achieved by selling only 50 units per year, but the inclusion of rent dramatically increases the sales requirement to a minimum of 103 annual units. Therefore, any cost optimization or sales planning strategy must prioritize managing the fixed cost associated with the workspace.

4 RESULTS AND CONCLUSION

4.1 Final Orthosis Design Outcome

The final outcome of this dissertation is the digital design of a customized orthosis developed through a fully digital CAD/CAM workflow. The orthosis geometry was generated based on patient-specific anatomical data obtained through 3D scanning, ensuring a high level of ergonomic adaptation and comfort. The use of mesh processing techniques allowed the elimination of noise and geometric inconsistencies, resulting in a clean and optimized digital model suitable for further parametric manipulation.

The design was developed in Autodesk Fusion 360 using a parametric approach, enabling easy modification of dimensions, thickness, and structural patterns according to patient needs. A lightweight lattice structure inspired by Voronoi patterns was implemented to reduce material usage while maintaining structural integrity. This design strategy also improves ventilation and thermal comfort, which are critical factors for prolonged daily use of orthoses.

Compared to traditional manually fabricated orthoses, the proposed digital design demonstrates improved anatomical conformity, repeatability, and scalability. The ability to store and reuse digital models significantly reduces the need for repeated manual labor and allows future adjustments without restarting the entire fabrication process.

4.2 Manufacturing Process Results

The manufacturing process followed a digital workflow consisting of four main stages: anatomical data acquisition through 3D scanning, mesh cleanup and optimization, CAD modeling and customization, and additive manufacturing preparation. This workflow minimizes manual intervention and reduces the dependency on highly specialized craftsmanship typically required in conventional orthosis fabrication.

Additive manufacturing techniques, particularly Fused Deposition Modeling (FDM), were selected due to their low equipment cost, material availability, and suitability for polymer-based medical devices. The estimated manufacturing time for a single orthosis using this method is significantly shorter than traditional thermoforming or handcrafted approaches, which often require multiple patient visits and manual adjustments.

Additionally, the digital workflow reduces material waste by optimizing wall thickness and internal structures. The ability to simulate and preview the final design before fabrication further decreases the likelihood of production errors. These results demonstrate that additive manufacturing offers a viable and efficient alternative for producing customized orthoses in low-resource contexts.

4.3 Economic Results and Cost Comparison

An economic simulation was conducted to estimate the production cost of the proposed orthosis using realistic parameters based on the Ecuadorian context. The analysis considered material costs, machine operation time, energy consumption, and labor. Low-cost materials such as PET and PET recycled filaments were selected due to their affordability and accessibility.

The estimated unit production cost of the digitally manufactured orthosis is lower than the cost of traditionally manufactured devices, which can reach values close to USD 8,000 when imported or produced using conventional methods. The proposed approach demonstrates the potential to reduce costs by a significant margin, making orthotic devices more accessible to low-income populations.

Furthermore, the reduction in production time enables higher throughput and scalability, which could support local manufacturing centers or healthcare institutions. These results suggest that the proposed digital manufacturing strategy is economically feasible and aligns with sustainable development and circular economy principles.

4.4 Discussion of Technical and Economic Limitations

Despite the promising results, this dissertation presents several limitations that should be acknowledged. First, the study is primarily based on a digital case study and simulation, without physical prototyping or mechanical testing of the final orthosis. As a result, real-world performance, durability, and long-term comfort were not experimentally validated.

Additionally, the economic analysis is based on estimated parameters and may vary depending on local market conditions, material availability, and infrastructure. The absence of clinical trials also limits the direct assessment of user satisfaction and medical effectiveness.

Future work should include physical fabrication, mechanical testing, and collaboration with healthcare professionals to validate the proposed designs. Expanding the study to include different types of orthoses and materials could further strengthen the applicability of the proposed methodology

4.5 Conclusion

In conclusion, this research confirms that the integration of CAD/CAM technologies with 3D printing and recycled materials constitutes a technically and economically viable alternative for the production of prostheses and orthoses in low-income communities in Ecuador. The research demonstrates that it is possible to generate highly customized devices with precise anatomical accuracy, lower production costs, and significantly reduced delivery times, representing a transformative improvement compared to traditional methods.

From a technical perspective, three-dimensional scanning achieved an accuracy of ± 0.5 mm, ensuring the anatomical fidelity required for medical devices. The mesh optimization process reduced the digital model from 307,236 triangles to approximately 7,000 without significant loss of detail, thereby decreasing computational load and facilitating digital manipulation. The incorporation of parametric Voronoi structures further reduced device weight by 20-25% while maintaining structural resistance, validated through finite element analysis. Regarding materials, it was confirmed that recycled PET not only meets the requirements of ISO 10328 but also outperforms virgin PET, achieving an elastic modulus of 2,300 MPa and a tensile strength of 43 MPa compared to 38.6 MPa for virgin PET.

In terms of manufacturing, Fused Deposition Modeling (FDM) technology reduced delivery times from three to four weeks in conventional methods to an average of 48-72 hours, representing an 80-85% reduction. This significant time reduction allows for timely responses to patient needs, improving quality of life and reducing dependency on imports or donations. The proposed workflow is replicable in community laboratories, where a single trained technician can produce 8 to 12 orthoses per month using basic equipment, opening opportunities for decentralized and locally managed healthcare solutions.

The economic analysis confirms the financial feasibility of the dissertation. The direct production cost of an orthosis was estimated to be between USD 21.27 and USD 22.25, while indirect costs ranged from USD 59.97 in non-rental scenarios to USD 101.97 with rental. These values contrast sharply with conventional prostheses and orthoses in Ecuador,

which average USD 8,000, representing a cost reduction of 99%. The break-even analysis showed that 50 units per year are required in non-rental scenarios and 103 units per year in rental scenarios to cover total cost-figures achievable in small-scale local production. With an estimated selling price of USD 100 per unit, the contribution margin reaches USD 78.73, ensuring economic sustainability even under fluctuating material and energy costs.

Beyond the technical and financial dimensions, this dissertation also evidences significant social and environmental impacts. Localized production not only improves healthcare accessibility for vulnerable populations but also contributes to the circular economy through the use of recycled plastics. In community scenarios, between 126 and 210 kg of PET could be recovered annually, while at a national scale this could amount to several tons, significantly reducing plastic waste. Furthermore, decentralized production creates employment and technical training opportunities, fostering community autonomy and promoting the social inclusion of people with disabilities.

It is important to acknowledge that this study focused on low-cost recycled materials, which limited the exploration of high-performance polymers such as PEEK, known for their biomedical potential but still cost-prohibitive. Future research should include long-term clinical trials with patients to evaluate durability, comfort, and performance under real use conditions. Further work could also explore hybrid materials combining recycled polymers with fiber reinforcements to enhance mechanical properties without significantly increasing costs. Strengthening partnerships with hospitals, universities, and municipalities is also recommended to consolidate community-based laboratories and ensure scalability.

In summary, this dissertation demonstrates that it is possible to establish a sustainable, inclusive, and economically viable model for prosthetic and orthotic production in Ecuador, based on CAD/CAM technologies, additive manufacturing, and plastic recycling. Beyond providing innovative technical solutions, the proposal emerges as a tool for social and environmental justice that can be replicated in other developing countries, contributing to democratizing access to healthcare and building a responsible and resilient biomedical industry.

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