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ALEXSANDRO GARGALIS NOGUEIRA

# MONO-PART CUSTOM FIT DESIGN CONCEPT OF WRIST SPLINT ORTHOSIS

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**ALEXSANDRO GARGALIS NOGUEIRA**

# MONO-PART CUSTOM FIT DESIGN CONCEPT OF WRIST SPLINT ORTHOSIS

Dissertation submitted to the Mechanical Engineering Graduate Program at Pontifical Catholic University of Paraná in fulfillment of the Master's Degree.

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DISSERTAÇÃO ELABORADA PARA OBTENÇÃO DE GRAU DE MESTRE NO CURSO DE MESTRADO EM ENGENHARIA MECÂNICA, PROGRAMA DE PÓS-GRADUAÇÃO EM ENGENHARIA MECÂNICA, DO CENTRO DE CIÊNCIAS EXATAS E DE TECNOLOGIA DA PONTÍFICA UNIVERSIDADE CATÓOLICA DO PARANÁ, PELA SEGUINTE EXAMINADORA:

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CURITIBA, 28 DE JUNHO DE 2019.

“Intelligence without ambition is a bird without wings”

(Salvador Dali)

To my wife Renata, my children Victor and Leticia,
and all the people that I do love, that are close
even being many miles away.

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ABSTRACT

Wrist Splint Orthosis (WSO) is a conservative medical device prescribed to treat patients with wrist diseases or injuries, being an Assistive Technology (AT) that both prevents or assists in the movement of the limb, and is available commercially in several different shapes, materials and costs. Some patients, however, require a very personalized WSO due to their disease or wrist shape. This demand for a both unique and personalized WSO presents the need for a design concept geared toward a specific patient's requirements. As with much of the human condition, necessity breeds invention and this product design is custom-made and custom-fit based on the most relevant requirements needed to enable and encourage patients to carry out everyday activities and improve their quality of life. This new WSO design is made possible through 3D technologies, such as 3D scanning system, Computer Aided Design (CAD), Finite Element Analysis (FEA) software and the freedom allowed by the Additive Manufacturing (AM) process resulting in a novel Mono-Part design, fulfilling functional, pleasant, comfortable, robust and safe WSO requirements.

**Keywords**: Wrist Splint Orthosis (WSO), Computer Aided Design (CAD), 3D Scanning.

# RESUMO

Órteses de punho são dispositivos médicos conservativos, normalmente prescritos para tratar pacientes com doenças ou lesões no punho, sendo uma tecnologia assistiva que previne ou mesmo auxilia no movimento dos membros e estão disponíveis comercialmente em muitas formas, materiais e custos diferenciados. Alguns pacientes no entanto exigem uma órtese de punho extremamente personalizada devido ao tipo de doença ou mesmo ao formato do punho. Essa demanda por uma órtese de punho personalizada, gerada pelos requerimentos do paciente, suportam a criação de um novo design específico que podem ser construídos através de sistemas computacional 3D e que suportado por um processo de manufatura aditiva permite a liberdade de geração de um modelo 3D de peça única no formato desejado. Esse processo deve ser auxiliado por um sistema de digitalização 3D, para geração da superfície base do punho e um software de elementos finitos que permita o apropriado cálculo estrutural da órtese. Esse processo então resulta em um design de órtese de punho funcional, agradável, confortável, robusto e seguro.

**Palavras chave**: Ortese de punho, design auxiliado por computador, escaneamento 3D.

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## *LIST OF ABBREVIATIONS*

| | | |
|---|---|---|
| 3D | - | Three-Dimensional |
| AFO | - | Ankle-Foot Orthosis |
| AM | - | Additive Manufacturing |
| AT | - | Assistive Technology |
| b | - | Beam width (mm) |
| BJ | - | Binder Jetting |
| CAD | - | Computer Aided Design |
| CDLP | - | Continuous Digital light processing |
| CT | - | Computed Tomography |
| CTS | - | Carpal Tunnel Syndrome |
| DLP | - | Digital Light Processing |
| DMLS | - | Direct Metal Laser Sintering |
| DOD | - | Drop On Demand |
| E | - | Flexural modules (MPa) |
| EBAN | - | Electron Beam Additive Manufacturing |
| EBM | - | Electron Beam Melting |
| FDM | - | Deposition Modelling |
| FEA | - | Finite Element Analysis |
| FFF | - | Fused Filament Fabrication |
| FO | - | Foot Orthosis |
| L | - | Beam length (mm) |
| LENS | - | Laser Engineering Net Shape |
| LMD | - | Laser Metal Deposition |
| LOM | - | Laminated Object Manufacturing |
| MJM | - | Material Jetting Modeling |
| MJF | - | Multi Jet Fusion |
| MRI | - | Magnetic Resonance Imaging |
| NPJ | - | Nano Particle Jetting |
| P | - | Push Force (N) |
| PB | - | Plaster-Based 3D Printing |
| PBIH | - | Powder Bed and Inkjet Head |
| PLM | - | Product Life Management |

| | | |
|---|---|---|
| Q | - | Deflection Magnification Factor (%) |
| SHS | - | Selective Heat Sintering |
| SLA | - | Stereolithography |
| SLM | - | Selective Laser Melting |
| SLS | - | Selective Laser Sintering |
| t | - | Beam thickness (mm) |
| UC | - | Ultrasonic Consolidation |
| UV | - | Ultraviolet |
| W | - | Mating force (N) |
| WSO | - | Wrist Splint Orthosis |
| Y | - | Deflection (mm) |
| Ymax | - | Maximal allowed deflection (%) |
| $\alpha$ | - | Lead angle (degrees) |
| $\epsilon$ | - | Maximal Strain (mm) |
| $\epsilon 0$ | - | Initial Strain (%) |
| $\mu$ | - | Coefficient friction (%) |

# SUMMARY

# 1. INTRODUCTION

A physical impairment can be defined as different motor conditions that affect people by compromising mobility, general motor coordination and speech as consequence of neurological, neuromuscular, orthopedic or congenital or acquired malformations (MEC, 2004).

As defined by the World Health Organization an impairment is a problem in body function or structure; an activity limitation is a difficulty encountered by an individual in executing a task or action; while a participation restriction is a problem experienced by an individual in involvement in life situations.

According to WHO (2018), disability is an umbrella term and is a complex phenomenon that impairs, interferes with or restrict the way that someone can live their life, reflecting the interaction between features of a person's body and the society in which he or she lives. The term disability encompasses not only impairments, but also is described as a problem in body function or structure. It is estimated that approximately 720 million people worldwide have at least one type of disability. Furthermore, estimates suggest that 92 percent of people with disabilities from intentional or unintentional damage live in low- or middle-income countries.

Y. Jin, J. Plott, R. Chen, J. Wensman, A. Shih (2016) estimated that 7.3 million people will need a medical devices in 2020. In general, individuals with disabilities suffer significant consequences because they are more likely to have poorer health and also to be underemployed or unemployed and be socially isolated. Therefore, interventions to remove social and environmental barriers are necessary to overcome the difficulties encountered by people with disabilities, aiming to improve their quality of life and social inclusion.

Among several disabilities and physical impairments, wrist disability is one of the most common deficiencies faced by people. According to Craig L. Taylor and Robert J. Schwarz (1955), the wrist and hand functions are result of a highly complex and versatile structural arrangement. A wrist disability can have a profound effect on a person's physical functioning, mobility, dexterity or stamina, activity limitations and participation restrictions.

Some studies (KIM EDWARD LeBLANC and WAYNE CESTIA (2011), and Lisa Newington, E Clare Harris, and Karen Walker-Bone (2015)) show that Carpal Tunnel Syndrome (CTS) is the most common entrapment neuropathy, with a prevalence close to 10% in the general adult population. Its mild form causes 'nuisance' symptoms including dysesthesia and nocturnal waking. However, at its most severe it can significantly impair motor function and weaken pinch grip. CTS is often associated with repetitive maneuvers, obesity, pregnancy, arthritis, hypothyroidism, diabetes mellitus, trauma, mass lesions, amyloidosis, sarcoidosis, multiple myeloma and leukemia. Some studies (KIM EDWARD LeBLANC and

WAYNE CESTIA (2011), and Lisa Newington, E Clare Harris, and Karen Walker-Bone (2015)) show that CTS is the most common entrapment neuropathy, with a prevalence close to 10% in the general adult population. Its mild form causes 'nuisance' symptoms including dysesthesia and nocturnal waking. However, at its most severe it can significantly impair motor function and weaken pinch grip.

The wrist, specifically is the part of the hand that is nearest the forearm and consists of the carpal bones and the associated soft tissues. The eight carpal bones are arranged in two rows. One row of carpal bones joins the long bones of the forearm (the radius, and, indirectly, the ulna). Another row of carpal bones meets the hand at the five metacarpal bones that make up the palm as shown in *Figure* 1.

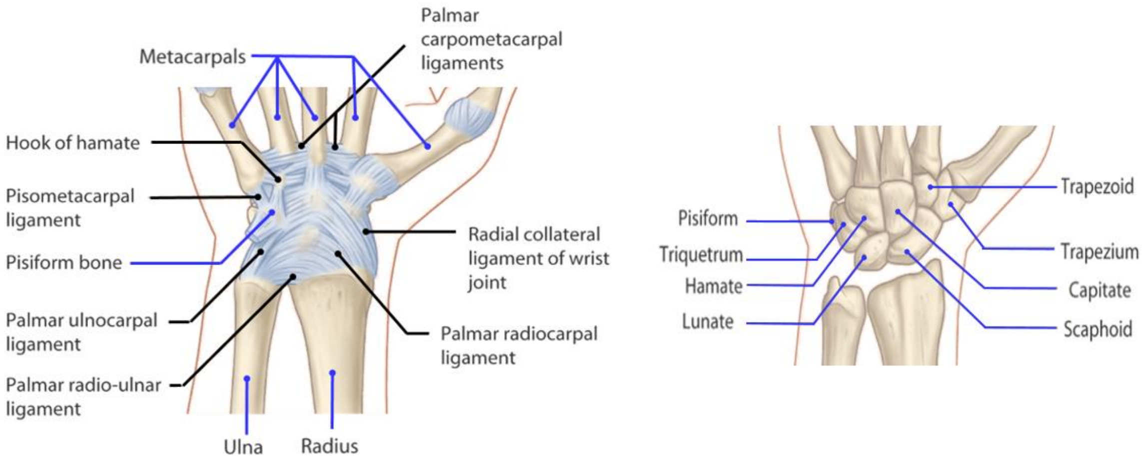


*Figure 1 - Wrist Joints (Source: Basicmedical Key, 2019)[*]*

Physicians have been treating people with wrist disabilities, like injured muscles, joints, carpal tunnel, sprains and strains, arthritis, and tendonitis, surgically or focused physiotherapy treatments usually culminating with the prescription for a very conventional Wrist Splint Orthosis (WSO).

Orthoses are external mechanical devices developed to protect healing body structures, maintaining or enhancing a joint's range of motion, substituting for or improve impaired function, or serve as the basis for attachment of self-help equipment (Elaine Ewing Fess, 1995). A custom designed, made and fit WSO would improve a person's functioning and would in essence elevate their overall well-being.

WSO are often recommended during rehabilitation to limit wrist movement and provide additional support. Often these devices are prescribed for night-use and or during inactive periods, but they have become commonly suitable in the workplace. Generally, WSO are applied to the dorsal portion of the hand supporting the wrist joint reducing the extensor muscle activity. This way, it is possible to diminish the need for muscular co-contraction to maintain posture (Jennifer Di Domizio et

[*] *Available in* <https://basicmedicalkey.com/wrist-and-hand-joints/> *Access in Ap. 22 2019.*

al., 2008). WSO fall under the umbrella of Assistive Technology (AT), AT's main purposes are to maintain or improve an individual's function and independence, to enhance overall well-being and also helping to prevent impairments and secondary health conditions that could develop if the injury/disease is ignored. These device types are developed for individuals that require treatment of problems related to injuries, diseases, birth defects or the aging process. In specific cases of hand wrist orthoses, their functions are widely diversified, offering specific support for medical and therapeutic needs, in an individualized way. However, it is highly recommended to consult a trained and experienced physician before choosing an orthosis for individual use.

According to Shingo Nobuta, Katsumi Sato, Tomowaki Nakagawa, Masahito Hator (2008) wrist splinting is most effective in cases of minimal or intermediate lesions. According to Lucia Ramsey, BSc (Hons), OT, Robert John Winder, PhD and Joseph G. McVeigh, PhD (2014) a WSO is a very effective first-line therapy and although there is little evidence concerning recommended splinting duration, effectiveness has been seen out to one year.

WSO have an immobilization function in order to keep the wrist in the correct natural position and to provide the hands the support they need while maintaining a full range of motion of the thumb and fingers. Fabric WSO (*Figure 2*) are the most common type of orthosis and can be found at any drugstore or supermarket in a reasonable price range.

*Figure 2 - Fabric WSO (Source: DJO ComfortFORM™, 2019)* [*]

Due to some patient disabilities or even their very particular wrist shape, a more personalized WSO is required *(Figure 3*). The most known and used process to build a personalized WSO is the manual

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[*] *Available in <https://www.djoglobal.com/products/procare/comfortform-boxers-splint> Access Ap. 21 2019*

formation process of a low-temperature thermoplastic plate in which a final product will vary according to the professional experience. It could also cause patient discomfort, if it doesn't allow for air circulation it is difficult to wear for a long time due to skin hygiene problems and itching due to sweating, and in extreme cases patient depression due to product appearance

*Figure 3 - Personalized WSO (Source: Rolyan Radial Bar Wrist Cock Up Splint, 2019)*[*]

Several research efforts have emphasized the need to identify a new manufacturing process capable of providing a more satisfactory WSO solution, the polymeric Additive Manufacturing (AM) process is currently occupying the lead position. AM is a manufacturing method characterized by fabrication without tools directly from a three-dimensional dataset. The AM technologies have the potential to overcome the traditional manufacturing methods providing freedom to explore complex geometries that are required for a custom made and custom fit product (*Figure 4*).


*Figure 4 - AM Wrist Orthoses*[*]

[*] Available in <https://www.healthandcare.co.uk/pre-cuts-pre-formed-splints/rolyan-radial-bar-wrist-cock-up-splint-pack-of-3.html> Access Ap. 21 2019

[*] *Available in < https://www.lboro.ac.uk/research/excellence/beacons/manufacturing/manufacturing-for-medicine/> , <https://www.fabbaloo.com/blog/2018/9/11/nasa-testing-antibacterial-3d-print-materials-but-should-you> , < https://www.xkelet.com/>  Access Ap. 21 2019*

The Selective Laser Sintering (SLS) is an AM method whereby a component is created by applying layers of a plastic material in powder form; it is one of the AM techniques that explicitly uses a laser as its power source to sinter powdered material. By aiming the laser automatically at points in space defined by a 3D model, binding material together to create a solid structure. There are several feedstock options available, but every AM machine manufacturer has a small variety of feedstock and once the precision of the process is developed it does not allow much variation. The Polyamide 12 (PA 12) is a material vastly used in the medical field

In order to design the WSO 3D model, several steps must be followed. Paterson, A., Bibb, R. J. and Campbell, R. I. (2010) described in their work the process to generate a wrist plaster from an alginate mold, the data acquisition through a 3D scanning procedure and the precise work involved in the modeling of a custom WSO.

## *1.1. Objective*

The following objectives were stablished to propose a custom-fit mono-part design for a Wrist Splint Orthosis:

### 1.1.1. WSO design elements

Identify WSO design elements, based on patient requirements and WSO functions defined by a physician, using a focus matrix process to prioritize the WSO development activities.

### 1.1.2. WSO Streamline technologies resources

Identify streamline technological resources to support the WSO development like manufacturing process, feedstock, data acquisition, 3D modeling and simulation software.

### 1.1.3. WSO Modeling and Validation Process

Effectively guide a designer with a step-by-step modeling path to properly accomplish and validate a WSO design,

## 2. LITERATURE REVIEW

A literature review was required to gather technological resources to fulfil the custom-fit mono-part design concept. Sources of contributing citations were diverse, and included books, journal papers, websites and government-led reports. A range of search engines were used to establish data, including Elsevier and commonly used internet based search engines such as Google. The PUC-PR library and the public libraries of Michigan were also fundamental during the research period.

In designing the WSO it was necessary to have an in-depth knowledge of the workings of the human wrist, there were both simple and complex explanations of how the hand works in the research of the Institute for Quality and Efficiency in Health Care (IQWIG, 2010). Furthermore, the anatomical and functional viewpoint as explained by Napier (1956) showed the movements of the hand in two basic patterns of movements which he termed precision grip and power grip. Using his research propelled a concern that the device while limiting movement as prescribed by a physician, must maintain a maximum range of motion. It was also necessary to understand the anatomical basis of hand mechanics, and the work of Taylor and Schwarz (1955) shows that normal hand function is the result of not only a highly complex and versatile structural arrangement.

The research then extended to what treatments and orthoses are already in use. Many authors such as Larisa (2017) have studied developed and designed biomechanical hand orthosis to extend the wrist and the fingers of the hand. Others such as Meals, Castro and Moss (2016) have analyzed WSO regarding material wall thickness, ridging effects, allowing to hone in on improvements that are still not explored in the field of treating diseases, injuries and disabilities of the wrist. Agarwal (2016) provided a way to learn about the essentials of prosthetics and orthotic in both old school and new technologies. The research of Lusardi, Jorge and Neilsen (2012) was relevant providing the requirements in clinically relevant rehabilitation.

Several research efforts have emphasized the need for custom foot orthosis (FO). A particularly significant group of studies was published by Menz (2009), meriting the prefabricated versus the customized FO. Caselli (2004), presents diverse types of custom made orthoses and different materials used in the treatment of foot pathology. The limitation of these studies is that the ankle is a more load bearing limb and the wrist is used in more task-oriented highly complex actions. While others like Dalgarno, Pallare, Woodburn, Xaio, Wood, Goodridge and Ohtsuki (2006) offered research that outlined the current state of the art medical devices and customization of implantable parts or systems, Domizio, Mogk and Keir showed that wrist bracing should be limited and put forth parameters that limit the WSO's that exist in the market today. When searching for a framework for designing compliant features the work of Fausitini, Crawford, Neptune, Rogers and Bosker (2005) was enlightening especially concerning transtibial sockets and manufacturing prototypes using SLS.

The research of Collier, Thomas (2002) and Fess (2002) was essential to understanding the total wrist range of motion permitted by four different styles of wrist extension orthoses and offered a window into the primary historical factors and events that shaped the evolution of current splinting technique and practice. Fess (1995) review selected basic mechanical principles that apply to splint endeavors and too contrasted mechanical theory with specific splinting techniques currently employed in clinical practice.

While all of the aforementioned authors, scientists and researchers were essential to this project, one in particular has researched the wrist, injuries, treatments and WSO development in a way more indispensable to this particular endeavor. The research of Abby Paterson involving the whole process of digital splint design and manufacture, from data acquisition through to data manipulation in Three-Dimensional (3D) Computer-Aided Design (CAD) to support AM was immeasurably useful to the task at hand; the simple difference being that the intent was to design a mono-part WSO including a closure that would not involve straps of a different material. Dr. Patterson's claims as proved in her 2014 study that difficulties keeping splints clean and dry, Induced perspiration, subsequently leading to odor issue, poor aesthetics, fasteners (e.g. Velcro straps) which may initially be difficult to fix, adjust, remove and replace. She also proved that Velcro straps (if used), for example, can also adhere to fabrics, subsequently causing damage to garments and upholstery. Also that poorly fitted splints can cause paresthesia and pressure points, limit function and compromise performance in performing everyday activities. Her research for example, proved grip capabilities may be restricted due to the shape of the splint impacting within the palmar grasp, as well as reduced sensory information in the palm. Finally difficulty putting on or removing splints due to fastener types or the shape of the splint. Her study provided a base problems that would be solved by the proposed single material custom made and fit WSO.

Many studies involve the making of orthoses through the manufacturing process that are not specific to the wrist, but have implication in the materials chosen, manufacturing technologies and engineering process' involved. One such study is that of N. Wierzbicka, F. Górski, R. Wichniarek, W. Kuczko (2017) it presented a design and a manufacturing process of an individualized ankle orthosis using additive manufacturing technologies and reverse engineering. While G. Baronio, P. Volonghi, and A. Signoroni (2017) provided insight to a device that was developed based on the hand immobilization requirements when acquiring the palmar hand side of mobility-limited patients to extend the wrist and the fingers of the hand by means of 3D scanners. A more in-depth review of the AM used in the manufacturing of custom orthosis was needed and was in Y. Jin J. Plott, R. Chen, J. Winsman and A. Shih (2015) report. Many methodologies that employ both 3D modelling and 3D printing for building orthoses one such report by M. A. de Souza, C. Schmitz, M. M. Pinhel, J. A. P. Setti and P. Nohama (2017) was very informative, another by G. Baronio, S. Harran, A. Signoroni (2016) described the design and testing of the essential steps for the entire production process of an orthosis.

Several researchers have addressed the AM process in the medical field; A. Paterson, R. Bibb, R Campbell, G. Bingham (2015) compared four different AM process to assess their suitability in the context of upper extremity splinting. Many of these studies worked throughout the process and procedures that did not making the design of this custom mono-part WSO clearly feasible. Even the studies that involved in foot orthosis were enlightening providing a design that could and would be produced. One such study involving custom foot orthoses by M. S. Jumani (2013) explored the commercial scale application of rapid manufacturing techniques and to assess a rapid manufacturing based design and fabrication system for production. Another study by Pallari, Dalgarno, Munguia, Muraru Peeraer, Telfer and Woodburn approached the design and manufacture of personalized foot and ankle-foot orthoses (FO and AFO) using additive fabrication technology.

The lack of studies about specific wrist WSO's made it even clearer the need for a custom orthosis for the wrist. In one report, foot orthoses were produced on a mass scale by M. S. Jumani, Z. A. Memon, and J. Larik (2013), making clear the feasibility of producing the WSO through AM. Even though it is a different extremity that may bear more weight, much of the engineering and design applies to the goal of designing a custom orthosis. In embracing additive manufacture: implications for foot and ankle orthosis design it was reported that the intended biomedical modes of action were indeed achieved. Telfer, Pallari, Munguia, Dalgarno and Woodburn (2012) and Gibson, Rosen and Stucker (2010) provided a conceptual overview of rapid prototyping and layered manufacturing showing the potential of AM applications. Further studies such as Designing for additive manufacturing by Vayre, B (2012) showcased a design methodology for metal AM.

Many types of materials were considered for this design the goal was to find a material that would provide biocompatibility, while offering excellent mechanical and thermal properties. Authors Petten and Avila (2010) analyzed several material's effects on hand function and supported the use of a polymer in the WSO. An industrial perspective of the use of composite materials was offered through Campbell (2010) giving insight into fiber polymer matrix composites narrowing the options of a feasible material. The polymer material finally chosen for this project was studied by Kimble (1992) who had identified materials currently being used in the SLS process and showed an inherent advantage to Polyamides. The study of Begum and Islam

(2013) would be useful if the WSO required more robustness using natural fiber reinforcement. The work of Paton, Jones, Stenhouse and Bruce (2007) offered material characteristics relevant to this project through their classification and comparison process.

The objective to design a custom-fit orthosis led to the need for very specialized data acquisition. One study by Cau (2017) studied ways to obtain reliable geometric measure of the arm, with good reliable methods to measure the circumferences and volumes of the arm paying attention to reliability and reproducibility of the results using laser scanning. The Department of Computer Science in Zurich and Stanford supported the study from Weyrich, T; Pauly, M.; Deiser, R.; Heinzle, S. Scandella S.; Gross, M (2004) that through the post-processing 3D Scanned Surface Data, developed software that is used for the cleaning of raw scan data, as in with ancient artifacts missing features. This can be used to solve issues in cases of scan data errors.

Finally through the research pertaining specifically to the wrist by Paterson, Bibb and Campbell (2010) a suitable wrist data acquisition process was identified, regards to accuracy, resolution, patient comfort and safety. Paterson (2013) explained the benefits of using a 3D CAD virtual environment to capture the therapists design intent. Her results concluded that the digitized data approach is feasible and beneficial when personalizing a WSO.

In order to attend the medical field demand Kurtz, Mulready, Murphy and Tao (2017) have designed and fabricated an affordable hand orthosis for persons with reduced grip strength, showing the need for custom-fit medical device. Bernier, Reinhardand and Luyt's study in 2015 explained in detail the 3D technologies helping to explain basic rules for design when scanning and creating, using AM. While researching articular orthosis mechanisms at the design stage Regufe, Duarte, Ramos, Nadeau, Perry, and Mesnard (2017) used an exhaustive method that obtained a design methodology concept in order to get a better user experience, culminating in an user-centered orthosis design. Li and Luis (2016) also provided information on how to collect data through CT-MRI in order to understand the best approach to collect data to develop the 3d model of the WSO.

Dassault System provide to users several tutorials to guide the 3D modeling and the structural analysis with its CATIA software. Drumm and Kelly (2015), Micallef (2015), Smyth (2015) and Bernier, Reinhardand and Luyt (2015) books were reseached to understand the necessary design elements and how to use them in a 3D modeling for additive manufacturing.

The books by Zienkiewicz (1971) and Strang and Fix (1973) were used to lay the foundations to understand the FEA software principles for mathematical calculation of the proposal simulations. Gianini (2003) and Cazon (2017) analyzed multi material wrist splint designs using FEA methods, the results were varied, but the research was useful in that from a technical point of view, once the AM has the same level of performance regarding displacements and stress values compared to the typical low-temperature thermoplastic approach.

# 3. METHODOLOGY AND DESIGN APPROACH

A crucial step for a product development and a robust design is its methodology definition. A design methodology is an all-encompassing approach which may include a set of philosophies, principles, processes and techniques.

The methodology to develop the WSO design concept will follow the INPUTS and OUTPUTS shown in *Figure* 5. The main advantage of stablishing a systematic methodology is to avoid late new ideas.

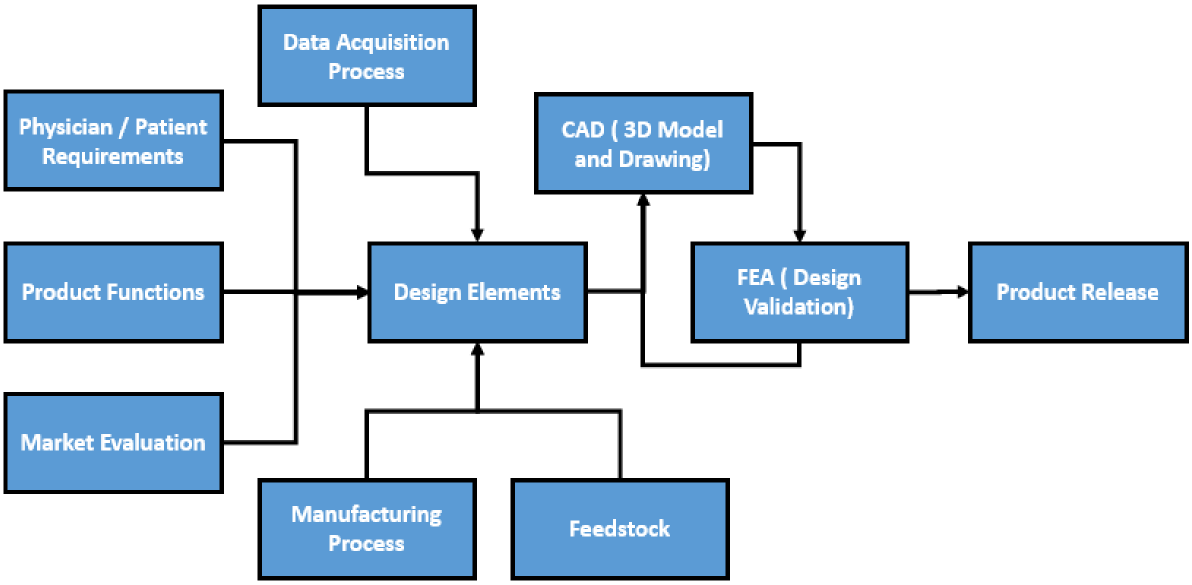



*Figure 5 - Methodology*

According to PAHL and BEITZ (2007), a conceptual design involve sensible phases such as:

- *Abstracting to find the essential problems* (requirements from patient necessary to release the physical impairment)
- *Establishing function structures* (WSO functions defined by Physicians)
- *Searching for working principles* (Feedstock, manufacturing process, basic data acquisition process, CAD and FEA software)
- Combining working principles into working structures (Definition of design elements)
- *Collecting a suitable working structure and firming it up into a principle solution* (WSO Design concept)

WSO **requirements** and **functions** are to be collected by patient and its physician that will analyze and understand the deficiency. **Feedstock** and the **manufacturing process** are inputs complementary to each other, once material is a manufacturing process premise. It is extremely difficult to design a WSO without a well-defined surface base, the 3D scanning process takes an important role to support the designer in order to **acquire the wrist data**. **Design** is how a concept or idea can be formalized into tangible information. According to Caldecote (1989), design is the process of converting an idea into information from which a product can be made. A powerful **CAD** software must provide to designers the appropriate tools required to **design** the WSO and an equal powerful **FEA** tool must provide to the simulation team the tools to properly **evaluate the design**.

According to Mital, et al. (2014), any product development strategy that is not based on market needs will lead to failure. The key to new product development is the information that indicates what people want, what features of the product are considered absolutely essential, what price they are willing to pay for it, what features are desirable but can be sacrificed for a lower price, current and potential competitors, and likely changes in the market size. Knowing what the market needs is essential in order to develop innovative new products; this knowledge is what leads to developing a successful business strategy.

Before combining the working principles into working structures it is required to fully understand the basic fundamentals of essential problems, functions structures and the working principles.

### 3.1. *Wrist and WSO Functions*

Function can be described as the way in which something works or operates. It is how an INPUT can be converted in an OUTPUT.

Concerning the wrist specifically, it is possible to determine three distinct movements: flexion and extension, supination and pronation, and ulnar and radial flexion, represented in Figure 6. Flexion refer to the movement of curving the palm down, in the direction of the wrist, while extension describes the motion of raising the back of the hand. Supination and pronation describes the movement of rotating the forearm into a palm up and down position and, at last, ulnar flexion refers to the movement of bending the wrist to the little finger side, while radial flexion is the movement of curving the wrist to the thumb side.

The WSO's functions are varied depending on the specifications needed by the patient. A few functions of the WSO are that it should help people with disabilities to rehabilitate, protect an affected area, and correct a deformity, properly balanced between stabilization and flexibility. According to Cazon, Aitor et al. (2017), the functions must describe the task and establish the overall geometry of the WSO. The main WSO function that will be considered in this work is stabilization, keeping the hand and wrist system in a specific position, while allowing for power and precision grip movement. According to J. R. Napier (1956), precision grip refers to the pinching of an object between the flexor aspects of the fingers and that of the opposing thumb. While power grip movement is when the object held is in a clamp between the flexed fingers and the palm counter pressure is applied by the thumb lying more or less in the plane of the palm.

According to E. E. Fess (2002), orthotic devices have different ways of achieving functionality requirements, enhancing function, preventing or correcting deformities, protecting healing body structures, restricting movements and allowing for tissue growth or remodeling.

According to Taylor, Hanna and Belcher (2003), the WSO functions must be framed in at least one of those categories: Immobilization, Protection, Mobilization, Prevention, symptom relief or rest. Even though Egan et al. (2001), says that there is no evidence to prove that WSO are effective regarding symptom relief.

The question being is there a WSO that can keep the neutral position of the wrist (in a specific alignment with the forearm), while allowing the best range of motion possible; protecting the wrist, while using the hand. According to the text above, the WSO function must then block all of the 6 wrist movements as shown in Figure 6, while allowing for the movement of all fingers, retaining power and precision grip functions as shown in Figure 7.

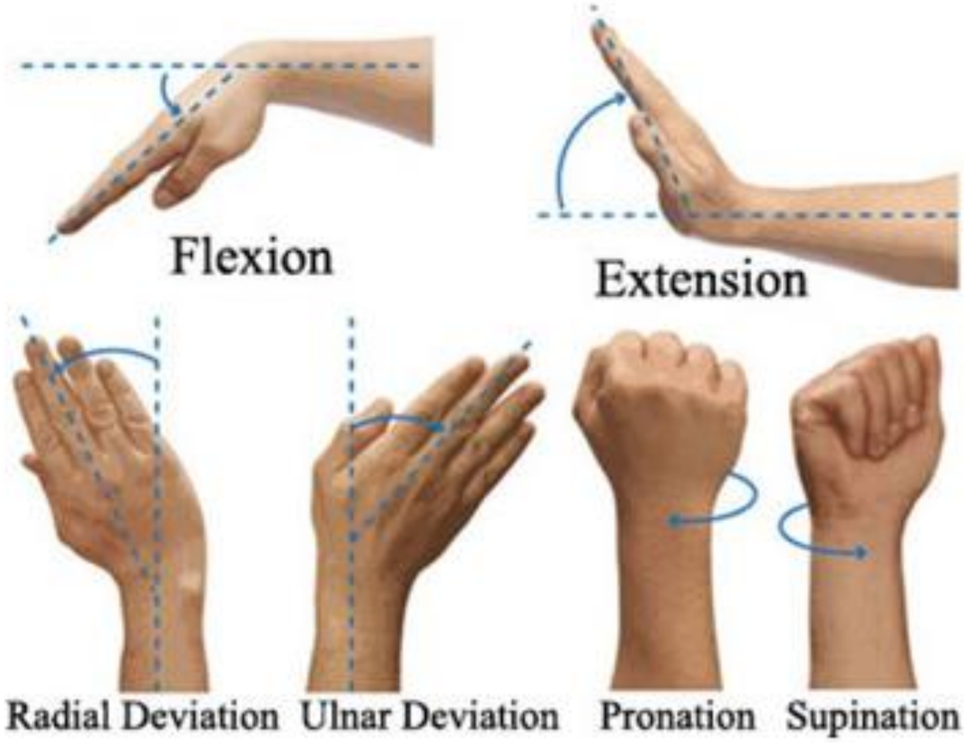



*Figure 6 - Wrist Movements (Source: Invictus Fitness, 2019)*[*]

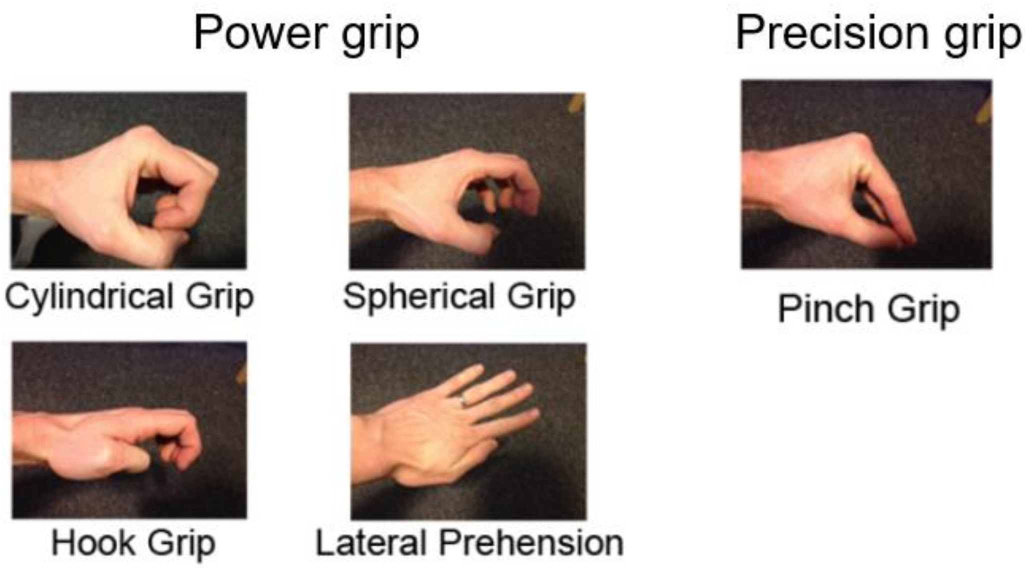



*Figure 7 - Power and Precision grip (Source: Leonard Van Gelder, 2019)* [**]

[*] Available in <https://www.crossfitinvictus.com/blog/simple-solutions-for-poor-wrist-mobility/> Access in Ap. 22 2019
[**] Available in <https://functionalanatomyofthehand.wordpress.com/2016/04/14/power-spherical-grip/> Access in Ap. 22 2019

## *3.2. Requirements*

The risk of project or a product to success and failure depends on the quality of the requirements captured. A requirement is a mandatory factor that must be applied or incorporated into a project, product or component to perform a function. A requirement must be clear (understand what are the customer needs), measureable, feasible, necessary, prioritized and concise. A requirement must defines the “what” and not the “How”. A requirement defines what deliverable is expected. Requirements can be gathered through interviews, brainstorm, observation, questioner, surveys and reverse engineering.

Orthotics splints need to have a practical functionality in patients who suffer from pain in the wrist achieving some basic requirements, such as being comfortable, durable, safe, practical, and easy to take on or off. They also should be aesthetically pleasing, and finally should have a good cost-benefit (Cazon, Aitor et al., 2017 and Connor Kurtz et al., 2017). One must also consider the physician’s perspective, which focuses on improving the well-being of the patient (Connor Kurtz et al., 2017).

It is vital to understand the mechanical principles applied to orthotic devices in order to properly design an orthosis. Designing a suitable orthotic device involves assessing how and where significant stresses occur and what can be done to eliminate or reduce such stresses. Utilizing mathematical formulas in conjunction with mechanical principles to identify where and how the largest loads will act on the orthosis. Thus, it is important to allow for the necessary motion, resistance to static and dynamic forces, have a minimum fatigue effect, to be resistant to environmental effects, as well as to have a pleasant appearance and be toxicologically compatible when the orthosis is in contact with the skin (Agarwal, A.K., 2013). Several factors are essential to fulfill these requirements. First it is crucial to properly evaluate the patient's needs, in order to achieve a truly usable design one must utilize knowledge of the mechanical principles to identify where the largest loads will act on the orthosis, possess knowledge in materials and manufacturing processes and also include the inspection and training for the use of these special devices. The *Table 1* shows a list of requirements that were defined to develop and limit the WSO design.

*Table 1 - Requirement Table*

| Nr. | Requirement | Category | Unit | Weight |
|---|---|---|---|---|
| 1 | Single component product | Practical | 1 unit | W |
| 2 | Short time to market | Practical | 1 day | W |
| 3 | Easy to assemble and disassemble (no tools) | Practical | <10seconds | W |
| 4 | Customized and appealing shape | Pleasent | - | W |
| 5 | Fits to all people size (age) | Comfortable | from 75 to 400mm length | W |
| 6 | Adjustable | Practical | 10 mm | W |
| 7 | Light | Comfortable | <200grams | S |
| 8 | Non Toxic | Safe | Compatible with skin | B |
| 9 | Hazard free | Safe | No sharp edges | B |
| 10 | Aeration | Comfortable | Minimum contact with skin | S |
| 11 | Treatment lifetime durable | Durable | 1 year | S |
| 12 | Temperature resistant | Durable | -40degC to 40degC | S |
| 13 | Waterproof | Durable | No loss of functionality during lifetime | S |
| 14 | Weather resistant | Durable | No loss of functionality during lifetime | S |
| 15 | Water proof | Durable | IPX-4 | S |
| 16 | Electrical isolate | Durable | No loss of functionality during lifetime | S |

**Requirement table weight legend:**

- B => Basic (Must be)
- S => Standard (Needed)
- W => Wish (Advanced)

### *3.3. Feedstock*

Feedstock must be suited to the application in order to have successful results, however, material properties can only be evaluated when the manufacturing process is considered. Materials are often classified into the six broad classes: metals, ceramics, glasses, elastomers, polymers and composite (*Figure 8*). Below are some of the materials studied and applied into vary orthosis types.

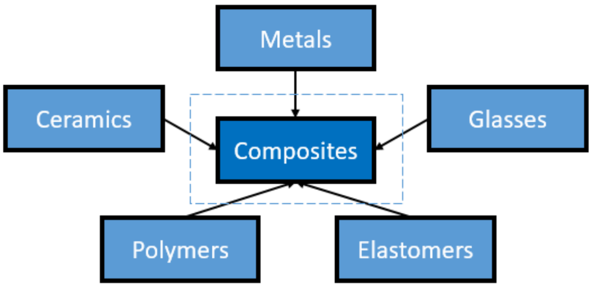



*Figure 8- Raw materials examples*

In orthotic rehabilitation the research of new and better materials is constant and essential to proper material selection. According to specialists, the selection of an appropriate material to develop the WSO should not be disregarded. Furthermore, the essential characteristics of the materials used in the development of these devices are density, resilience, stiffness, coefficient of friction, durability and compressive strength (Paton, Joanne et al., 2007). Per Mark A Caselli, 2004, there is a wide variety of materials available on the market; the most common of them are classified into the following groups: metals, leather, rubber, fabrics, polymers and composites. Metals can be used for joint components, the most popular being stainless steel and aluminum alloys, but they are not cosmetically pleasing and are heavy.

Despite the extensive use of the materials cited above, there are still some limitations present including low tensile and flexural strength, low elastic modulus and low fatigue strength. In addition, these materials are susceptible to time-dependent problems, such as creep, which may affect their ability to correct structural deficiencies.

The introduction of high and low-temperature thermoplastics provides a significant advantage to the orthotic industry, mainly due to the combining of substances with distinct properties. In particular, polymer matrices reinforced with long or short fibers can improve the mechanical properties of orthotics and prostheses, including the strength-to-weight ratio, flexural strength, elastic modulus, fatigue and creep resistance (Lusardi, Michelle M. et al., 2012). More recently, composite materials are being introduced as a substitute for polymers; these composites can be described as the "combination of two or more materials that results in better properties than those of the individual components used alone" (F.C. Campbell, 2010). This substitution occurs because these materials can increase the mechanical strength and reduce the weight of the device. Reinforcements applied in the orthotic industry include glass fibers, aramid fibers and carbon fibers. These reinforcements consist of synthetic fibers, which have high mechanical properties and are used extensively in the aerospace, automotive and sports industries (K. Begum; M. Islam, 2013). The materials mentioned above have a high cost of production and are ecologically problematic (ISPO, 1996). Besides, many of them are not readily available in developing countries, where most people with disabilities live.

Successful additive manufacturing depends on selecting the right material for the process, plastic resins and compounds must conform not only to the process but also to the design and end-use application. AM requires specialized resins and compounds tailored to provide the desired properties.

Additive manufacturing materials usually come in filament, powder or resin form. Polymers and metals are the two main additive manufacturing material groups, while other materials, such as ceramics or composites, are also available. Polymers can be broken down further into thermoplastics and thermosets.

Thermoplastics are best suited for functional applications, including manufacturing of end-use parts and functional prototypes. They have good mechanical properties and high impact, abrasion and chemical resistance. They can also be filled with carbon, glass or other additives to enhance their physical properties. Additive Manufacturing engineering thermoplastics (such as PA, PEI and ASA) are widely used to produce end-use parts for industrial applications.

Thermosets (resins) are better suited for applications where aesthetics are important, as they can produce parts with smooth injection-like surfaces and fine details. Generally, they have high stiffness but are more brittle than thermoplastics, so they are not suitable for functional applications.

Specialty resins are available, that are designed for engineering applications (mimicking the properties of ABS and PP) or dental inserts and implants.

If the required material is already known, selecting a 3D printing process is relatively easy, as only a few technologies produce parts from the same materials. In those cases, the selection process usually becomes a cost versus properties comparison as we can see in Figure 9.

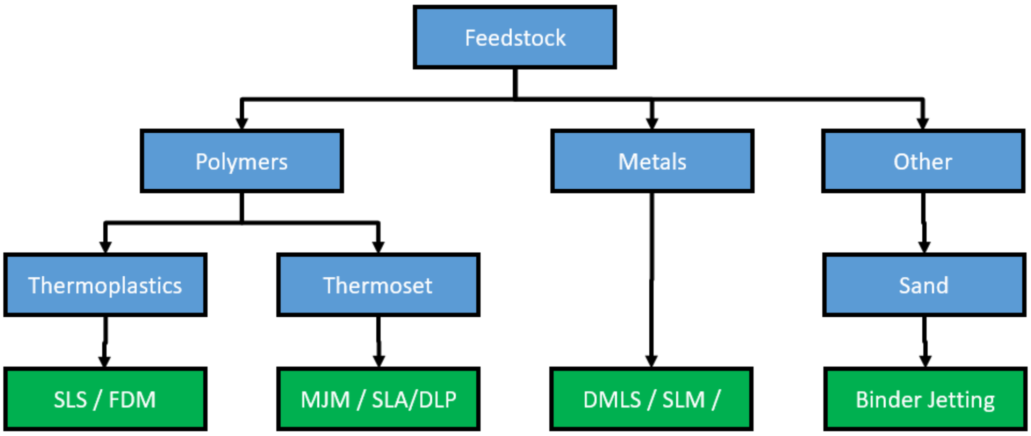



*Figure 9 - Feedstock selection according to Manufacturing Process*

The *Table 2* shows a material selection based on materials that can be considered in the WSO design, its attributes and the possible manufacturing process. The data was developed by the company Protolabs but the color evaluation was done to fulfill the WSO requirements in which the green materials (ABS-Like, PA (Polyamide) and PC-like) could be considered in this studied.

*Table 2 - Material analysis**

| Material | Material Category | Attributes | Manufacturing Process |
|---|---|---|---|
| ABS | Plastic | Cosmetic appearance<br>Dimensional stability<br>Impact resistance | Injection Molding<br>CNC Machining |
| ABS-Like | Plastic | Accuracy<br>Durability<br>Impact resistance | 3D Printing |
| ABS/PC | Plastic | Cosmetic appearance<br>Dimensional stability<br>Impact resistance | Injection Molding |
| Aluminum | Metal | Corrosion resistance<br>High strength-to-weight ratio<br>Temperature resistance | Sheet Metal Fabrication<br>CNC Machining<br>3D Printing |
| Brass | Metal | Chemical resistance<br>Ductility<br>Strength | Sheet Metal Fabrication<br>CNC Machining |
| Cobalt Chrome | Metal | Biocompatibility<br>Corrosion resistance<br>High strength-to-weight ratio | 3D Printing |
| Copper | Metal | Corrosion resistance<br>Electrical conductivity<br>Thermal conductivity | Sheet Metal Fabrication<br>CNC Machining |
| CPVC | Plastic | Flame resistance | CNC Machining |
| Digital Photopolymer | Elastomer / Silicone Rubber | Durability<br>Flexibility<br>Optical clarity | 3D Printing |

* *Available in < https://www.protolabs.com/materials/select-a-material/> Access in Jun. 9 2019.*

| | | | |
|---|---|---|---|
| ETPU | Plastic | Crack resistance<br>Durability<br>Impact resistance | Injection Molding |
| HDPE | Plastic | Durability<br>Impact resistance<br>Stiffness | Injection Molding<br>CNC Machining |
| Inconel | Metal | Strength<br>Temperature resistance<br>Corrosion resistance | 3D Printing |
| LCP | Plastic | Strength<br>Temperature resistance | Injection Molding |
| LDPE | Plastic | Crack resistance<br>Flexibility<br>Impact resistance | Injection Molding<br>CNC Machining |
| LLDPE | Plastic | Flexibility | Injection Molding |
| Low Carbon Steel | Metal | Ductile<br><br>Malleable | Sheet Metal Fabrication<br>CNC Machining |
| LSR | Elastomer /<br>Silicone Rubber | Cosmetic appearance<br>Durability<br>Flexibility<br>Temperature resistance | Injection Molding |
| LSR (Fluorosilicone) | Elastomer /<br>Silcone Rubber | Fuel and oil resistance<br>Suitable for fluids<br>Temperature resistance | Injection Molding |
| LSR (Medical) | Elastomer /<br>Silicone Rubber | Biocompatibility<br>Temperature resistance | Injection Molding |
| LSR (Optical) | Elastomer /<br>Silicone Rubber | Temperature resistance<br>Optical clarity | Injection Molding |
| PA | Plastic | Rigidity<br>Strength<br>Temperature resistance | Injection Molding<br>CNC Machining<br>3D Printing |
| PBT | Plastic | Chemical resistance<br>Dimensional stability<br>Low moisture absorption | Injection Molding |
| Polycarbonate (PC) | Plastic | Dimensional stability<br>Impact resistance | Injection Molding<br>CNC Machining |
| PC-Like | Plastic | Accuracy<br>Stiffness<br>Temperature resistance | 3D Printing |
| PC/PBT | Plastic | Impact resistance | Injection Molding |
| PEEK | Plastic | Chemical resistance<br>Sterilizability<br>Stiffness<br>Strength | Injection Molding<br>CNC Machining |
| PEI (Ultem) | Plastic | Heat resistance<br>Impact resistance<br>Strength | Injection Molding<br>CNC Machining |
| PET | Plastic | Chemical resistance<br>Stiffness<br>Strength | Injection Molding<br>CNC Machining |
| PETG | Plastic | Durability<br>Optical clarity | Injection Molding |
| PMMA (Acrylic) | Plastic | Optical clarity<br>Rigidity | Injection Molding<br>CNC Machining |
| POM (Acetal/Delrin) | Plastic | Chemical resistance | Injection Molding<br>CNC Machining |

| | | | |
|---|---|---|---|
| PP | Plastic | Chemical resistance<br>Solvent resistance | Injection Molding<br>CNC Machining |
| PPE/PS | Plastic | Dimensional stability<br>Low moisture absorption<br>Suitable for fluids | Injection Molding<br>CNC Machining |
| PP-Like | Plastic | Accuracy<br>Durability<br>Flexibility | 3D Printing |
| PPS | Plastic | Chemical resistance<br>Temperature resistance | Injection Molding |
| PPSU | Plastic | Chemical resistance<br>Flame resistance<br>Impact resistance | Injection Molding<br>CNC Machining |
| PS | Plastic | Impact resistance<br>Stiffness | Injection Molding<br>CNC Machining |
| PSU | Plastic | Corrosion<br>Mineral Resistance<br>Sterilizability<br>Strength | Injection Molding<br>CNC Machining |
| PTFE (Teflon) | Plastic | Chemical resistance<br>Flame resistance<br>Temperature resistance | CNC Machining |
| PVC | Plastic | Chemical resistance<br>Corrosion resistance<br>Flame resistance | CNC Machining |
| SB | Plastic | Stiffness<br>Transparency<br>Warp resistance | Injection Molding |
| Steel Alloy | Metal | Durability<br>Strength | CNC Machining |
| Titanium | Metal | Corrosion resistance<br>Strength<br>Temperature resistance<br>Weight reduction | CNC Machining<br>3D Printing |
| TPE/TPV | Plastic | Flexibility | Injection Molding |
| TPU | Plastic | Abrasion resistance<br>Flexibility<br>Impact resistance | Injection Molding<br>3D Printing |
| UHMW | Plastic | Durability<br>Flexibility | CNC Machining |

The most common material for SLS is polyamide, a popular engineering thermoplastic with excellent mechanical properties. Polyamide is lightweight, durable and flexible; as well as stable against impact, chemicals, heat, Ultraviolet (UV) light, water, and dirt. Polyamides such as PA11 and PA12 are used in SLS AM process because they offer a good ‘sintering window’ which is calculated as the difference between the melting onset temperature and the crystallization onset temperature of a polymer. This is in contrast to the amorphous resins, used for fused deposition modeling, because they have uniform shrinkage and good consolidation, but they soften gradually leading to incomplete layer consolidation and parts with lower density, dimensional inconsistencies and sub-optimal physical properties.

The Polyamide, PA12 (*Figure 10*) sinter polymer was used to create the prototypes of this WSO design; it is a versatile material with excellent mechanical and thermal properties. PA12 has anisotropic mechanical properties, offers an excellent combination of strength and temperature resistance, a good surface finish and feature resolution, also offers high stiffness properties for load bearing applications as shown in *Table 3*.

Being a solid material, polyamide powder has the attractive feature of being self-supporting for the generated product sections thus making a support structure unnecessary. Polyamide allows the production of fully functional prototypes or end-use parts with high mechanical and thermal resistance. Polyamide parts have excellent long-term stability and are resistant against most chemicals. They can be made watertight by impregnation. The PA material is a biocompatible and food-safe under certain conditions.

*Figure 10 - PA12 powder (Source: EOS, 2019)*[*]

Table 3 - EOS Material Data Sheet Table, 2019[**]

| **Mechanical properties** | **Value** | **Unit** | **Test Standard** |
|---|---|---|---|
| Flexural Modulus, 23°C | 1500 | MPa | ISO 178 |
| Flexural Strength | 58 | MPa | ISO 178 |
| Izod Impact notched, 23°C | 4.4 | kJ/m² | ISO 180/1A |
| Izod Impact unnotched, 23°C | 2.8 | kJ/m² | ISO 180/1U |
| Shore D hardness (15s) | 75 | - | ISO 868 |
| Ball indentation hardness | 78 | MPa | ISO 2039-1 |
| **3D Data** | **Value** | **Unit** | **Test Standard** |
| Tensile Modulus (X Direction) | 1700 | MPa | ISO 527-1/-2 |
| Tensile Modulus (Y Direction) | 1700 | MPa | ISO 527-1/-2 |
| Tensile Modulus (Z Direction) | 650 | MPa | ISO 527-1/-2 |

[*] Available in <https://www.eos.info/werkstoffe-p> Access in May 2019
[**] *Available in < https://www.3dpromagic.com/datasheet/Datasheet_PA2200.pdf> Access in Ap. 29 2019*

| | | | |
|---|---|---|---|
| Tensile Strength (X Direction) | 48 | MPa | ISO 527-1/-2 |
| Tensile Strength (Y Direction) | 48 | MPa | ISO 527-1/-2 |
| Tensile Strength (Z Direction) | 47 | MPa | ISO 527-1/-2 |
| Strain at Break (X Direction) | 24 % | | ISO 527-1/-2 |
| Charpy impact strength (+23°C, X Direction) | 53 | kJ/m² | ISO 179/1eU |
| Charpy notched impact strength (+23°C, X Direction) | 4.8 | kJ/m² | ISO 179/1eA |
| Thermal Conductivity (X Direction) | 0.144 | W/(m K) | DIN 52616 |
| Thermal Conductivity (Y Direction) | 0.144 | W/(m K) | DIN 52616 |
| Thermal Conductivity (Z Direction) | 0.127 | W/(m K) | DIN 52616 |
| **Thermal properties** | **Value** | **Unit** | **Test Standard** |
| Melting temperature (10°C/min) | 176 | °C | ISO 11357-1/-3 |
| Vicat softening temperature A | 181 | °C | ISO 306 |
| Vicat softening temperature (50°C/h 50N) | 163 | °C | ISO 306 |
| Other properties | Value | Unit | Test Standard |
| Density (laser sintered) | 930 | g/cm³ | EOS Method |

**Characteristic**

| **Processing** |
|---|
| Laser Sintering |
| **Delivery form** |
| White |

| **Chemical Resistance** |
|---|
| General Chemical Resistance |
| **Ecological valuation** |
| US Pharmacopeia Class VI Approved |

## 3.4. Manufacturing Process

Manufacturing is derived from the Latin word *manufactus*, means made by hand. Manufacturing process is directly linked to the process of changing the form/dimension of a part. In modern context it involves making products from raw material by using various process, by making use of hand tools, machinery or even computer (Singh, 2006).

Plastic manufacturing processes have been developed to cover a wide range of applications and part geometries, still several factors must be considered when selecting a manufacturing process like: form, volume/cost and lead time. The most common manufacturing processes for plastic parts, from low volume to mass production are Injection Molding, Extrusion, Blow Molding, Vacuum Forming, Rotational Molding, Machining and AM. See *Figure 11* (Formlabs, 2018), showing that AM is a good solution for a unique custom fit design.

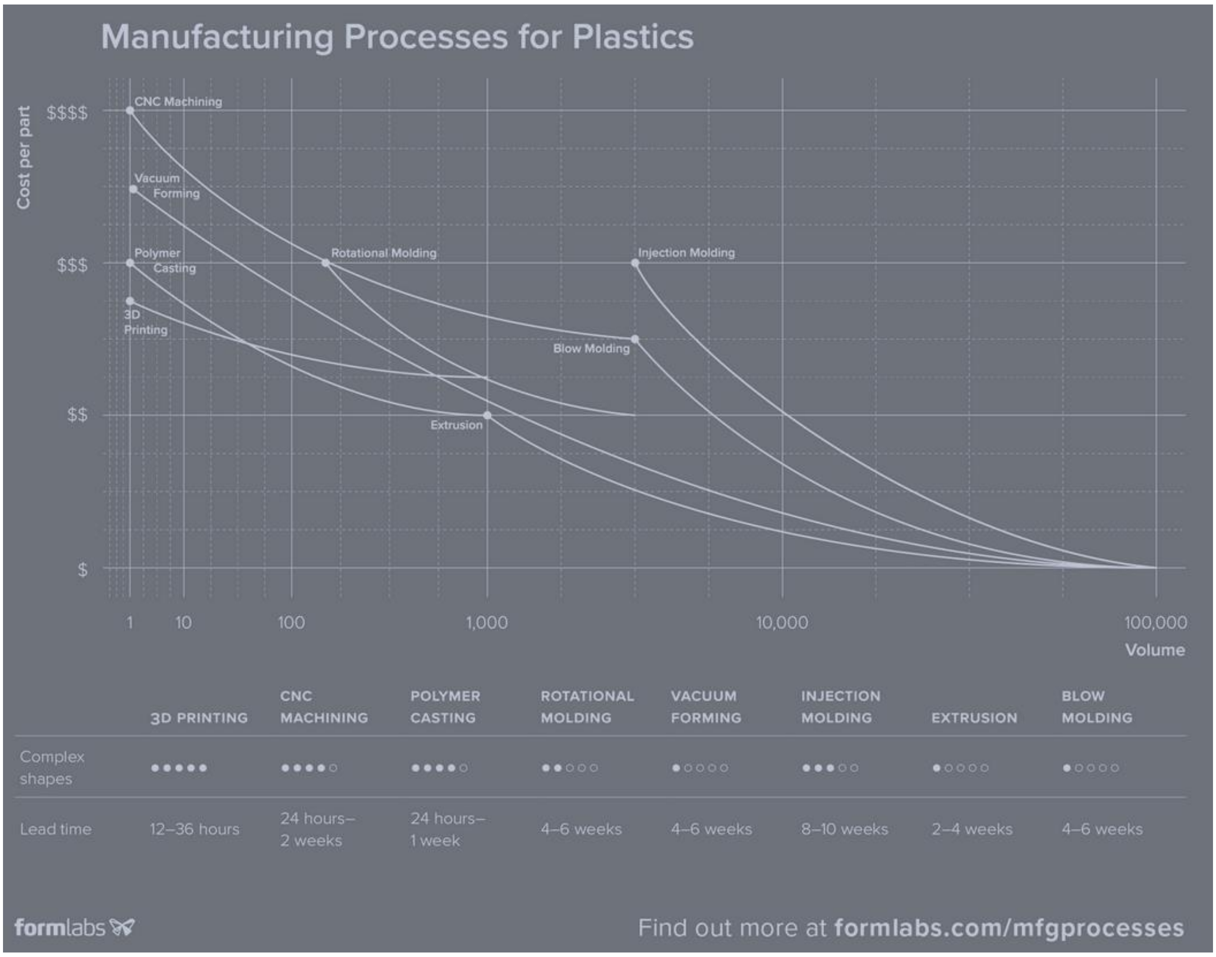



*Figure 11- Plastic Manufacturing Process (Source: 3D Hubs, 2019)[*]*

AM includes a group of tiered manufacturing technologies that have the potential to overcome the limitations of traditional manufacturing methods and specifically allows professionals to explore

[*] Available in <https://formlabs.com/blog/guide-to-manufacturing-processes-for-plastics/> *Access Ap. 29 2019.*

innovative features in orthotic design. AM can also be described as a powerful technology that enables the production of objects with complex geometry and reduces manufacturing time and costs (Gibson, Ian et al., 2010). AM technology is booming, and is being explored across many different fields of science, such as aerospace and medicine. One can create almost any geometry, regardless of complexity, resulting in almost complete design freedom. This freedom to design, has made AM an ideal fabrication method for upper extremity splints. In accordance with Abby Paterson and Daniel Harte (2017), the basic principle of this technology is that a model, initially generated using a 3D CAD system, can be fabricated directly without the need for process planning. The main feature of AM is its additive approach, where the CAD design of the part is first sliced through software in several thin layers, and then these layers can be used as guides to build a solid, layer-by-layer model until the object is constructed.

Compared to the high pressures of injection molding, additive manufacturing is a low or no pressure process using the application of thermal energy to create inter-layer adhesion and layer-to-layer consolidation. According to Samuel N. Bernier et al. (2015), there are many different types of AM technologies. Some of them extrude plastic filament, while others are based on "curing" light-sensitive resin using an ultraviolet laser. Other AM technologies utilize powder-based materials which are bound together with a high-intensity laser.

According to Samuel and Bernier (2015), AM process can be divided as:

- Vat photopolymerization: Stereolithography (SLA), Digital Light Processing (DLP) and Continuous Digital Light Processing (CDLP)
- Material extrusion: Fused Deposition Modelling (FDM) and Fused Filament Fabrication (FFF)
- Material Jetting: Material Jetting Modeling (MJM), Nano Particle Jetting (NPJ) and Drop On Demand (DOD)
- Binder Jetting: Binder Jetting (BJ), Powder Bed and Inkjet Head (PBIH) and Plaster-Based (PB)
- Powder Bed Fusion: Multi Jet Fusion (MJF), Selective Laser Sintering (SLS), Direct Metal Laser Sintering (DMLS), Selective Laser Melting (SLM), Selective Heat Sintering (SHS) and Electron Beam Melting (EBM)
- Direct Energy Deposition: Laser Engineering Net Shape (LENS) and Electron Beam Additive Manufacturing (EBAM) and Laser Metal Deposition (LMD)
- Sheet Lamination: Laminated Object Manufacturing (LOM) and Ultrasonic Consolidation (UC)

See Figure 12, showing all currently available AM technologies as state of art by 3D Hub Company.

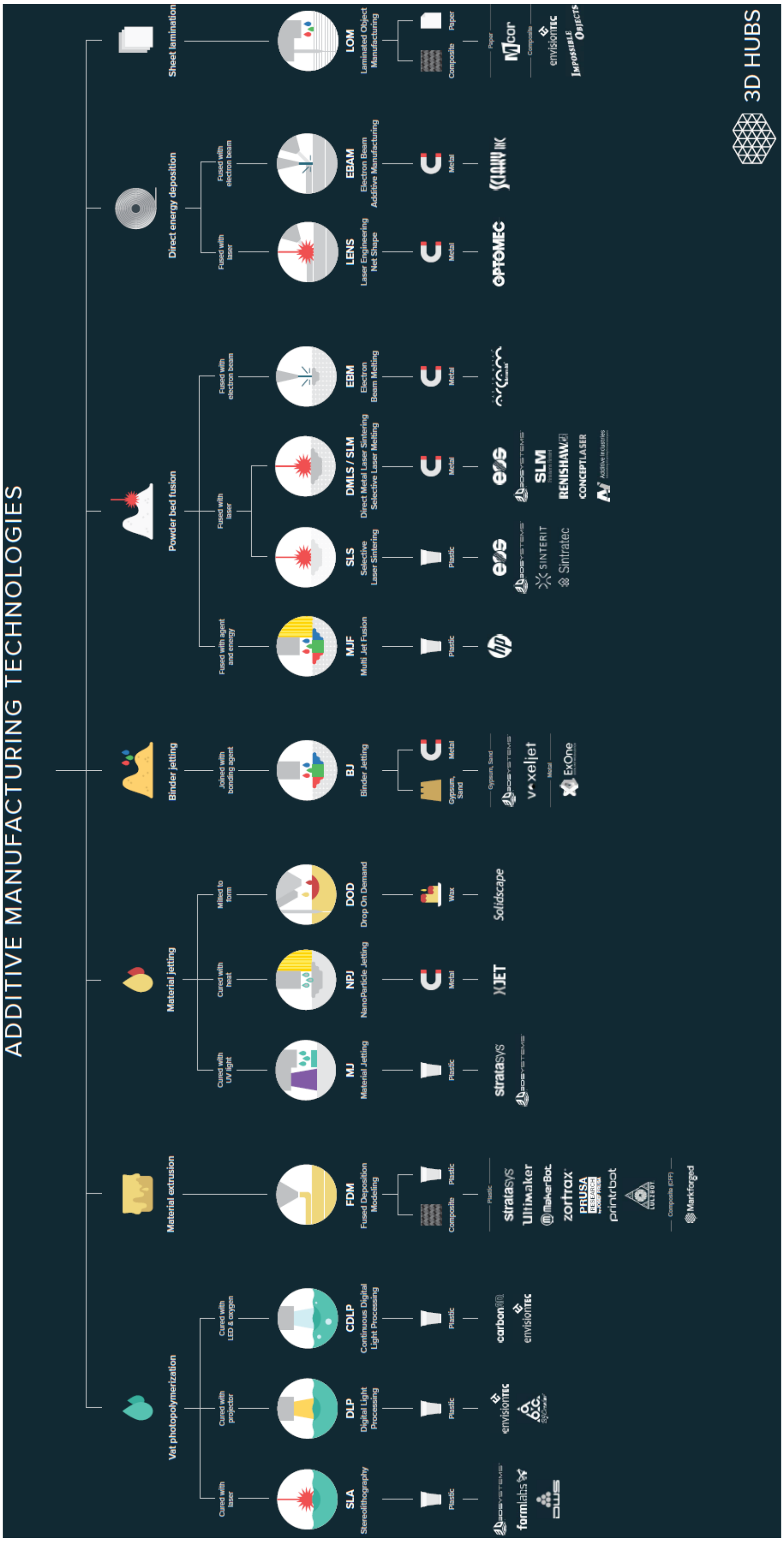



*Figure 12 - Manufacturing Process (Source: 3D Hubs, 2019)[*]*

[*] *Available in <https://www.3dhubs.com/knowledge-base/additive-manufacturing-technologies-overview> Access Ap. 29 2019.*

Each AM process offers unique strengths and weaknesses, but the perception of its advantages and disadvantages very much depends on the intended application (Harte and Paterson, 2017). However, one aspect all AM processes share is the geometric freedom offering the ability to create almost any 3D form. Considering the material selected, PA12 in Chapter 3.3, the AM process must be either Fused Deposition Modeling (FDM) or Selective Laser Sintering (SLS).

FDM or Fused Filament Fabrication (FFF), involves heating a thermoplastic filament to its melting point and then extruding it, layer by layer, to create a three-dimensional object. A weakness of the FDM process is that it has a special requirement for temporary scaffolding necessary to hold up free-standing portions of a part during printing which then has to both adhere to and support to the model, but later be readily removable after the printing is completed.

SLS is the most common additive manufacturing technology in industrial applications. According to Harte and Paterson (2017), these types of additive technology can melt powder particles together or adhesives are deposited to bind the powder. SLS is ideal for complex geometries, including interior features, undercuts, thin walls, and negative features.

This method uses powdered thermoplastics, which are sintered into a solid object using a computer-controlled laser. After each cross section is scanned, the powder bed is lowered by one layer of thickness, a new layer of material is applied on top, and the process is repeated until the part is completed. When the build finishes, the entire powder bed with the encapsulated parts is moved into a breakout station, where it is raised up, and parts are broken out of the bed. An initial brushing is manually administered to remove a majority of loose powder. Parts are then bead blasted to remove any of the remaining residual powder before ultimately reaching the finishing department. Given its versatility, this study utilized this SLS process to create the WSO 3D Model.

The growth in the Additive Manufacturing industry is predicted by many to be rapid and substantial, as more companies develop production equipment, more materials become available and more end-user industries adopt the technology, see *Figure 13* and *Figure 14*.


*Figure 13- AM market (Source: LinkedIn)*

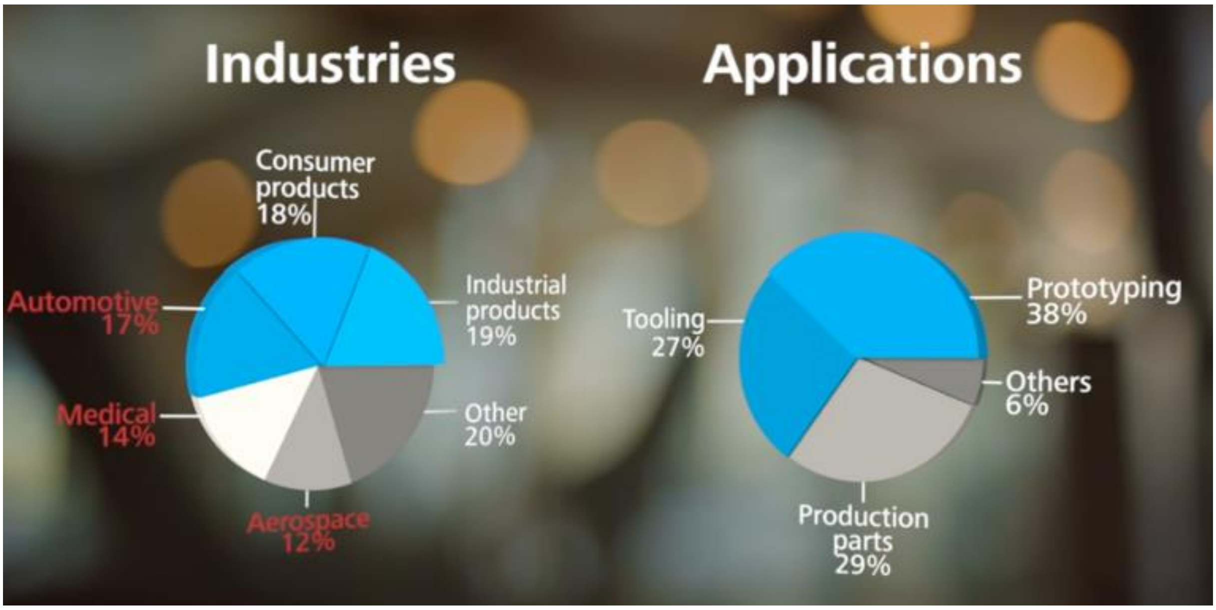



*Figure 14 - AM application (Source: LinkedIn)*

Parts produced with SLS printing have excellent mechanical characteristics, with strength resembling that of injection-molded parts. The combination of low cost per part, high productivity, and established materials make SLS a popular choice among engineers for functional prototyping, and also is a cost-effective alternative to injection molding for limited-run or bridge manufacturing. When compared with FDM and SLA, rough surface finishing and limited material options are cons of the SLS process, but Laser-sintered parts can be sandblasted, colored/impregnated, painted, covered and coated. The *Figure 15* shows a SLS machine from EOS and the *Figure 16* shows a prototype part sample.


*Figure 15 - EOS P 396 (SLS AM Machine)[*]*

*Figure 16 – Prototype*

[*] *Available in https://www.eos.info/systems_solutions/plastic/systems_equipment/eos_p_396 Access in Ap. 22 2019*

## 3.5. Data Acquisition

There are several methods of data acquisition such as: old school Calipers or more new methods such as: Computed Tomography, Magnetic Resonance Imaging and 3D laser scanning.

### 3.5.1. Computed tomography

Sometimes called "computerized tomography" or "computed axial tomography", is a noninvasive medical examination or procedure that uses specialized X-ray equipment to produce cross-sectional images of the body (e.g., diagnostic, treatment planning, interventional, or screening). Each cross-sectional image represents a “slice” of the person being imaged. These cross-sectional images are used for a variety of diagnostic and therapeutic purposes and can be used for 3D CAD software to recreate a studied object

### 3.5.2. Magnetic Resonance

Magnetic resonance imaging (MRI) is a widely used diagnostic modality mainly applied to the development of underlying tools for studying interactions leading to thermal injury by electromagnetic modeling, laboratory measurements, and thermometry and can also be used for 3D CAD software to recreate a studied object.

### 3.5.3. 3D Scanning

3D scanning is the process of analyzing a real-world object or environment to collect data on its shape in which the collected data can then be used to construct digital 3D models. A 3D scanner can be based on many different technologies, each with its own limitations, advantages and costs. Many limitations in the kind of objects that can be digitized are still present, for example, optical technology may encounter many difficulties with shiny, reflective or transparent objects. Collected 3D data is useful for a wide variety of applications. These devices are used extensively by the entertainment industry in the production of movies and video games, including virtual reality.

As this study is focused in the design and doesn’t requires scanning of hidden parts, it utilized the 3D laser scanning process, which preserves a level of realism that is difficult to obtain with 3D modeling. The 3D laser scanner employed in this design conceptualization is the David SLS-2 (see *Figure 17*) used to create the reference surface, which was the baseline to create the WSO design. This process is commonly called as 3D Scan for reference data. 3D Scan is also used for reverse engineering, parts inspection or parts quality control, and data archival.


*Figure 17 - David SLS 2 with turntable*[*]

David SLS2 is a high-resolution 3D scanner for professional applications. This system features high accuracy and reliability. This 3D scanner uses structured light scanning and consists of a video projector and industrial HDMI camera with HD lens. The scans can be captured every 2 seconds, capturing part images from 60 to 500mm with a resolution up to 0,05mm.

[*] *Available in <https://www.creativetools.se/hardware/3d-scanners-and-accessories/3d-scanners/david-structured-light-scanner-david-sls-2> Access in Ap. 29 2019.*

## 3.6. *Computer Aided Design (CAD)*

3D modeling is the process of developing a mathematical representation of any three-dimensional object using specialized software. CAD is used in the engineering industry to create 3D models of machine parts; in the automotive sector to create auto parts and miniature models; and in the architectural and construction industry to create models of projects, buildings and interiors. 3D modeling is also used to create models of the human body for medical education, emergency services training, researchers and artists. The media utilizes 3D models for animation films and advertisements. Since 3D models can be easily uploaded onto a website, it is also possible to share it widely to people across geographies through the Internet. 3D Modeling is also employed to create three-dimensional graphic representations of surfaces known as a digital elevation model or a digital terrain model; beneficial for surface analyses.

Companies can design prototypes and change them continuously in the virtual world, without going through the process of actually creating them and then having to alter them. There are several different types of 3D models one of which is Wireframe which is useful for initial design iterations and as reference geometry, serving as a 3D framework for subsequent modeling or modification. Another type is Solid modeling offering precise control over curved surfaces for precise manipulation and analysis. A third is Mesh modeling providing freeform sculpting, creasing and smoothing capabilities. A 3D model can include combinations of these technologies, and one can convert between them. For example, a primitive 3D solid pyramid can be converted into a 3D mesh to perform mesh smoothing. One can then convert the mesh to a 3D surface or back to a 3D solid to take advantage of their respective modeling capabilities as shown in *Figure 18*.

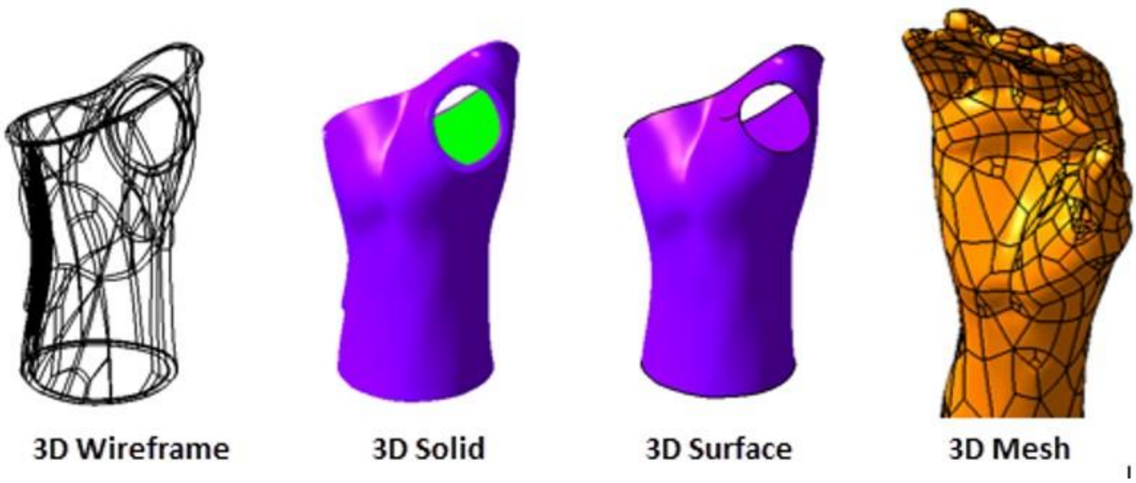



*Figure 18 - CAD technologies representation*

There is a great deal of CAD software essential to the automotive industry that is utilized in the medical field as well, like Catia, NX, CREO, Inventor and Solidworks to mention a few.

SolidWorks is designed and developed by Dassault Systems, who brought us CATIA and many other high-end programs; SolidWorks 2018 is a powerful software that is easier to use than many other advanced CAD programs on the market.  Autodesk Inventor is a CAD software used to create digital mechanical solid prototypes. This software is used for 3D mechanical design, design communication, tooling creation and product simulation. Furthermore, it enables users to produce accurate 3D models to aid in designing, visualizing and simulating products before they are built. Like its competitor Solidworks, Inventor is a highly advanced piece of CAD software that requires extensive training and advanced knowledge in engineering to unlock its full potential. If one brings both to the table, then Autodesk Inventor is among the best CAD software tools available.

Another Cad software, PTC brings technology solutions and leadership to the Internet of Things; their 3D CAD tool is ideal for innovative product development. CREO Parametric 3D is a product engineering software tool that improves quality and speeds time-to-market because it enables users to efficiently build 3D virtual prototypes and automates the product development process. A third related CAD was developed by the industrial manufacturing giant Siemens; NX is one of the best CAD software tools on the market. For one, it supports state-of-the-art parametric and direct solid/surface modeling. While the modeling history of other CAD software tools can box your freedom to develop your design into certain narrow avenues, NX’s a-synchronous modeling, on the other hand, opens exciting new perspectives on design. It is also an invaluable Product Life Management (PLM) software that covers the entire process of industrial design from beginning to end. As such users can check draft angles to ascertain that parts are tolerable.

Moreover, NX features comprehensive capabilities for analyzing a design’s structural integrity to ascertain the functional capacity of the finished product and its durability. With a feature-set like this, the applications of NX go beyond what many other CAD software tools can offer. For example, it can be used to create a proof-of-concept of complex designs. Furthermore, it also lets users create animations of complex machinery to facilitate its understanding when presenting to prospective customers.

CATIA is a program for expert and advanced designers and engineers. It is known as being both one of the most powerful program on the market as well as the most expensive. This work will utilize Catia V5 technology. Catia is a software manufactured by Dassault Systems that belongs to IBM. It is a CAD hybrid software, as it allows designers to create virtual products in solids and in surfaces. The automotive and the aerospace industries are the main Catia´s customer, due to its high models precision. CATIA started as an in-house development in 1977 by French aircraft manufacturer Avions Marcel Dassault, at that time customer of the CAD/CAM CAD software to develop Dassault's Mirage fighter jet, and then was adopted in the aerospace, automotive, shipbuilding, and other industries. Initially named CATI (Conception Assistée Tridimensionnelle Interactive — French for Interactive Aided Three-dimensional Design) — it was renamed CATIA in 1981, when Dassault created a subsidiary to develop and sell the software, and signed a non-exclusive distribution agreement with IBM. In 1998, CATIA V5 was released, which was an entirely rewritten version of CATIA, with support for UNIX, Windows NT and Windows XP since 2001 and in June 2011, Dassault launched CATIA V6.

Catia V5 was selected in this study because it has the best surface tools available in the market mainly considering the amount of surface work that will be required to design the WSO, besides of that, it will be also possible to validate the design thought its own FEA tools.

## 3.7. *Finite Element Analysis (FEA)*

The Finite Element Analysis (FEA) is the simulation of any given physical phenomenon using the numerical technique called Finite Element Method (FEM). FEM is based on the idea of building a complicated structural object with simple element, or dividing a complicated structural object into small and manageable pieces. The target of FEA is to reduce the number of physical prototypes and experiments and optimize components in their design phase to develop better products, faster modeling is the process.

Application examples of FEA in Mechanical, Aeronautics, Astronautics and Civil Engineering are: structural static analysis (linear or nonlinear problem), structural dynamic analysis (linear or nonlinear problem), thermal analysis, biomechanics, etc.

Main commercial FEM Software are:  Msc Nastran, Msc Adams, Ansys, Abaqus, Ls-Dyna, Algor, Cosmos, etc. Catia, as the others FEM software mentioned above, enables design analysis iterations to be performed rapidly from simple parts to complex assemblies. Due to its user friendly interface and its multidiscipline collaboration to the previously chosen CAD software, it will be used in this work during the WSO validation phase. The *Figure 19* was used as example to exemplify the results of a FEA process.

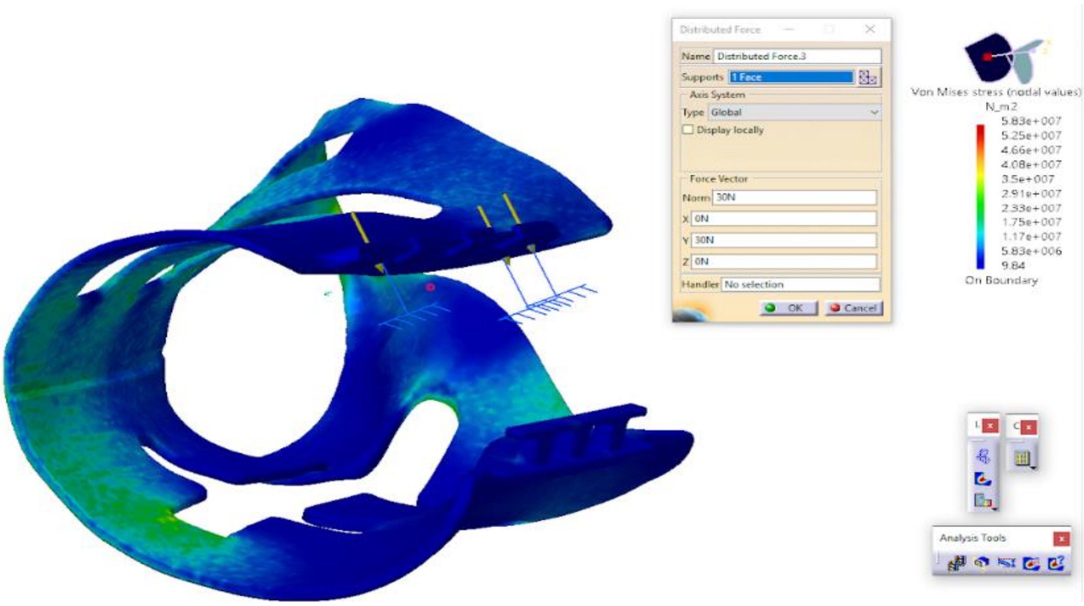



*Figure 19 - FEA*

## 4. WSO EMBODIMENT AND DETAILED DESIGN

As a basis for this work, the orthosis that are currently available were researched in order to understand materials and processes used in the field *(Table 4)*.

*Table 4 - WSO Materials and Process*

| Company | Product name | Manufacturing process | Material | Reference |
|---|---|---|---|---|
| Advent Medical Systems | CORFLEX WRIST HAND | Injection molding, Extrusion and Compression | Rigid polyethylene laminated to soft closed cell foam lining | https://adventms.com/upperr-extremity/162-corflex-wristhand-orthosis.html |
| Andiamo | ANDIAMO | SLS | PA | https://andiamo.io/ |
| Deniz Karasahin | OSTEOID | FDM | ABS | https://competition.adesignaward.com/design.php?ID=34151 |
| DonJoy | WRIST ORTHOSIS | Stamping | Neoprene | www.medicalexpo.ed/prod/donjoy/product-96003-610563.html |
| Evil Design | CORTEX | FDM | ABS | https://www,evildesign.com/cortex |
| Gintare Cer. | EXO | SLS | PA | https://cargocollective.com/gintarecer/Exo |
| Marina Scheninberg | TENSION | Foams | Common soft foam | https://www,dsgbr,ck.2013.08/brazo-orthopedico-tension-marina-scheinberg/ |
| MediPrint | NOVACAST | FDM | ABS | https://mediprint3d.com.mx/servicios/novacast-de-mediprint |
| MHOX and CRP | Generative Orthosis | SLS | CRP Group's polyamide material (Windform GT) | http://mhoxdesign.com/generative_orthoses-en.html |
| Podoactivia | YOUNEXT | SLS | PA | https://riunet.upv.es/bitstream/handle/10251/104704/AGUADO%20-%20Dise%C3%B1o%20de%20%C3%B3rtesis%20en%20impresi%C3%B3n%203D.pdf?sequence=1&isAllowed=y |
| Summit ID | ANAIS | SLS | PA | https://www.summitid.com/#/anais/ |
| UCLA's school of Architecture & Urban Design | SPLINT PLUS | SLS | PA | https://www.bitrebels.com/technology/customized-3d-printed-wrist-splint/ |
| Xkelet Easy Life SL | SKELET | SLS | PA | https://www.xkelet.com |

Using the methodology and design approach presented, it is possible to select the specifics of each process, as shown in Figure 20, considering current available University resources and designer know-how.

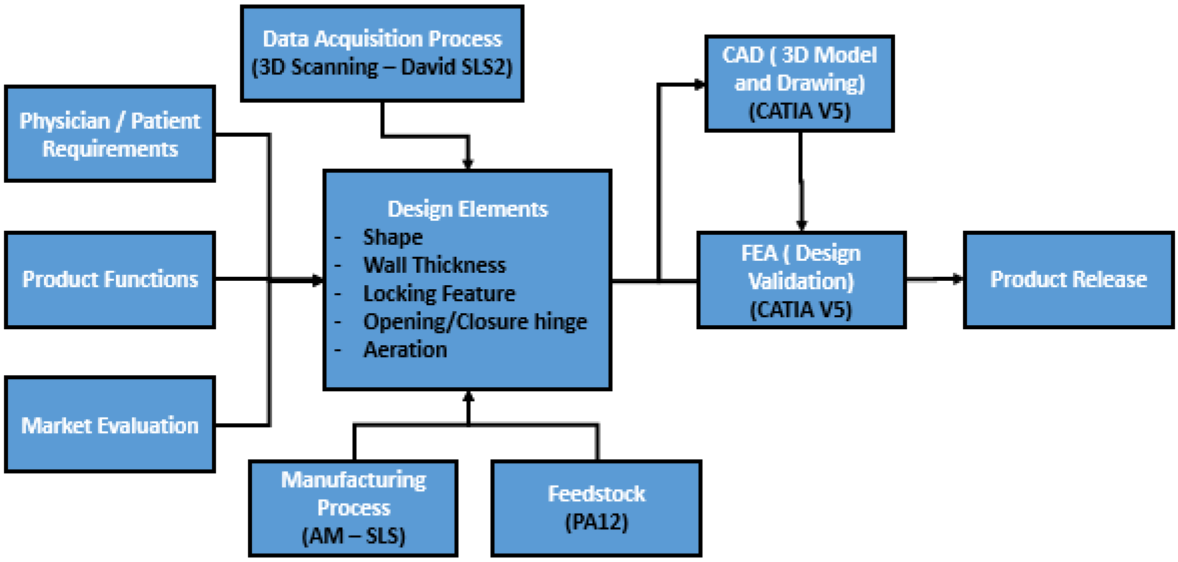



*Figure 20 - Methodology with defined processes*

The proposed design technique described below and the successful outcome of the detailed WSO design execution depends on the proper definition and understand of the design elements fulfilling the requirements and functions of the orthosis, the material and equipment selection for the creation of the mold and casting of the wrist, the 3D scanning quality and the designer experience with CAD and FEA Software tools.

### 4.1. Design Elements

Design elements are the basic units of any visual design which form its structure and convey visual messages. The specific design elements used in the development of this work are based on the relationship between functions and requirements, considering feedstock, manufacturing process and data acquisition.

The Ishikawa or fishbone diagram was developed initially as a quality control tool. In many industry sectors it is also used for analyzing complex problems and identifying the root causes. It is also useful when a different point of view to examine a problem is required, and to uncover bottlenecks and to identify where and why a process does not work, and to accelerate the process when traditional ways of problem-solving consume much time.

The Ishikawa diagram was used in this work, as illustration only, to organize and guide the WSO process development as shown in *Figure 21*. The green boxes are techniques to be used to release the WSO and the red boxes were disregarded due to treatment proposal.

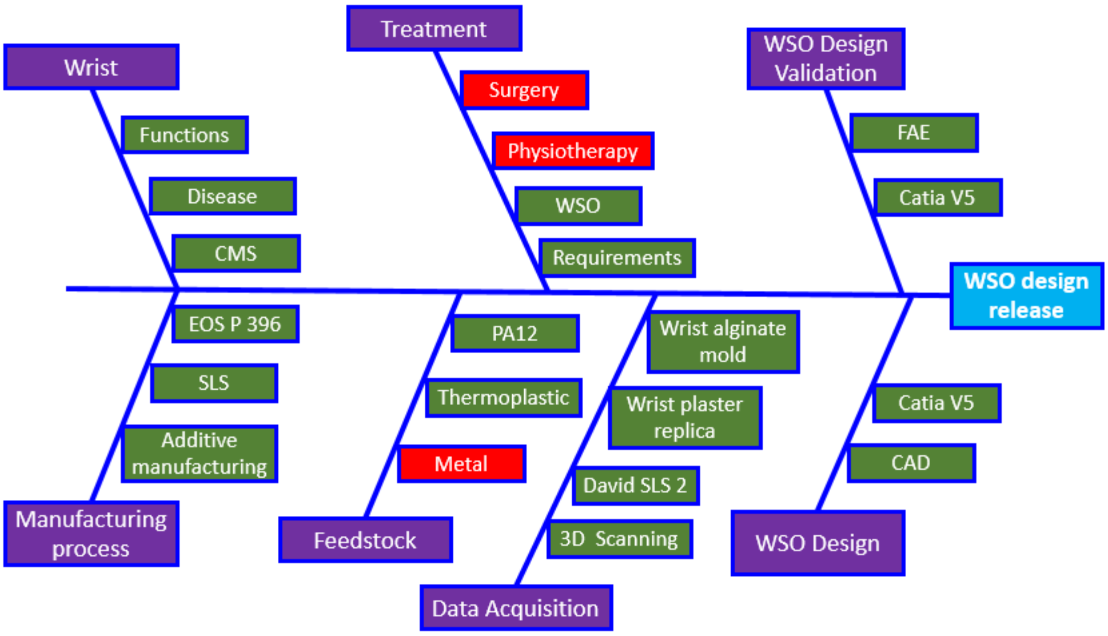



*Figure 21 - Ishikawa Diagram*

In order to develop a WSO design, understanding the relationship between requirements and functions is crucial, see *Table 5*. It is necessary to define which areas of the wrist would be covered by the WSO and incorporate the design elements that supported the final design shape. Design elements are the physical characteristics of the orthosis such as: wall thickness, material properties, locking feature (designed for ease of donning and doffing) and aeration.

*Table 5 - Design Elements*

| Design Elements | | Functions | |
|---|---|---|---|
| | | Restrict movement | Allow for movement |
| Requirements | Pleasant | WSO shape<br>Aeration distribution. | Minimal material as possible |
| | Comfortable | Light; (PA 12 density: 0.95 ±0.03 g/cm³)<br>Offset from skin<br>To have a min. surface contact | Rounded edges<br>Minimal material as possible |
| | Durable | Material properties<br>Heat resistance<br>Impact resistance<br>Minimal wall thickness | Minimal material as possible |
| | Safe | Material compatibility | Minimal material as possible<br>Rounded edges |
| | Practical<br>Easy to take on/off | Offset from skin<br>Low engagement / disengagement load | Minimal material as possible<br>Rounded edges |

Based on the defined design elements, wrist movements must to be analyzed in order to fulfill all WSO functions and requirements, taking into account:

- Areas that requires motion freedom
- Areas that must have motion blocked
- FEA regarding loads to define wall thickness and appropriate locking feature

SLS has very few constraints when compared to other AM technologies and one positive characteristic is that the surrounding unsintered powder is used as structure support allowing the development of highly complex and intricate part design. The design elements that must be considered for SLS with PA 12 are:

- Shrinkage (3-3.5%)
- Minimum wall thickness (0.3mm)
- Minimum holes (0.3mm)
- Minimum outside radius (0.4mm)
- Minimum inside radius (0.3mm)
- Minimum gap between joins /gaps (0.4mm)

Other design elements will not be considered due to the current design solution like: escape holes (to drain not used material), embossed and engraved details.

### *4.2. Mold and Casting*

In order to allow the 3D scanning process feasibility, a wrist plaster was created as shown in *Figure 22* using an alginate mold as shown in *Figure 22*, using the same casting process as used by Paterson Bibb and Campbell (2010), in order to create a reference for the 3D scanning process.

Casting is a manufacturing process in which a liquid material is usually poured into a mold, which contains a hollow cavity of the desired shape, and then allowed to solidify. The solidified part is also known as a casting, which is ejected or broken out of the mold to complete the process. Casting materials are usually metals or various time setting materials that cure after mixing two or more components together; examples are epoxy, concrete, plaster and clay. Casting is most often used for making complex shapes that would be otherwise difficult or uneconomical to make by other methods.

Plaster and other chemical curing materials such as concrete and plastic resin may be cast using single-use waste molds, multiple-use 'piece' molds, or molds made of small rigid pieces or of flexible material such as latex rubber (which is in turn supported by an exterior mold). When casting plaster or concrete, the material surface is flat and lacks transparency.

*Figure 22 - Alginate mold*

A detailed procedure is described below in order to create a reliable wrist plaster to be used as basis for the data acquisition process. The casting process is required due to the stability provided by the wrist plaster.

*Mold manufacturing procedure:*

1 liter of water was mixed manually with 750ml of alginate in ambient temperature during 1 minute and the result was add to a 600 mm high bucket. The hand was immediately immerse to the bucket and removed after 3 minutes.

*Casting manufacturing process:*

1 kilo of plaster powder was mixed with 1 liter of water during 1.5 minutes. The mixture was slowly poor into the alginate mold and the result was shown in *Figure 23.*

*Figure 23 - Wrist plaster*

## 4.3. 3D Scanning

The wrist plaster was placed on the automatic 360º rotating table T1 from David SLS2 and the process was achieved using 5 different procedures as shown in *Table 6* and the result is shown in *Figure 24*.

*Table 6 - 3D Scanning procedure*

| Process | Rotational increment angle (º) | Number of scans | Total scan time (seconds) |
|---|---|---|---|
| 1 | 10 | 36 | 324 |
| 2 | 15 | 24 | 220 |
| 3 | 18 | 20 | 180 |
| 4 | 20 | 18 | 162 |
| 5 | 30 | 12 | 108 |

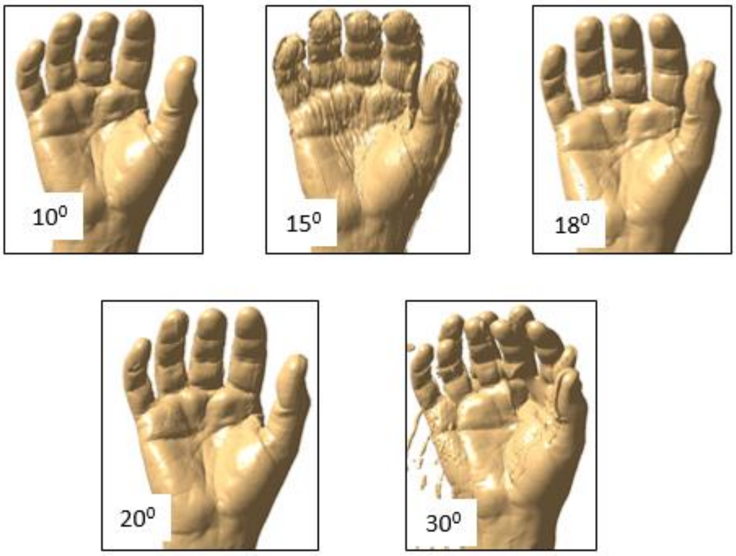



*Figure 24- 3D scanning results comparison*

Due to the best quality result of procedure number 1, with 10º angular increment, was chosen as final input data to the WSO 3D modeling process. *Figure 25* shows the output result of the David SLS-2 software.

*Figure 25- Chosen scanning output*

Considering the data, acquired via 3D scanner DAVID SLS2; knowing the SLS AM process and considering the feedstock characteristics PA12, it is possible to describe step by step the procedure to create a 3D modeling using Catia V5 as CAD software.

## 4.4. Modeling the WSO with Catia V5

Using the *Digitized Shape Editor* Module in the *Shape* environment from Catia V5, the scanned file was imported, from the 3D scanner David SLS2, as shown in *Figure 26*. Because of the immense nature of the scanned file, a powerful tool was needed to convert the file; which is not available in all CAD software. Even using the Catia V5 calculation tool, there still remained an imperfection that was detected in the lower right side of the wrist. This gave an image, but in order to be workable a surface must be created.

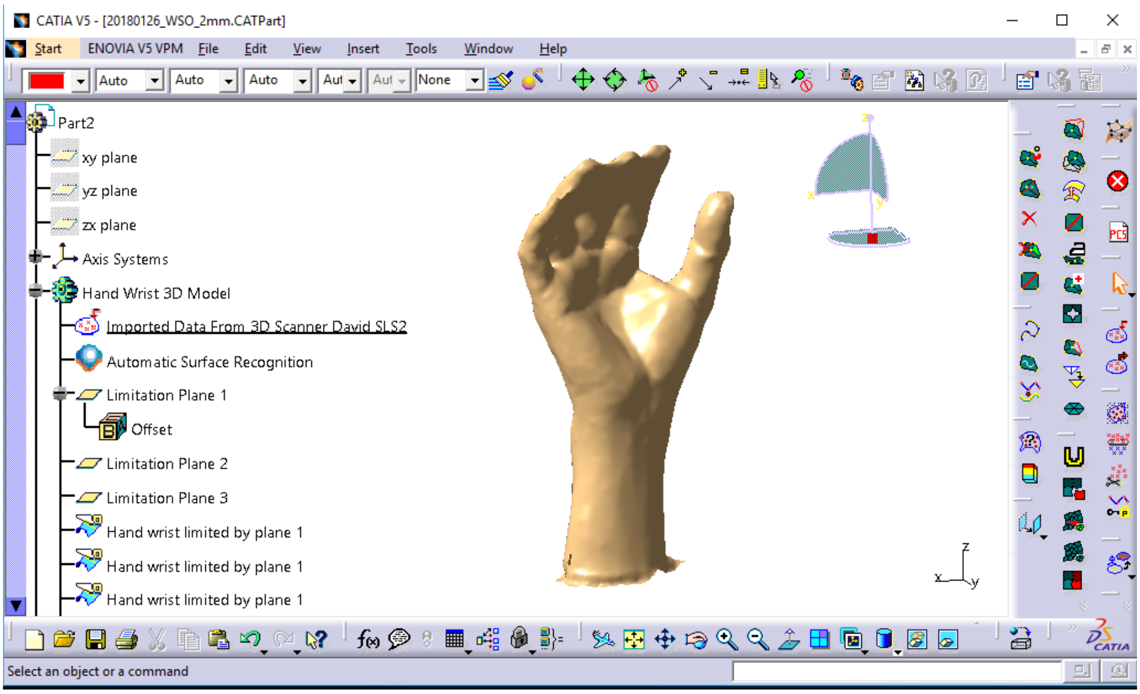



*Figure 26 - Imported data from David SLS2*

Still in the *Shape* environment but now in the *Digitized Shape Editor* module, a workable surface was created, as shown in *Figure 27*Figure 27. Through Automatic Surface Recognition Catia was able to automatically fix the small hole in the lower part of wrist, see *Figure 26*.

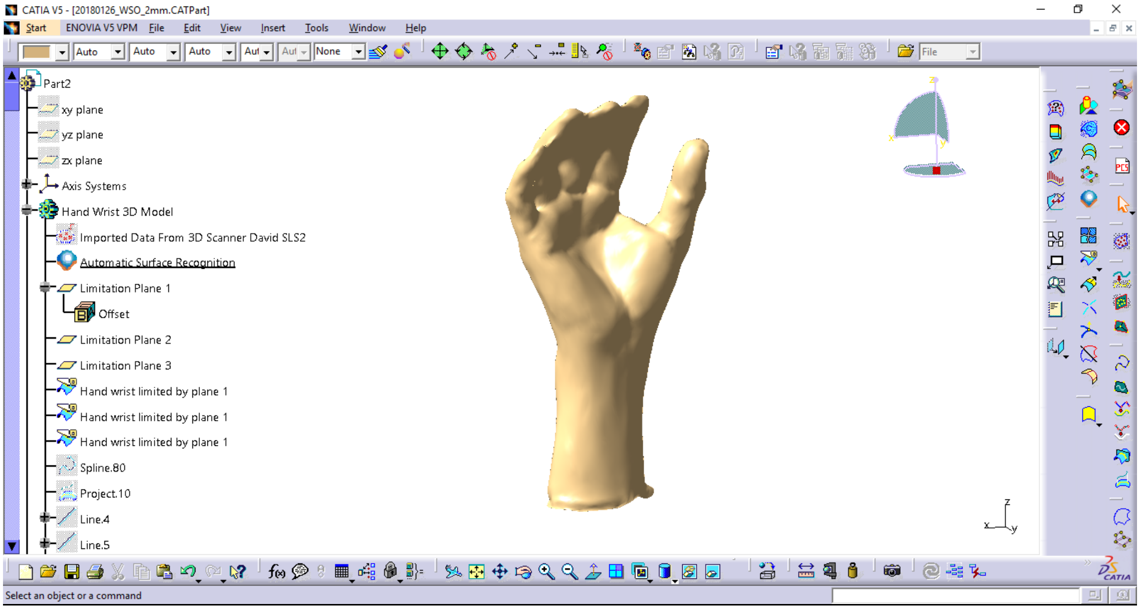



*Figure 27 - Surface Reconstruction*

Three planes were created in the module *Generative Shape Design*, as shown in *Figure 28* the lower horizontal plane involving the forearm will be used as reference to remove the unwanted surface, which occurred during the 3D scanning because of a shadow created while the plaster prototype was on the turntable. This imperfection occurs outside of the necessary parameters of the orthosis thus can be removed. The other two, however, were created to determine the outermost boundary of the orthosis, maximizing the amount of power and precision grip of the patient's hand. Thus finalizing the parameters of the desired WSO.

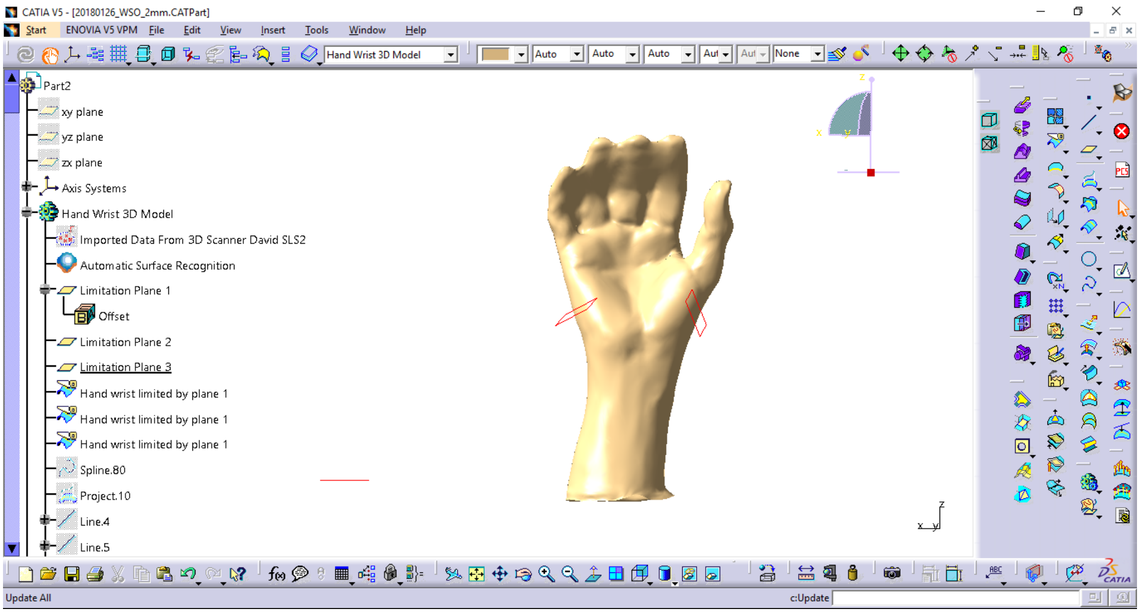



*Figure 28 - Plane creation*

Using the command *Surface Splint*, the wrist surface was trimmed based on the three planes in the areas of the palm and lower part of the wrist, as shown in *Figure 29*. Assuring that the necessary movements like grip and pinch are maximized, but adhering to necessary restrictions of wrist movements including flexion, extension, supination, pronation, ulnar and radial flexion as required by the specifications provided by the physician. With this modified 3D geometry the basic parameters were ascertained to initiate the WSO 3D modeling.

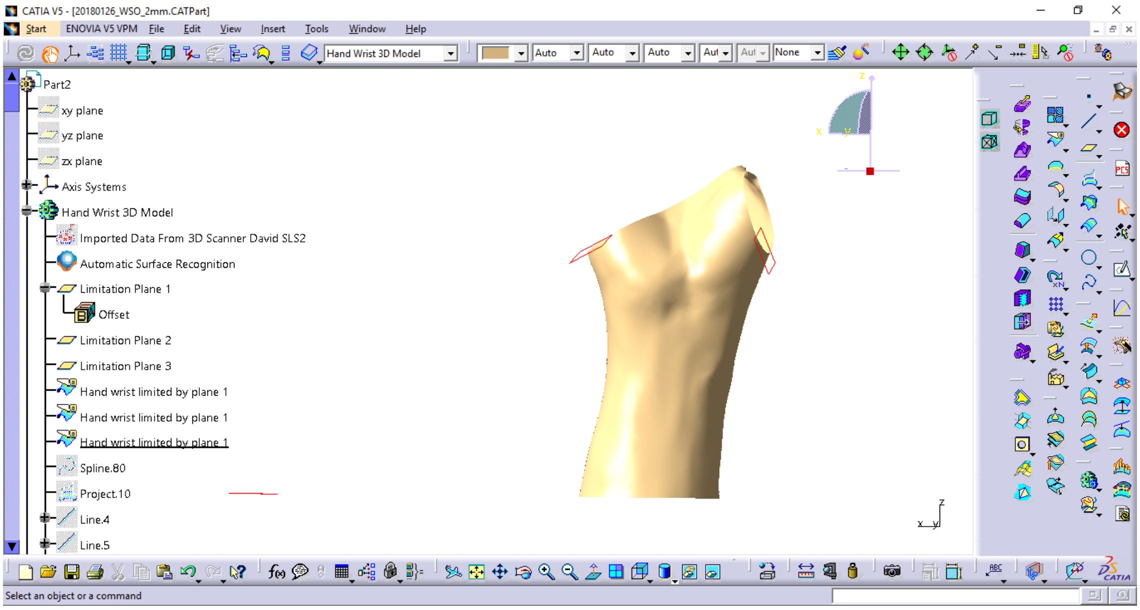



*Figure 29 - Trimmed Surface*

The surface area between the thumb and index finger (net hand region) shows a complex surface see *Figure 30*, thus cannot be used as a surface to originate the WSO. In order to create an offset from the patient's limb allowing for the generation of wall thickness, the software must be able to calculate an offset that does not generate a surface overlay. It is required to trim the problematic surface in the net hand region using the *Splint Surface* command shown in *Figure 31*.

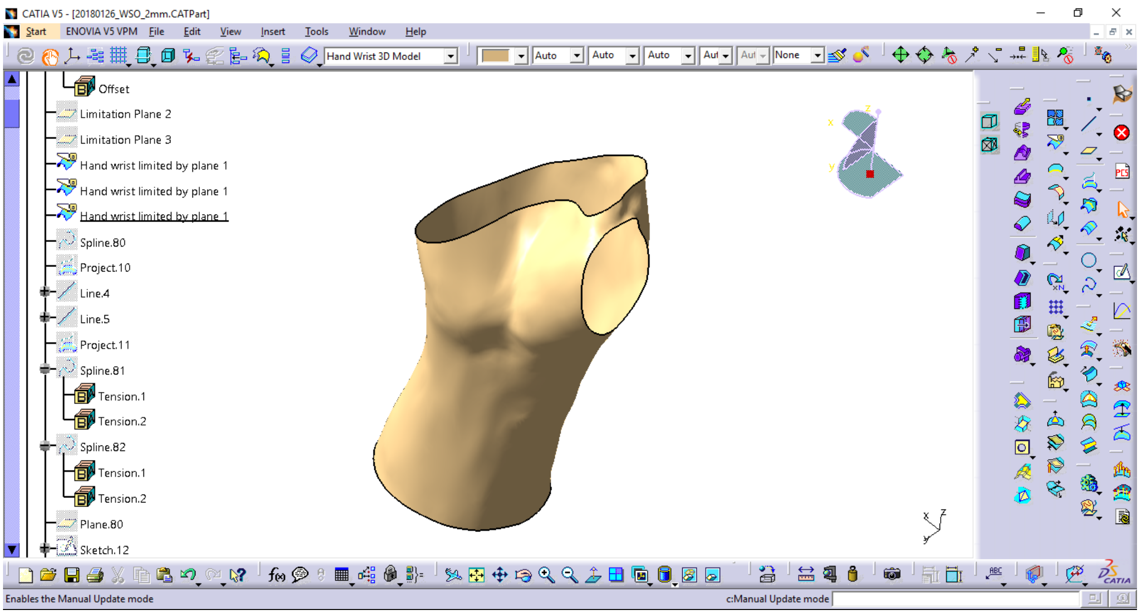



*Figure 30 - Net region to be reconstructed*

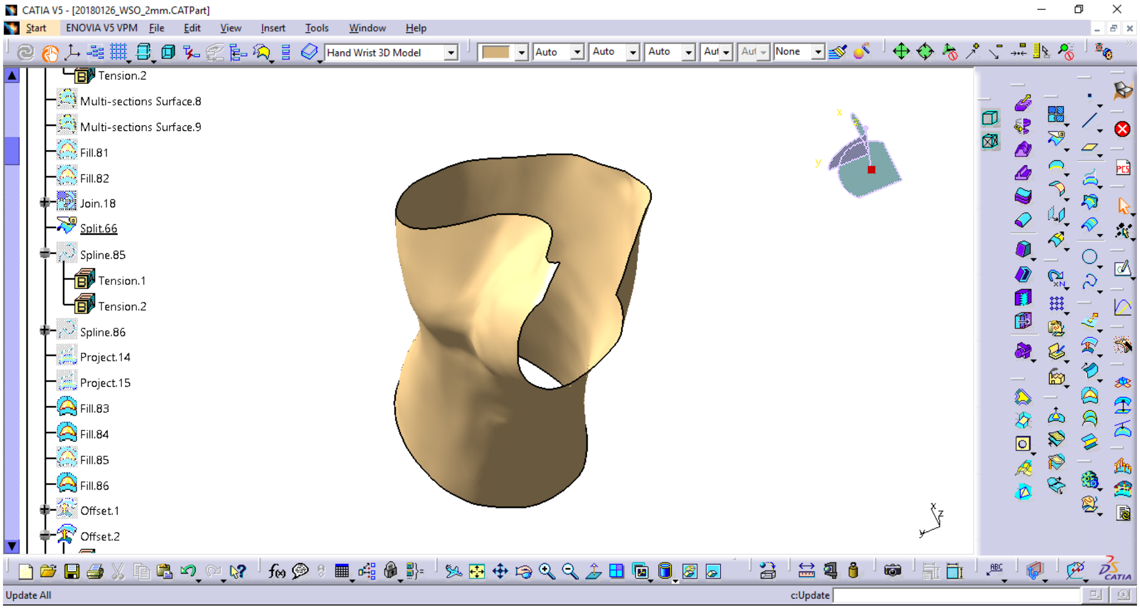



*Figure 31 - Trimmed surface*

It is now necessary to reconstruct the trimmed portion that will guarantee the generation of the smoother net geometry. This was accomplished using the *Surface command Fill*. Three other surfaces were created in order to close all openings of the current model as shown in the in *Figure 32*. This was necessary to convert the existing 3D surface geometry into a 3D solid model.

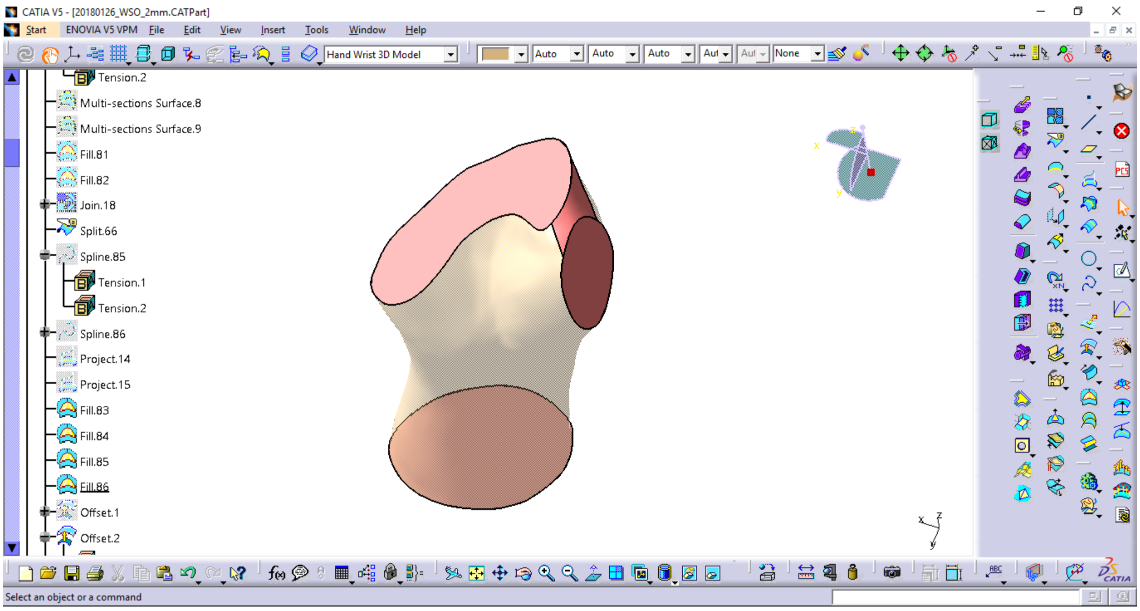



*Figure 32 - Net surface reconstructed and surfaces created to close the 3D model*

Using the *Surface command Offset*, the external surface of the WSO was created leaving a 2mm gap between the internal surface and the external surface, see Figure 33, originating the outside shape of the custom WSO and determining the 2mm WSO thickness (see drawing in *attachment 01*).

.

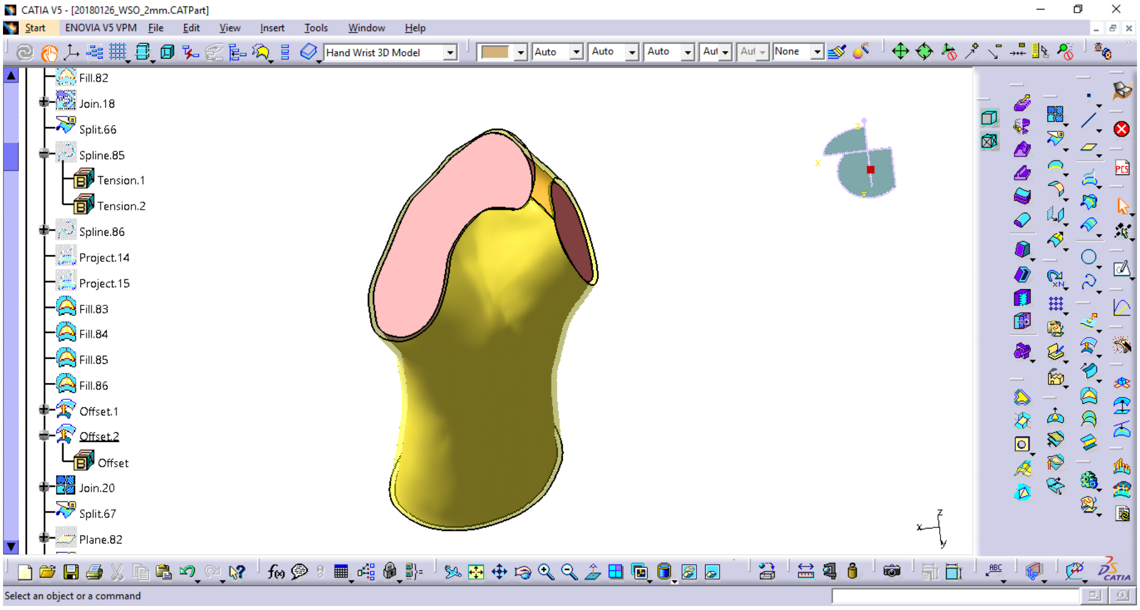



*Figure 33 - Surface offset (2mm)*

Using the command *Join*, the internal surfaces were connected to form a single surface that represents the internal shape of the orthosis which is an exact replica of the patient's hand as shown in the Figure 34.

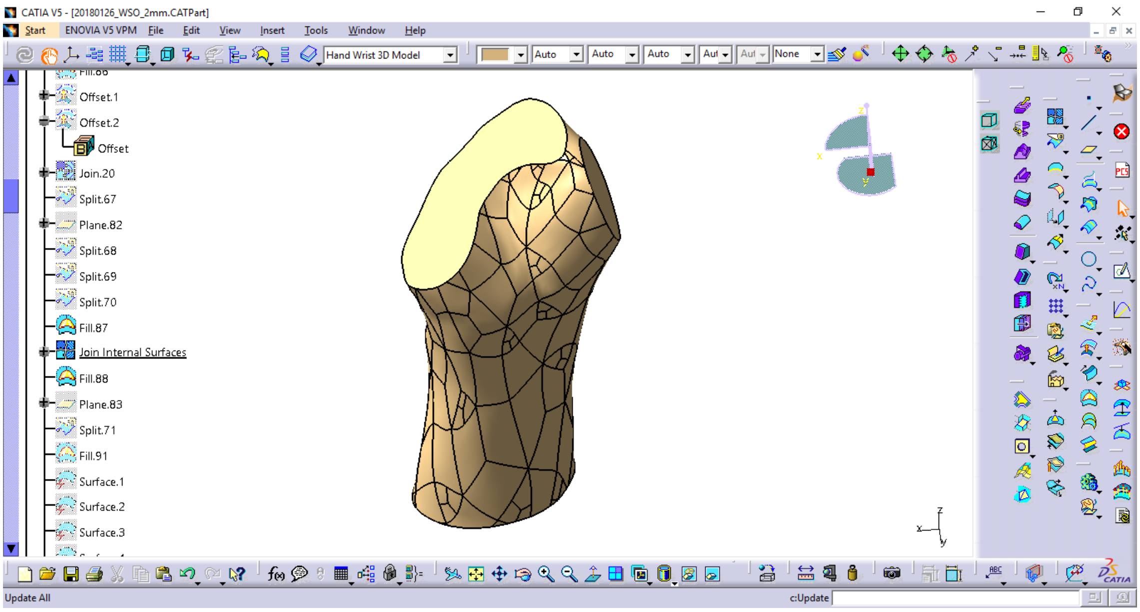



*Figure 34 - Inside surface union*

Using the same methodology, with the *Join command,* the external surfaces were also connected, see Figure 35Figure 35.

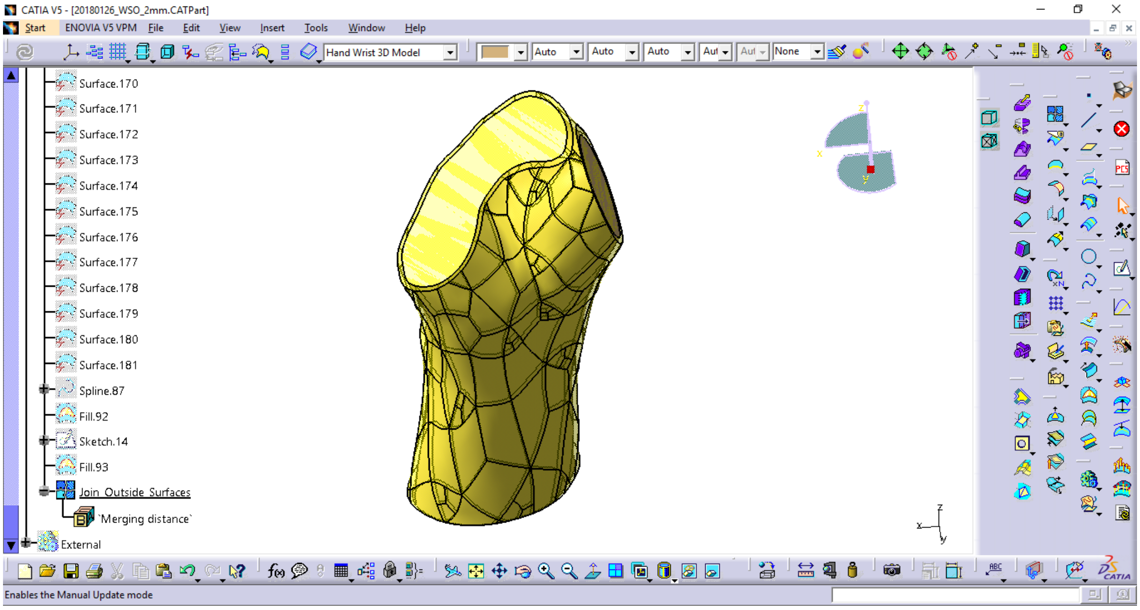


*Figure 35 - Outside surface union*

Now utilizing the *Solid* module, the external and the internal surfaces were converted into two solid bodies using the command *Close Surfaces* as shown in Figure 36.

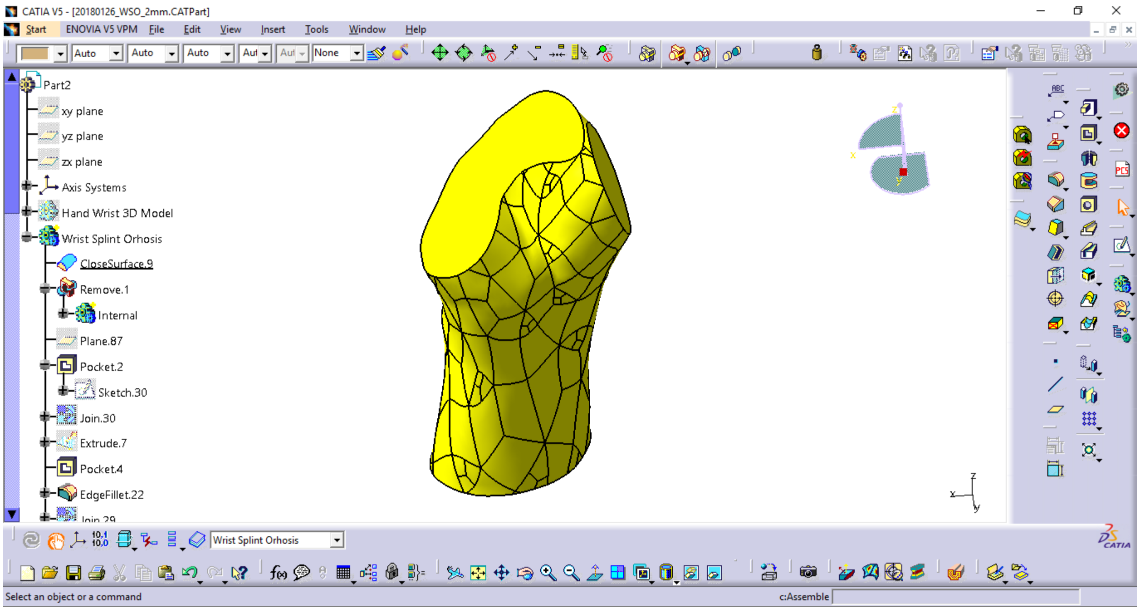


*Figure 36 - Outside solid model creation*

With the subtract command in the Boolean operation menu bar, the internal model was removed from the external model as shown in Figure 37.

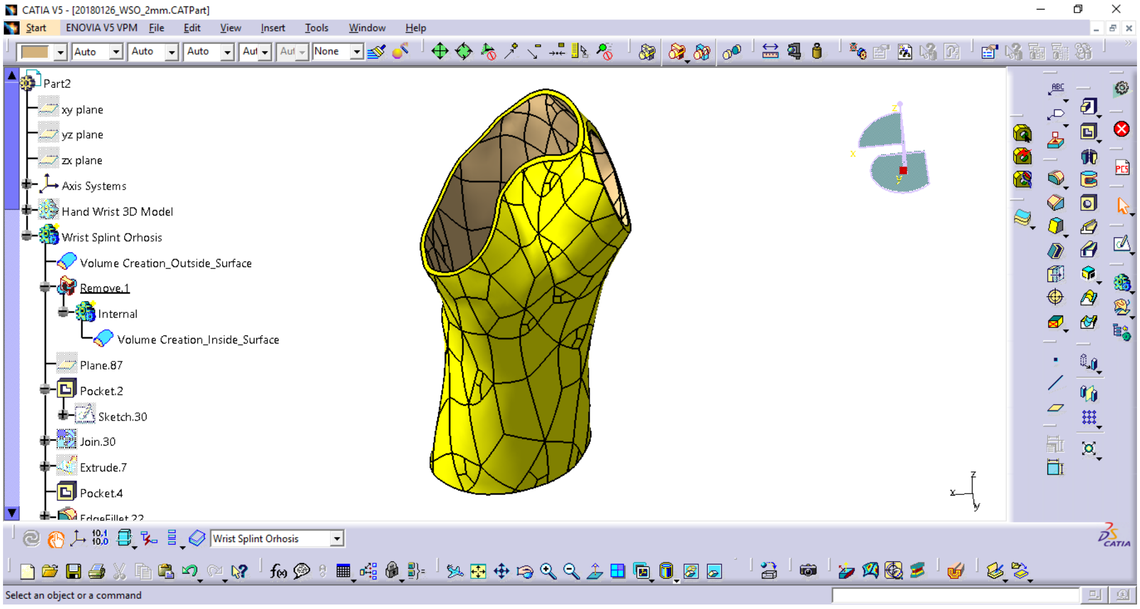
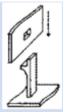
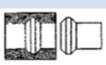
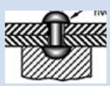
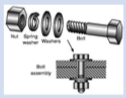



*Figure 37 - Model subtraction*

The basic structure of the WSO is now created according to the required functions, allowing and restricting movements based on the focus matrix analyses. However, there are still requirements to be worked like aeration, comfort, aesthetics and usability (Doffing/Donning). In reference to usability there needs to be a system that allows the patient an easy way to put on and take off the WSO. The current basic structure requires a design solution to open the WSO for the donning and later will require a locking feature to stabilize WSO and achieve the usability requirement.

A morphologic matrix is a creative thinking methodology that will be used to analyze the possible solutions and the design elements as shown in Table 7

*Table 7 – Morphologic Matrix*

| | Locking feature description | Cantilever hook | Compressive hook | Bayonet finger | Ball & Socket | Annular snap | Rivet | Screw | Bag-lock |
|---|---|---|---|---|---|---|---|---|---|
| | **Picture** |  |  |  |  |  |  |  |  |
| **Design elements** | **Pleasant** | ✓ | ✓ | ✗ | ✓ | ✓ | ✓ | ✗ | ✗ |
| | **Comfortable** | ✓ | ✓ | ✗ | ✓ | ✓ | ✗ | ✗ | ✗ |
| | **Durable** | ✓ | ✓ | ✓ | ✓ | ✓ | ✗ | ✓ | ✓ |
| | **Safe** | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| | **Practical** | ✓ | ✗ | ✗ | ✗ | ✗ | ✗ | ✗ | ✗ |

The cantilever hook or snap-fit is a common feature used in the industry and allows the WSO design to be configured as a single component. SLS is suitable for functional snap-fit prototypes or end use parts that will be opened and closed many times and for a maximum tear resistance the PA12 will be used as described in the feedstock chapter.

### *Calculating and Modeling a snap fit design solution*

"Snap joints are a very simple, economical and rapid way of joining two different components or parts. All types of snap joints have in common the principle that a protruding part of one component, e.g., a hook, stud or bead is deflected briefly during the joining operation and catches in a depression (undercut) in the mating component. After the joining operation, the snap-fit features should return to a stress-free condition. The joint may be separable or inseparable depending on the shape of the undercut; the force required to separate the components varies greatly according to the design." (BASF, 2007)

In order to design the snap fit feature, the dimensions were stablished based on BASF manual*. The equations were used as described below and for a better understand of dimensions and applied forces see *Figure 38*, *Figure 39* and *Figure 40*.

**Equation 1**

Maximal strain: $\epsilon = 1.5 * \frac{t * y}{L^3 * Q}$

| | | |
|---|---|---|
| t = beam thickness => | design => | 1.0 mm |
| Y = Deflection => | design => | 0.5mm |
| L = beam length => | design => | 3.5 mm |
| Q = Deflection Magnification Factor => | BASF Table => | 2.5 |
| **ϵ = Maximal Strain =>** | **calculated =>** | **0.007mm** |

**Equation 2**

Force: $P = \frac{b * t^2 * E * \epsilon}{6 * L}$

| | | |
|---|---|---|
| b = beam width => | design => | 85.9 mm |

* Available on: https://web.mit.edu/2.75/resources/random/Snap-Fit%20Design%20Manual.pdf. Access on May 10 2019

| | | |
|---|---|---|
| t = beam thickness => | design => | 1 mm |
| E = Flexural modules => | material => | 1300MPa |
| **ϵ = Maximal Strain =>** | **equation 1 =>** | **0.007mm** |
| L = beam length => | design => | 3.5 mm |
| **P = Push Force =>** | **calculated =>** | **37N** |

**Equation 3**

Mating Force: $$W = P * \frac{\mu + tan\alpha}{1 - \mu * tan\alpha}$$

| | | |
|---|---|---|
| **P = Push Force =>** | **equation 3 =>** | **37N** |
| μ = Coefficient friction => | BASF table (tan β) => | 0.35 |
| α = lead angle => | design => | 45° |
| **W = Mating force =>** | **calculated =>** | **77N** |

**Equation 4**

Maximal Deflection: $$Ymax = \frac{\epsilon_0 * L^3 * Q}{1.5 * t}$$

| | | |
|---|---|---|
| $\epsilon_0$ = Initial Strain => | Material => | 4%-15% => 0.04(conservative) |
| L = beam length => | design => | 3.5 mm |
| Q = Deflection Magnification Factor => | BASF Table => | 2.5 |
| t = beam thickness => | design => | 1 mm |
| **Ymax = Maximal allowed deflection =>** | **calculated =>** | **2.85** |

The calculation shows that it is possible to create a snap fit design as a locking feature solution but a simulation will validate the final design.

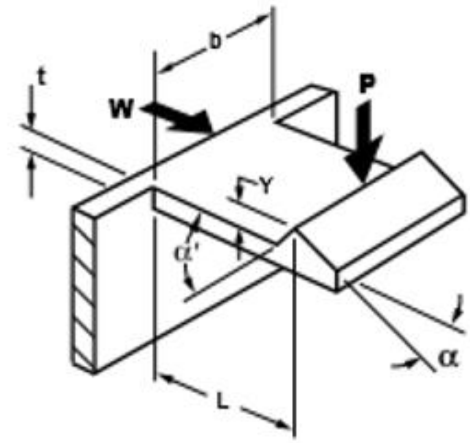



*Figure 38 - Snap fit design*

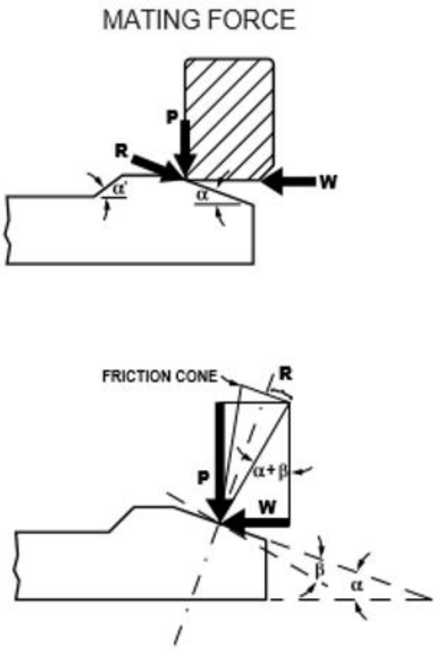



*Figure 39 - Snap fit forces*

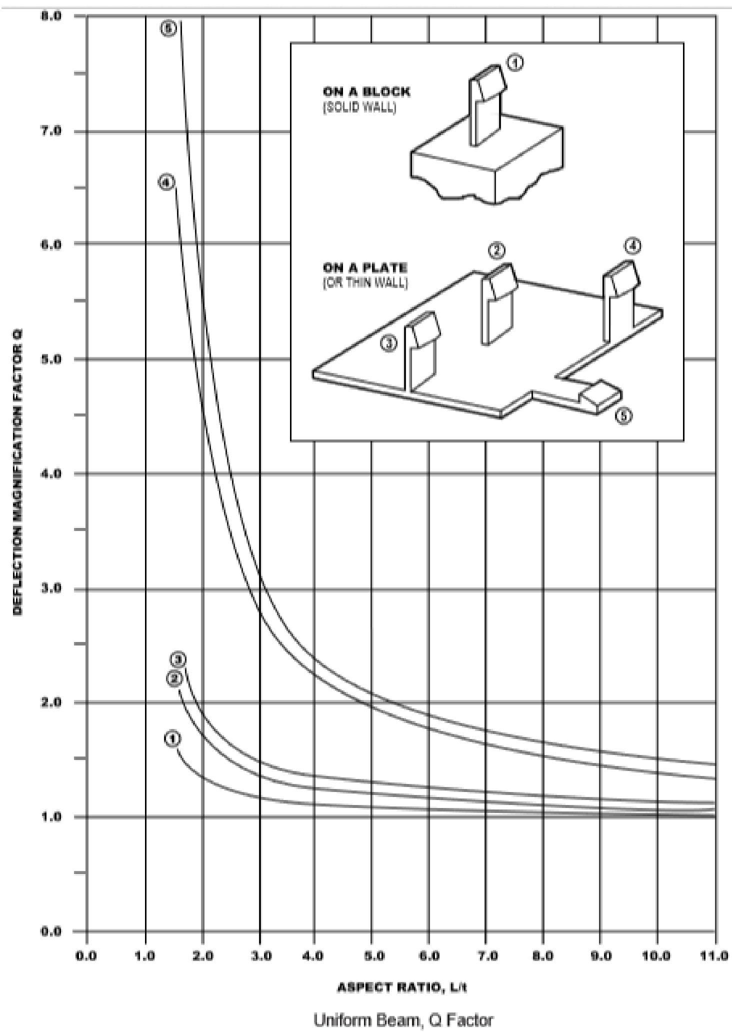



*Figure 40 - Deflection Magnification Factor*

Further modeling with Catia V5, utilizing the BASF formulas above, a plane in the middle of the wrist was created as the basis for the creation of the sketch used in the *Pocket command* to generate a 2mm gap as shown in Figure 41. This feature was designed to allow for the donning and doffing process.

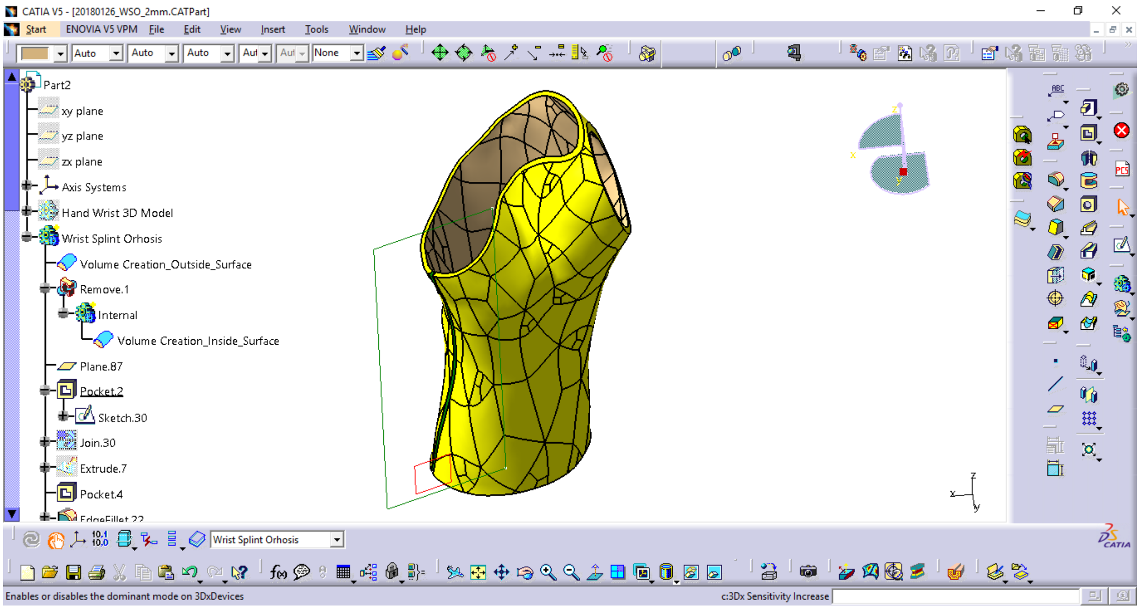



*Figure 41 - Pocket*

Using the *Pad command*, material was added as an initial profile of the cantilever that will form the snap-fit design, as shown in Figure 42 in red.

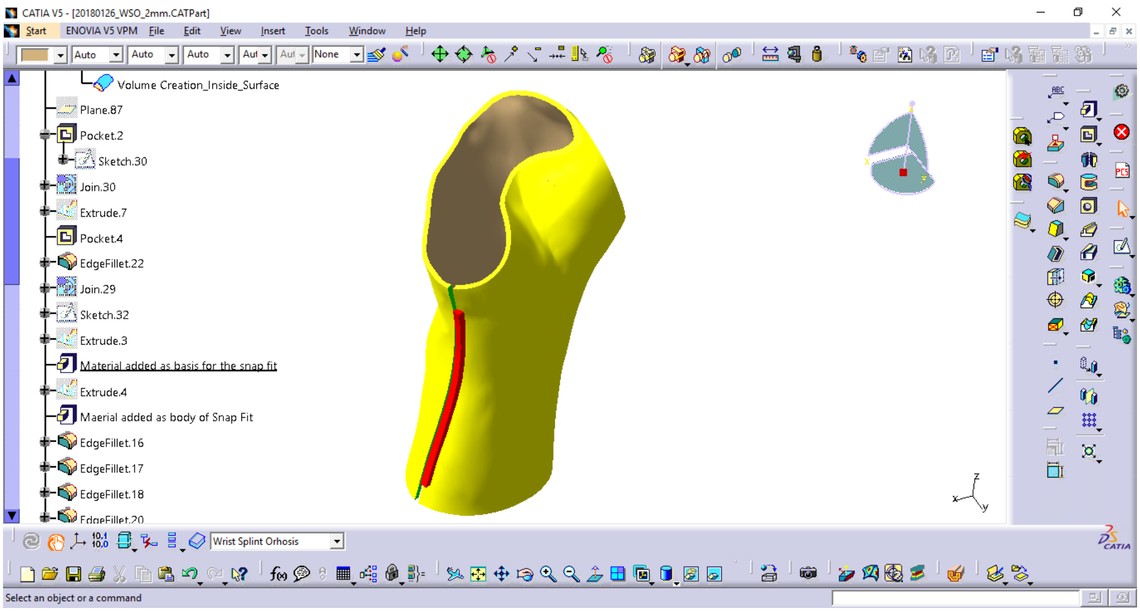



*Figure 42 - Pad*

Still using the command Pad, material was added as the back profile of the cantilever design as shown in the Figure 43 also in red.

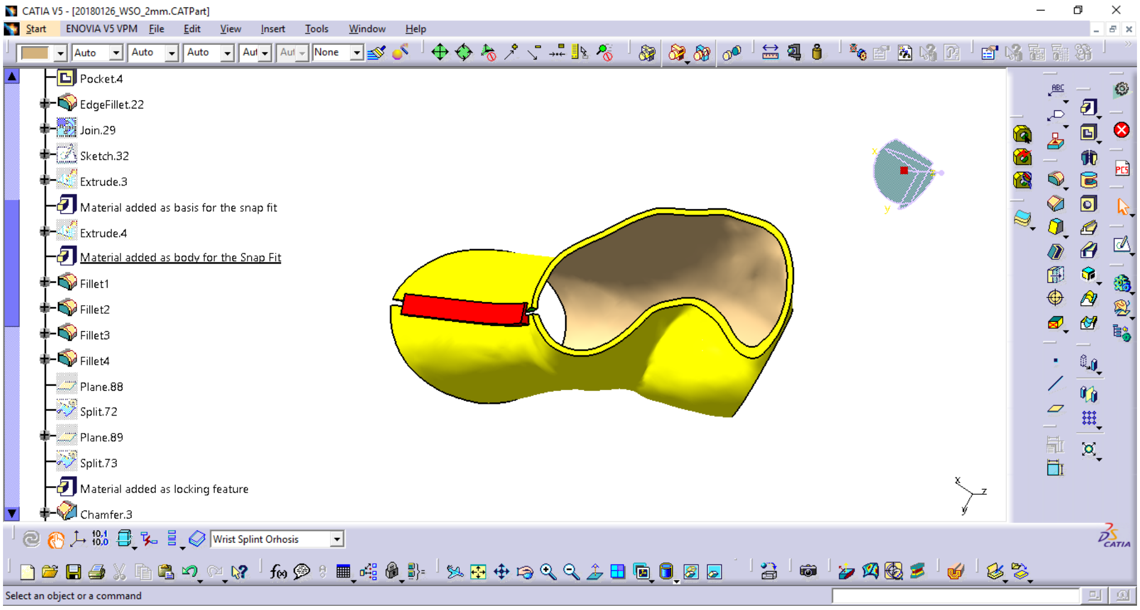



*Figure 43 - Pad*

Four fillets were added to the cantilever to increase its robustness and to avoid injury risk during doffing and donning process of the WSO, as shown in *Figure 44* in blue.

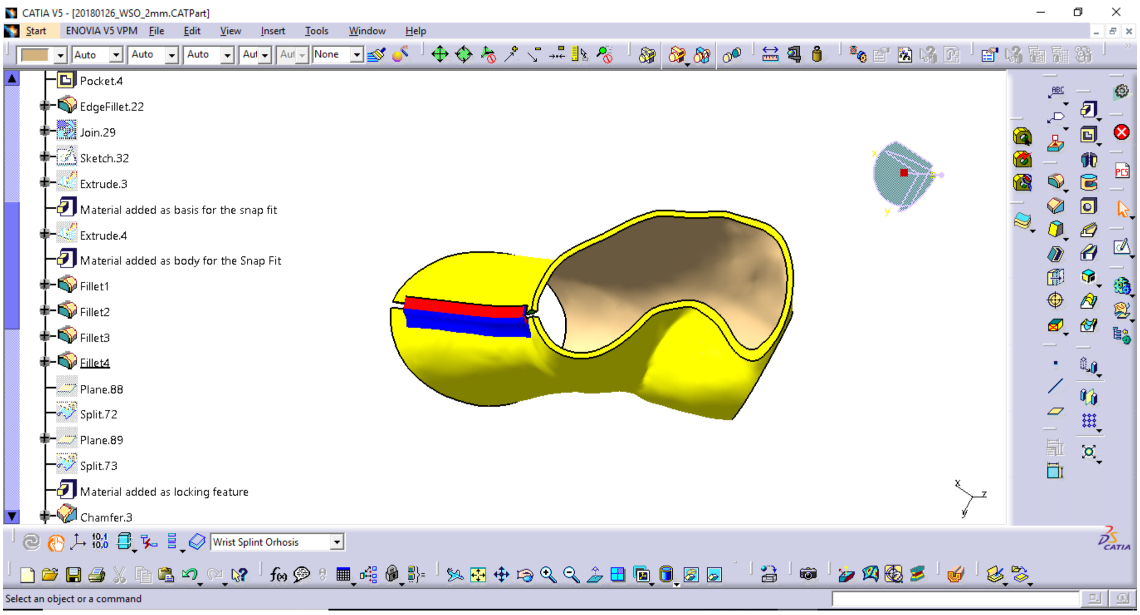



*Figure 44 - Locking feature Fillets*

Still using the *command Pad*, material was added to initiate the design of the locking feature, as shown in Figure 45 represented in orange.

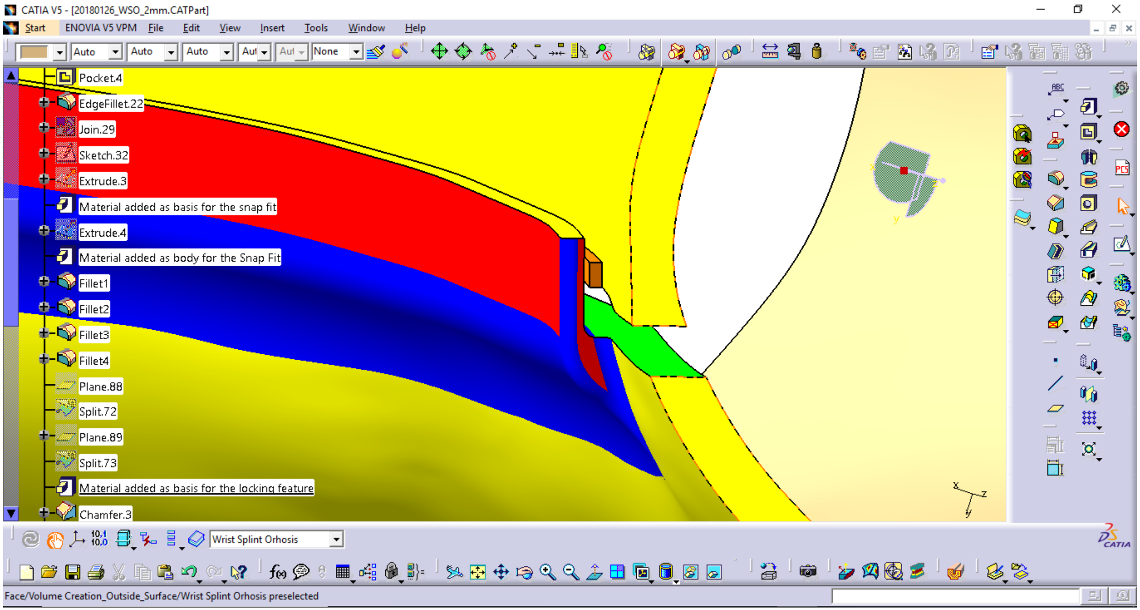



*Figure 45 - Locking feature Pad*

In order to accomplish the cantilever design, more material to form the overhanging feature was added, as shown in *Figure 46*, always following the limitation of the chosen AM process of minimum gap.

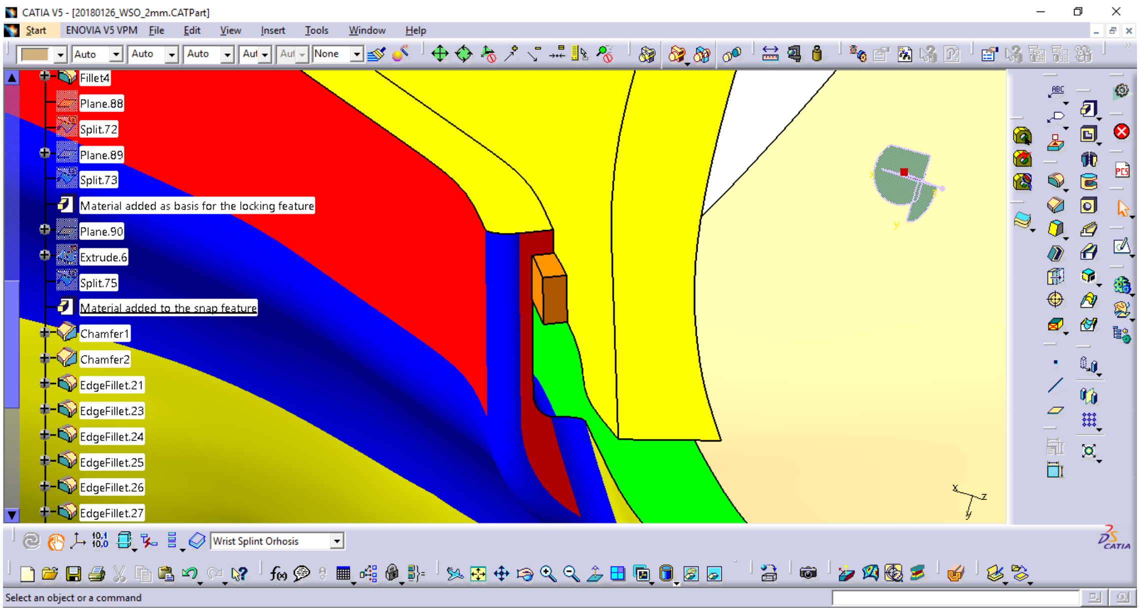



*Figure 46 - Locking feature Pad*

To facilitate the doffing and donning procedure chamfers were added to both sides of the locking feature as shown in the *Figure 47*.

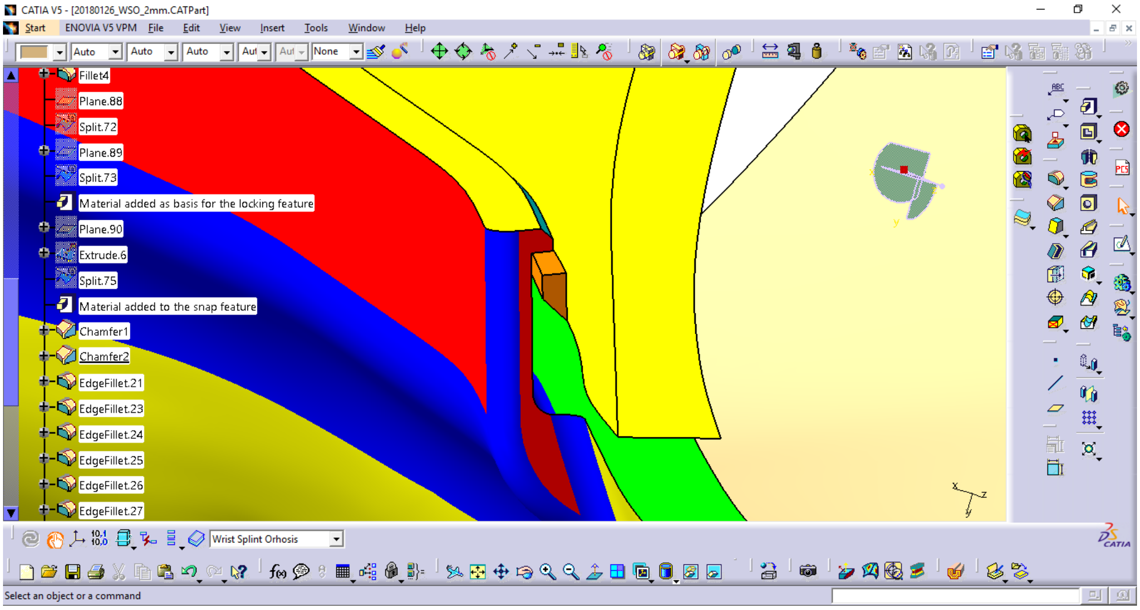



*Figure 47 - Chamfer*

A new set of fillets were added to avoid any risk of wrist injury against any sharp edges, as shown in *Figure 48*.

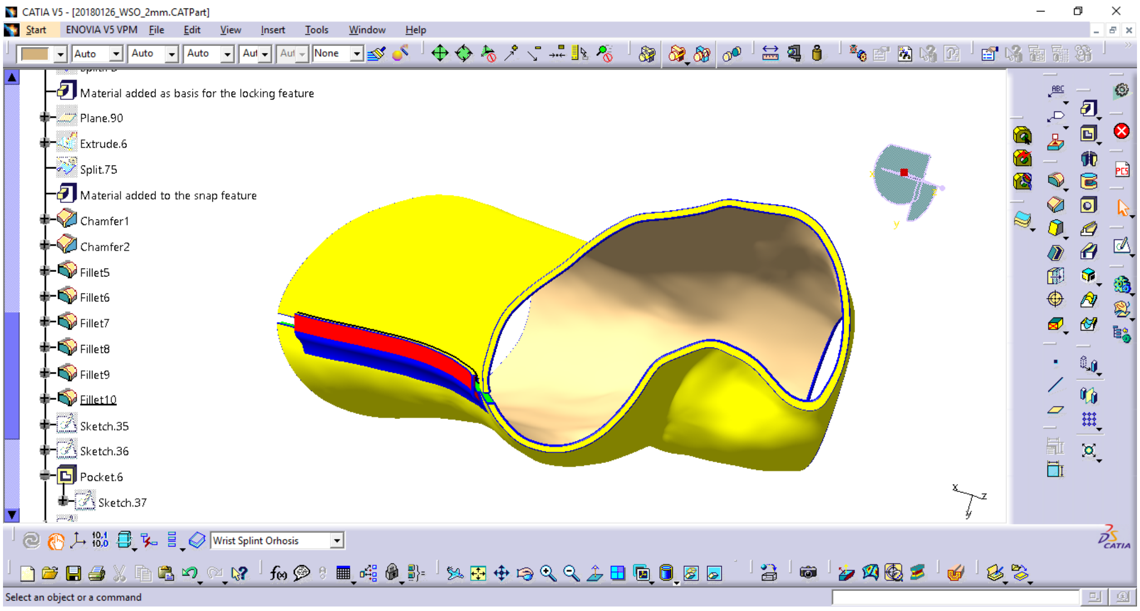



*Figure 48 - Fillets*

Using the *command Pocket*, material was removed from the upper (see Figure 49) and lower side (see *Figure 50*) of the orthosis, to fulfill the medical aeration requirement.

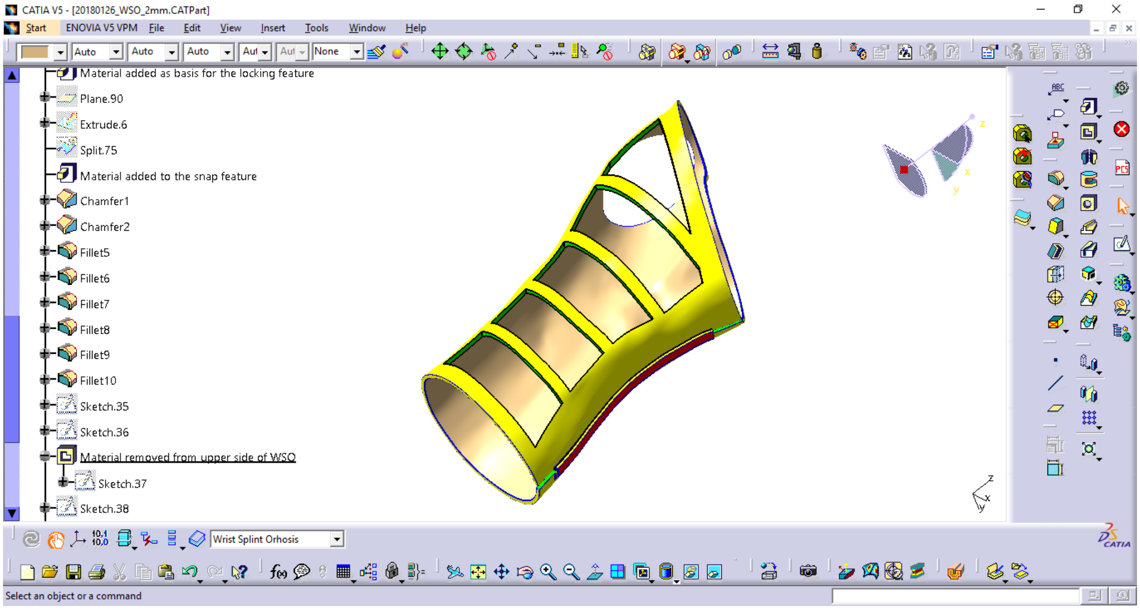



*Figure 49 - Upper WSO aeration pockets*

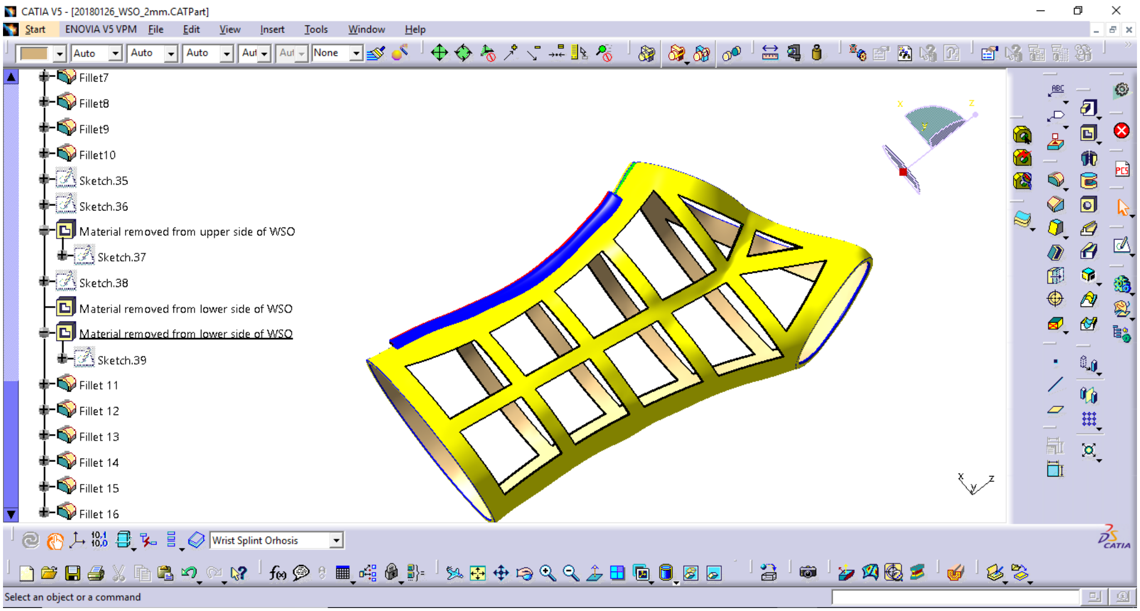



*Figure 50 - Lower WSO aeration pockets*

As the last step of this design a new set of fillets were made to give the appropriate smoothness of the WSO to avoid both injuries and discomfort as shown *Figure 51*.

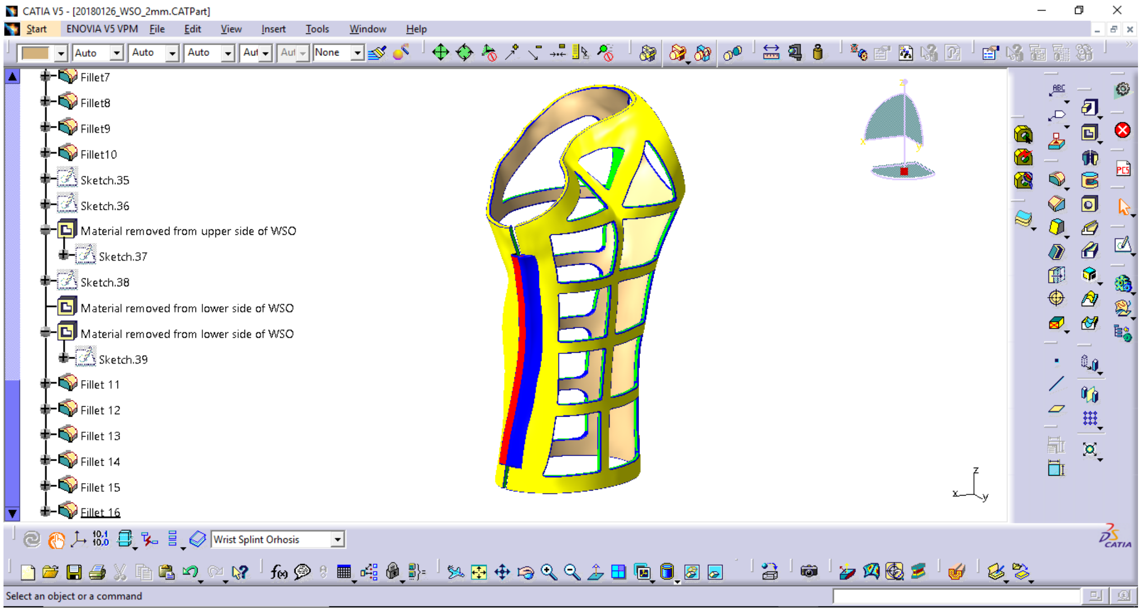



*Figure 51 - WSO fillets and final design result*

There have been many studies using a FEA tool to generate the lightest WSO possible while keeping the necessary robustness of the product. As the novelty of this work was established on the locking feature being a mono-part, made to represent freedom for the patients to be free of secondary components such as Velcro while being able to personalize the design still conforming to the necessary orthosis strength. Before leaving the *Part design module* it is required to apply the PA material to the geometrical design using the *command Apply Material*.

### *WSO design validation via FEA*

Finite Element Analysis (FEM) is a tool that can provide a proper balance between strength, mass and stiffness, also called Topology Optimization. FEM allows the calculation for the optimal material contribution to the desired part's properties.

The BASF formula to calculate the snap-fit design must now be validated using a (FEM) software. Catia V5 offers a highly interactive FEA capable of validating design. The biggest advantage of using CATIA for design validation is the associativity with CATIA solid modeling module. Any change in 3D model (Geometry, Material Assigned) are immediately reflected in the FEA scenario.

Activating FEM Solid 2 product license and starting the *Generative Structural Analysis* module it is possible to open the 3D solid model thus converting a mesh model. This mesh is composed of elements and nodes which allow Catia to analyze the structure`s deformation during the application of the load needed to disengage the snap-fit. The *Octree Tetrahedron Masher* command allows modification of the nodes on the mesh surface providing a better analysis of load propagation. Through the *Clamp* command the orthosis was constrained on the upper geometry of the snap-fit area as shown in *Figure 52* by the blue constraint indicators.

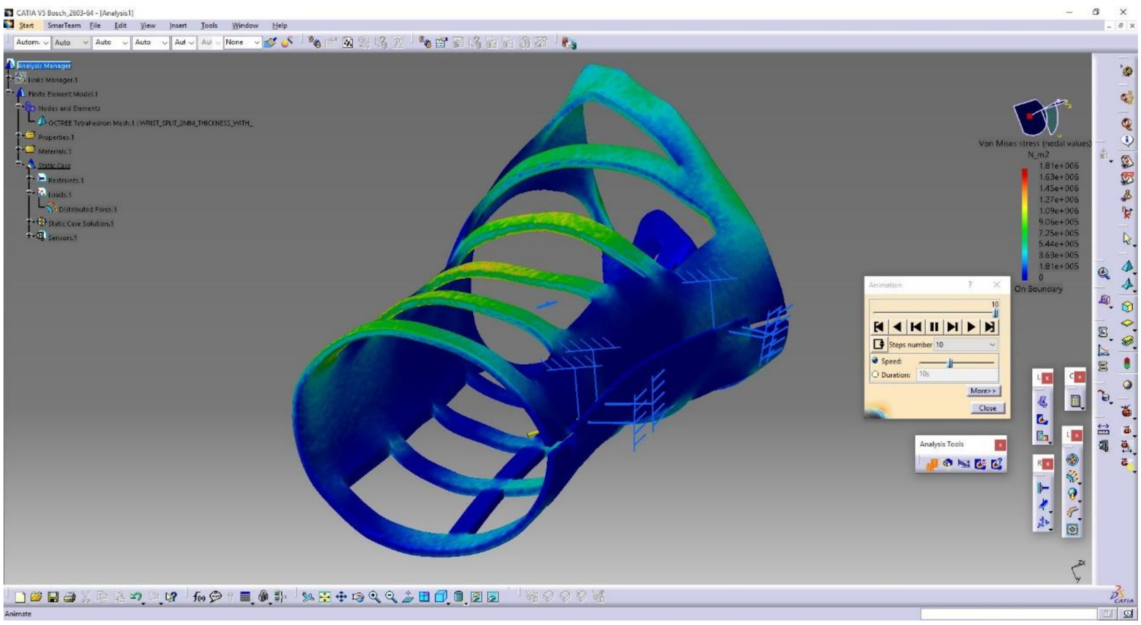



*Figure 52 - Constrained orthosis*

Using the command *Distributed Force, load*s were applied to the snap-fit closure, through the *Compute* command the displacement of the locking feature was simulated until it released as shown in *Figure 52*Figure 53. The hypothesis was that the lower portion of the snap-fit would deform enough to disengage; however, when the load was applied to the closure as shown in *Figure 53* the deformation occurred across the whole orthosis causing it to open by minimal activity. The load required to disengage the snap-fit was below the expectation.

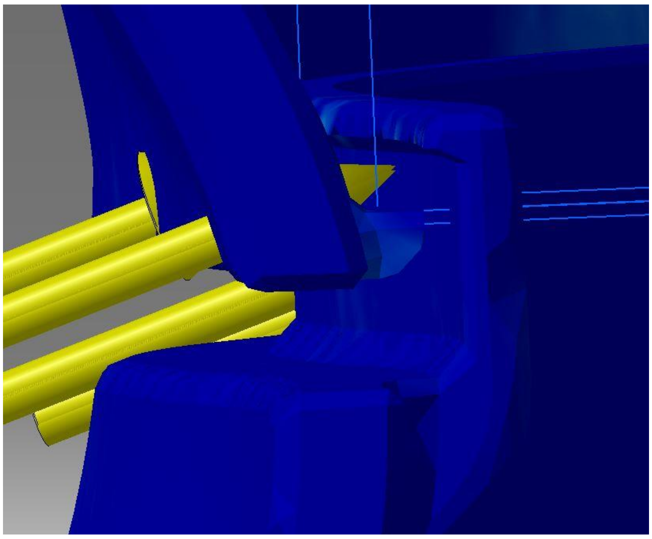


*Figure 53 - Load*

The simulation results show that at 2N the locking feature was dislodged, allowing orthosis opening. The simulation also shows that the snap-fit was not deformed with the load of 2N in accordance with the BASF formula; however, the contour of the orthosis could not provide enough structural integrity to withstand the 2N.

A new improved design was created as show in the *Figure 54* mirroring the concept of the snap-fit closure dividing it into three engageable segments which hypothetically would allow the orthosis to deform during normal activity without full disengagement as shown in *Figure 55*.

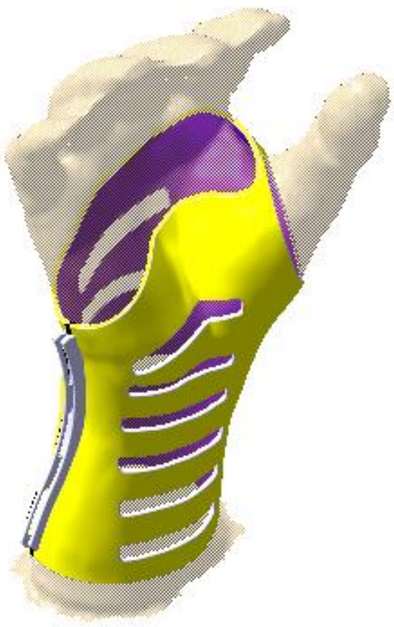


*Figure 54 - Improved orthosis design*

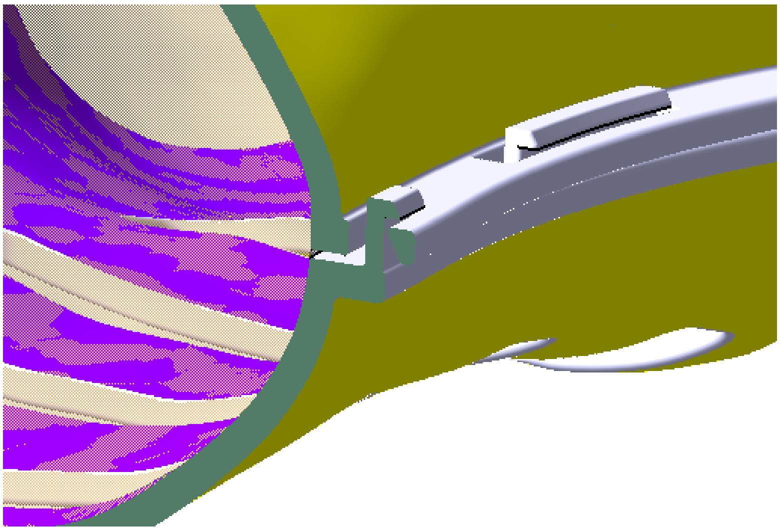


*Figure 55 - Improved locking feature*

The simulation was processed once again with a similar result, again the load required to disengage was less than the formula calculated. The locking feature functioning in a reverse direction with segmented points of engagement made it less likely to disengage during normal activity, showing a design improvement. This simulation was freeform and not yet simulated with constraints provided by the wrist.

The results of the freeform simulation show that the patient would need to apply a force of 1.5N on each of the engaged points of the snap-fit design in order to open the orthosis as shown in *Figure 56*. A secondary simulation was necessary to calculate the impact of the orthosis containing the wrist. When the orthosis contains a wrist the constraints were replaced, from only the upper side of the snap-fit closure to the whole internal surface of the orthosis. The orthosis would be self-constrained by the wrist as shown in Figure 57. In this simulation a load of 3.6N was necessary to disengage each of three locking features individually, making the total load needed to be 10.8N.

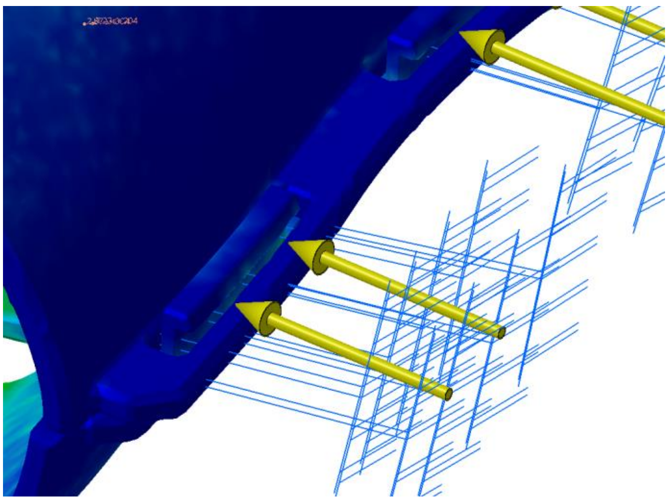


*Figure 56 - Load of 1.5N in each of the 3 locking features - WSO freeform*

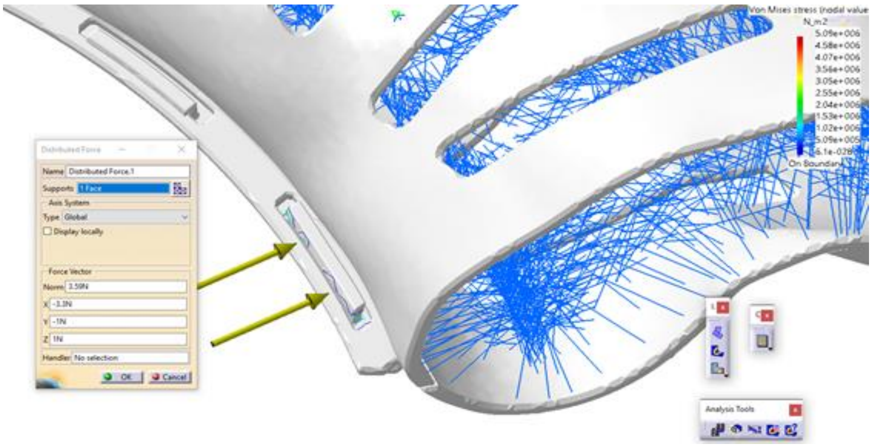


*Figure 57- - Load of 3.6N in each of the three locking features - WSO containing Wrist*

The second WSO prototype was manufactured in the PUC-PR lab with the EOS SLS AM machine however some requirements were still not sufficiently fulfilled. Such as, the WSO reported to be too tight on the patient requiring an offset to be generated from the original 3D scan wrist surface. Another result was that the force required to doff and don the orthosis is too high not due to the locking feature, but due to the orthosis robustness generated by its wall thickness. It was also noted that there is still a possibility of sequential disengagement of the snap closures because of orthosis' deformation during normal activities.

In order to improve the WSO design a new 3D model was created, using the same Catia V5 commands, but now generating an offset of 1 millimeter between the scanned wrist surface and the WSO as shown in *Figure 58*.

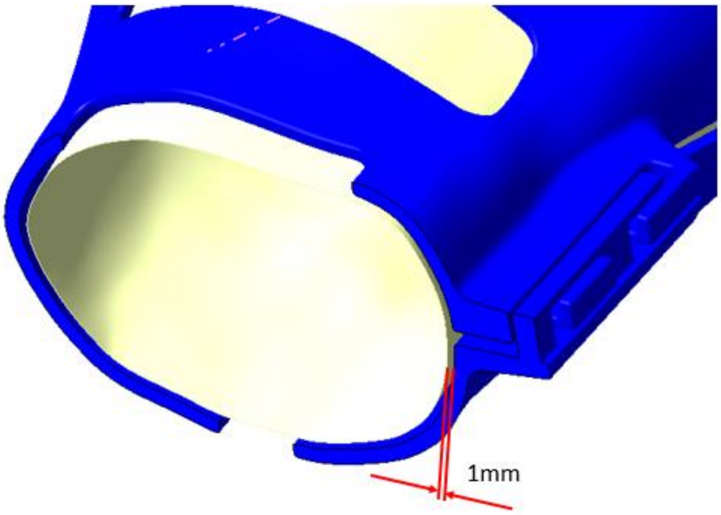



*Figure 58 - Offset 1mm*

It was also necessary to remodel the locking feature concept as shown in *Figure 59* and *Figure 60*. Using the architectural style of an entablature and columns, a new locking feature was designed to secure the WSO to the wrist during regular activities, providing support able to withstand greater wrist loads. For specific locking feature measurements see drawing in *attachment 1*.

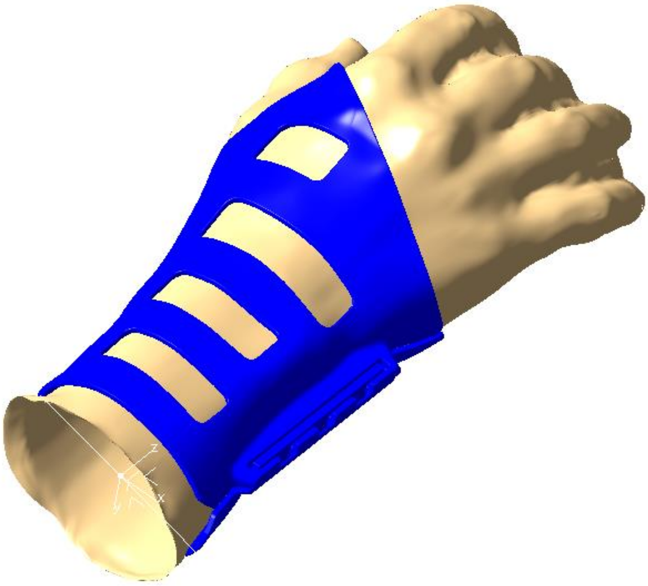


*Figure 59 - Improved locking feature*

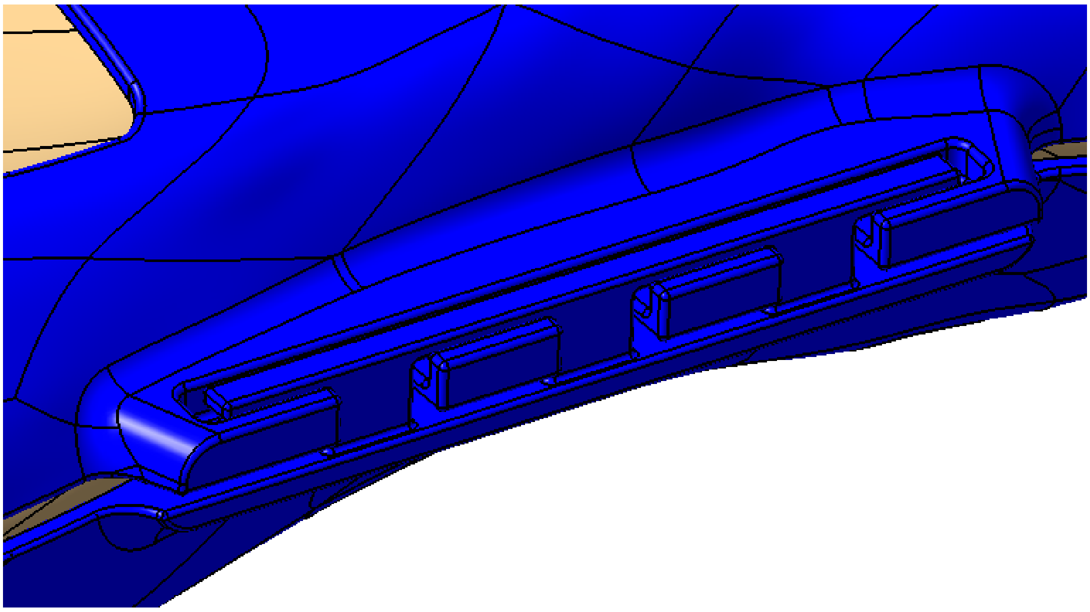


*Figure 60 - Improved locking feature*

In order to facilitate and guide the doffing and donning of the WSO, another important feature was developed, a living hinge. A living hinge is a thin flexible web of plastic that connects two or more rigid sections. Typically the larger rigid sections and the living hinge will be made of one continuous piece of plastic. The low cost and simplicity of living hinges make them a popular option for many applications. They can be found on almost every commercial product: from drink and shampoo bottles to workshop storage containers and food packaging. Through the Catia V5 *Slot Command*, the wall thickness was decreased by one millimeter horizontally, along the whole orthosis, developing a concave channel opposite from the locking feature as shown in *Figure 61*. A simulation was conducted to test the concept, that this reduction of wall thickness would allow more flexibility at the slot juncture as shown in *Figure 61, Figure 62* and drawing in *attachment 01*.

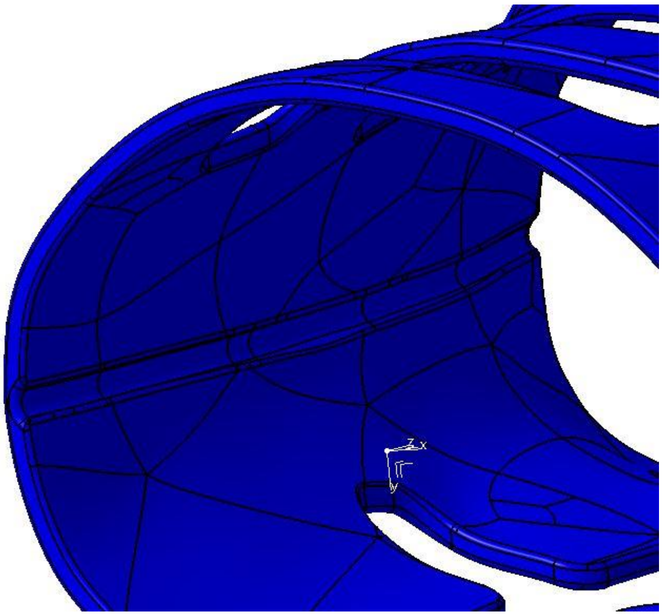


*Figure 61 - Decreased wall thickness to support doffing and donning*

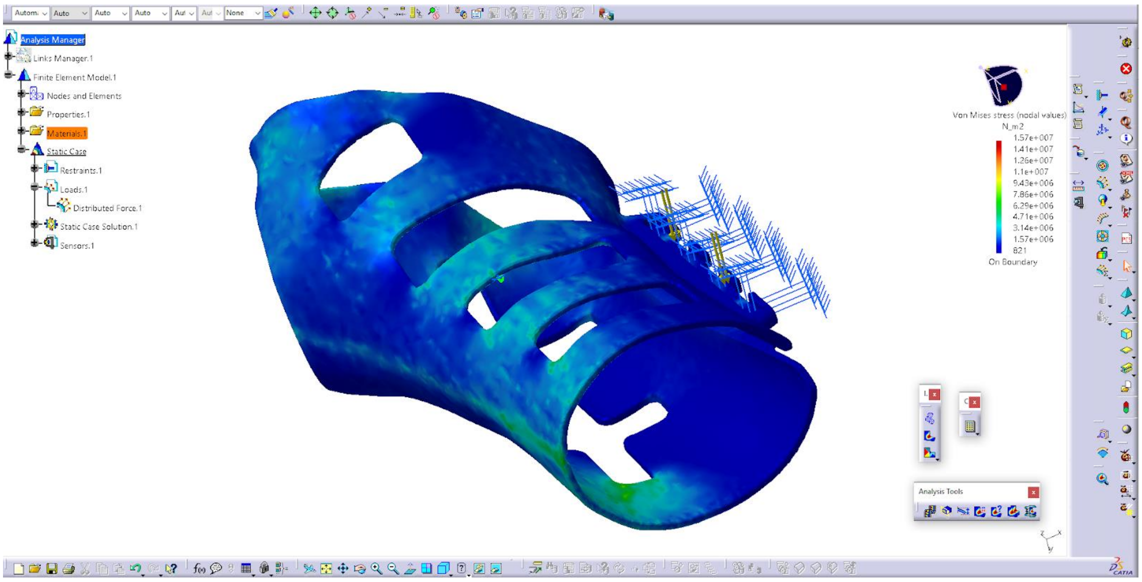



*Figure 62 - Simulation showing WSO and its load propagation through the slot feature*

A simulation was conducted to identify what loads are needed during the process of wearing the orthosis. The first step in the simulation was to use a 1N load to compress the upper and lower parts of the locking mechanism releasing the entablature from the slot see *Figure 63*. During the second step a 15N load was then simulated perpendicular to the orthosis' axis to release the locking feature see *Figure 64*. The final step in the simulation was done to generate a load of 30N used to fully open the orthosis in order to place it on the wrist see *Figure 65*, providing information necessary to validate the WSO design according to the mechanical load requirements.

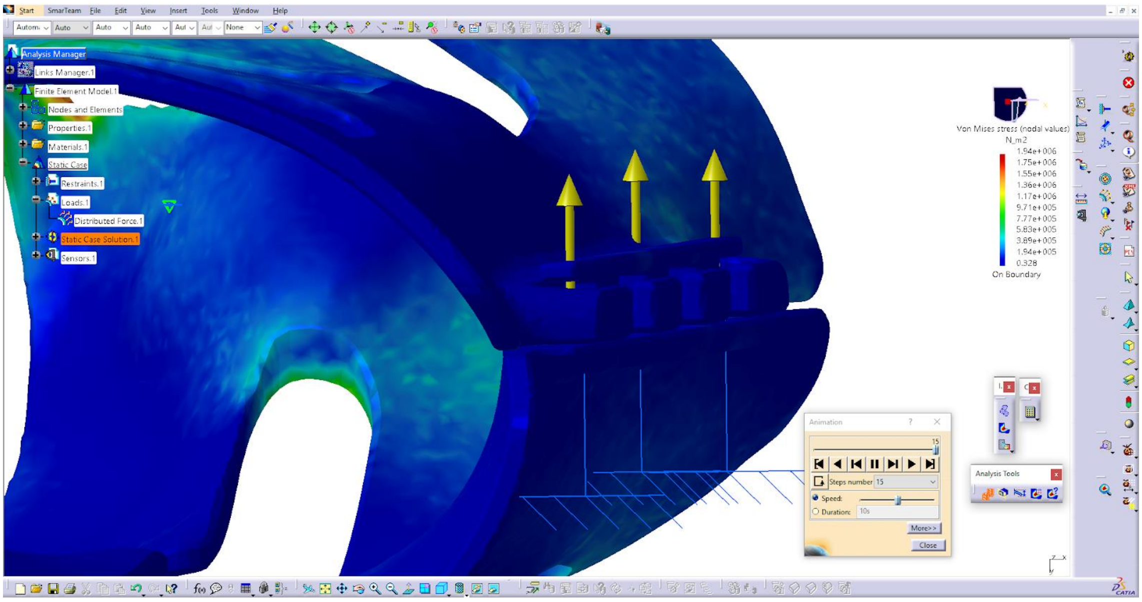



*Figure 63 - Initial disengagement step requires 1N load*

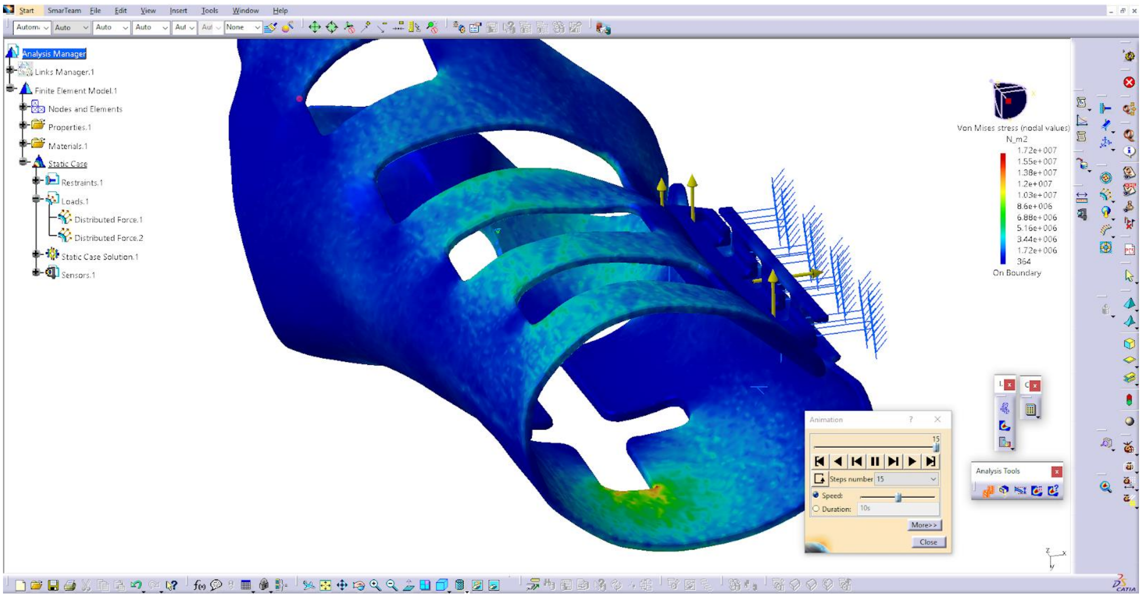



*Figure 64 - Second disengagement step requires 15N load*

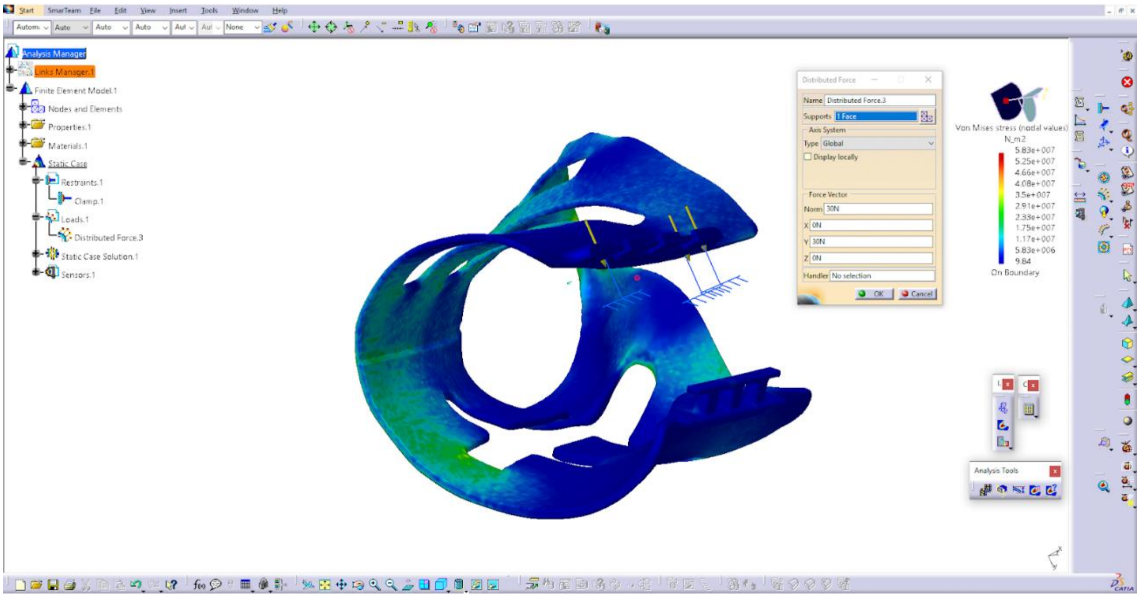


*Figure 65 - Last disengagement step requires 30N Load*

# 5. CONCLUSION

This study provides the medical industry with a guide to make a custom fit mono-part orthosis based on design elements, streamline technologies resources and a step-by-step 3D modeling process. It was also proven that the current technologies (CAD and FEA software, Data acquisition equipment and the Additive Manufacturing Process) and resources (Feedstock and AM Machines) available in the market can provide significant advantages for the patient compared with standard manual modeling of a WSO.

Unfortunately it is clear noticed that even a well-trained designer can take a long time to prepare the final design of the WSO considering all the necessary steps described in this work.

## 5.1. WSO design elements

Following an engineering product development path, and based on the physicians and patients requirements such as: being comfortable, durable, safe, practical, and easy to take on or off, and WSO functions such as: movement restriction and movement freedom, it was possible to identify design elements to properly define design elements such as: the type of locking feature avoiding WSO dislodgement during its use, the offset between the wrist shape and the WSO to assure WSO removal and avoid wrist pressure, the minimal WSO wall thickness to assure WSO robustness, the maximal WSO aeration possible to avoid long term skin issues but still ensure patient pleasure and the defined design avoiding sharp edges.

It is also clearly demonstrated that due to the WSO robustness and shape the initial proposed snap-fit locking feature did not fulfill the doffing and donning requirements, but the final locking feature design can withstand the WSO load requirements, supporting the daily activities and is easy to put on and take off. The WSO design then included a channel of decreased wall thickness to facilitate the doffing and donning process. The WSO wall thickness was defined based on stablished manual conformation process of a low temperature thermoplastic plate.

## 5.2. WSO Streamlines technologies resources

The material PA12 was selected due its biocompatibility and its versatility including excellent mechanical and thermal properties.

The SLS manufacturing process is the most common additive manufacturing technology in industrial applications. It was selected due its versatility compared with SLA and FDM process, and can create almost any geometry, regardless of complexity, resulting in almost complete design freedom

### *5.3. Modeling Process*

As the WSO design was developed to be a custom-fit part, most of the dimensions were intentionally hidden, but all the necessary CAD commands to accomplish the 3D model were specifically described, even considering that this is not the only command sequence solution. The FEA used for design validation also using CATIA V5 has shown that the rework cycle was required and have improved the final WSO design.

# 6. *FURTHER DEVELOPMENT*

The medical field can be explored in many ways and the additive manufacturing process will provide the tools for many new medical applications.

Regarding the WSO here developed, a study with different locking features could be developed once there are many examples to improve the current design.

The wall thickness was defined in this study based on current WSO available in the market and also a few samples made using the SLS machine EOSP396 but a more detailed study could improve this specific design element providing a lighter design solution and also to better open the WSO by decreasing the wall thickness in the life hinge area or modifying its profile.

An automatized mathematical process to define and customize the aeration voids, chosen by patient, would improve the design, avoid loss of robustness and can be used for further study.

A softer or more rubbery material in the internal part of the orthosis could also be used to improve the patient comfort which could be developed in subsequent studies, closing the loop of all studied designing elements.

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Attachment 01