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isec Engenharia

MESTRADO EM ENGENHARIA MECÂNICA

Tailor Made Cervical Collar Instrumented with Sensors

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Coimbra, April 2022

DEFINITIVE

INSTITUTO POLITÉCNICO DE COIMBRA

INSTITUTO SUPERIOR DE ENGENHARIA DE COIMBRA

DEPARTAMENTO DE ENGENHARIA MECÂNICA

Tailor Made Cervical Collar Instrumented with Sensors

Relatório de Trabalho de Projeto para a obtenção do grau de Mestre em Engenharia Mecânica

Especialização em Construção e Manutenção de Equipamentos Mecânicos

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Acknowledgment

Firstly, I would like to thank my girlfriend Catarina and my parents for all their help, strength, and confidence throughout this journey. Without their support, it would be unthinkable to reach the end of this chapter.

I also thank the rest of my family members and friends who supported me during this project.

I am grateful for all the help from my colleagues at the Biomechanics Laboratory for the help, especially to my friend and Engineer Nuno Cruz, as he provided essential basis and knowledge to continue my project.

Thanks to my colleague and Engineer Alex Guedes Cosme for the patience, ideas, and fellowship that we shared on our Russian adventure.

I would also like to thank my friend and physical therapist João Reis for sharing with me important ideas and documents to carry out all this work.

Regarding the work carried out in Russia, a big thank you to my friend and Professor Maxim Safronov for the precious collaboration in the entire electronic chapter of the device and his friendship and hospitality during my stay in Penza, Russia.

I would also like to thank my advisor Professor Luís Manuel Ferreira Roseiro and Luís Miguel Moura Neves de Castro for all his help from the beginning to the end of this master's project.

Resumo

O colar cervical é um equipamento médico cuja principal função é manter a coluna cervical em posição neutral e anatomicamente correta, normalmente durante o período de recuperação. O tempo de utilização deste equipamento permite a divisão em dois grandes grupos: colar de emergência e colar de recuperação. Embora os colares de recuperação tenham uma função de correção, apresentam o inconveniente de serem utilizados por um tempo relativamente longo, o que pode conduzir a problemas específicos, como atrofia muscular e úlceras, devido aos níveis de pressão e / ou humidade na pele.

Como contribuição para evitar esses problemas, foi desenvolvido uma metodologia de conceção e o protótipo de um colar cervical personalizado. O projeto que se apresenta recorre a uma metodologia de engenharia inversa com digitalização 3D, fabrico aditivo com implementação de uma camada de espuma entre a pele e o equipamento e inclui um sistema eletrónico para monitorização de alguns parâmetros vitais. O utilizador pode visualizar os parâmetros em tempo real com recurso a uma aplicação que foi desenvolvida e que pode ser instalada num dispositivo móvel.

Este relatório apresenta todo o desenvolvimento do protótipo do colar, que foi desenvolvido no Laboratório de Biomecânica aplicada no Instituto Politécnico de Coimbra, Portugal, em cooperação com a Penza State University (PSU), na Rússia.

Palavras-Chave: Projeto Mecânico; Colar Cervical; Biomecânica de Reabilitação; Engenharia Inversa

ABSTRACT

The cervical collar is medical equipment whose primary function is to maintain the cervical spine in a neutral and anatomically correct position for an extended recovery period. The time of use of this equipment allows the division into two large groups: emergency collar and recovery collar. Although recovery collars have a correction function, they have the inconvenience of being used for a relatively long time, which entails specific problems, such as muscle atrophy and skin ulcers, due to high-pressure levels and/or humidity in the skin.

As a contribution to avoid these problems, a tailor-made methodology and a prototype of a personalized cervical collar were developed. The project uses reverse engineering through 3D scanning, additive manufacturing with the implementation of foam between the skin and the equipment and includes an electronic system for monitoring some vital parameters. The user can visualize the parameters in real-time with an application that can be installed on a mobile device.

This report presents the collar prototype, which was developed in the applied biomechanics laboratory of Polytechnic of Coimbra, Portugal, in cooperation with Penza State University (PSU), in Russia.

Key Words: Mechanical Project; Collar Cervical; Biomechanics of Rehabilitation; Reverse Engineering

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SYMBOLS AND ABBREVIATIONS

3D	3 Dimensions
CAD	Computer Aided Design
CRPU	C-Collar Related Pressure Ulcer
CT	Computer Tomography
EPUAP	European Pressure Ulcer Advisory Panel
HS	Humidity Sensor
ICP	Intracranial Pressure
IQR	Interquartile Range
ISEC	Instituto Superior de Engenharia de Coimbra
MRI	Magnetic Resonance Imaging
ONSD	Optic Nerve Sheath Diameter
PLA	Polylactic Acid
PCB	Printed Circuit Board
PS	Pressure Sensor
PSU	Penza University State
PU	Ulcer Pressure
STL	Standard Triangle Language
TMCCIS	Tailor Made Cervical Collar Instrumented Sensors
USB	Universal Serial Bus
WHD	Wearable Health Devices

1. INTRODUCTION

The cervical collar is medical equipment whose main function is to maintain a cervical spine in a neutral and anatomically correct position for a long period of recovery.

The time of use of this equipment allows the division into two large groups: emergency collar and recovery collar, the last one will be being the focus of this work.

Although recovery collars have a correction function, they have the inconvenience of being used for a relatively long period, which entails certain problems.

One of the main problems with the collars is muscle atrophy in some areas of the neck where the equipment is applied. The construction and use of standard models of necklaces can also lead to discomfort on the part of its users due to anatomical differences.

The long use of certain standard cervical collars can develop ulcers due to high pressure exerted in certain areas of the patient. Another problem due to the long use of the collar is the poor oxygenation of the skin in areas where the device is applied, which consequently causes humidity. The development of humidity increases the risk of developing ulcers.

Taking this problem into account, the hypothesis of this project emerged, which seeks to alleviate these difficulties using 3D scanning and the application of foam between the patient and the equipment, including a system for monitoring some vital parameters and the possibility of the patient visualise in real time through a mobile device the values of the sensors.

This work was developed in the applied biomechanics laboratory of ISEC in cooperation with Penza State University (PSU) in Russia. The mechanical component of the project was developed and implemented in Portugal, and the electronic part was prepared and implemented in Penza, in the framework of an ICM Mobility.

All work will be divided essentially into 3 large groups. The first chapter is the state of the art, where basic knowledge and essentials of the anatomy of the neck and cervical spine will be addressed to frame the entire theme of this project. The various cervical recovery collars on the market will also be mentioned and the problems they can bring to the patient after a long period of use. Patents that present projects where there is also a desire to find solutions to the disadvantages of collars on the market, or projects where they also present instrumentation mechanisms with sensors, will also be referenced. The next chapter is Tailor-made methodology to create a cervical collar, where solutions that seek to solve the problems existing in cervical collars on the market will be listed. Then, the construction of all the equipment begins, passing by the reference of the technologies used, such as reverse engineering and the manufacturing process by addition and the materials used. The various steps taken using the *Solidworks®* tool will also be described with the help of figures. In the final phase of the chapter, 2 examples of cervical collars will be available for two different volunteers.

The last chapter is Cervical Instrumented collar with monitoring sensors developed in cooperation with Penza State University (PSU) in Russia. The electronic component was prepared and implemented in Penza, as part of an ICM Mobility. This chapter will refer to the various types of pressure and humidity sensors on the market and the choice for the medical equipment. It will also be described some electronic components that have high importance throughout the structure. Finally, the application created for the necklace user who, through it, can access the values that the implemented sensors return, will be described and with the aid of images.

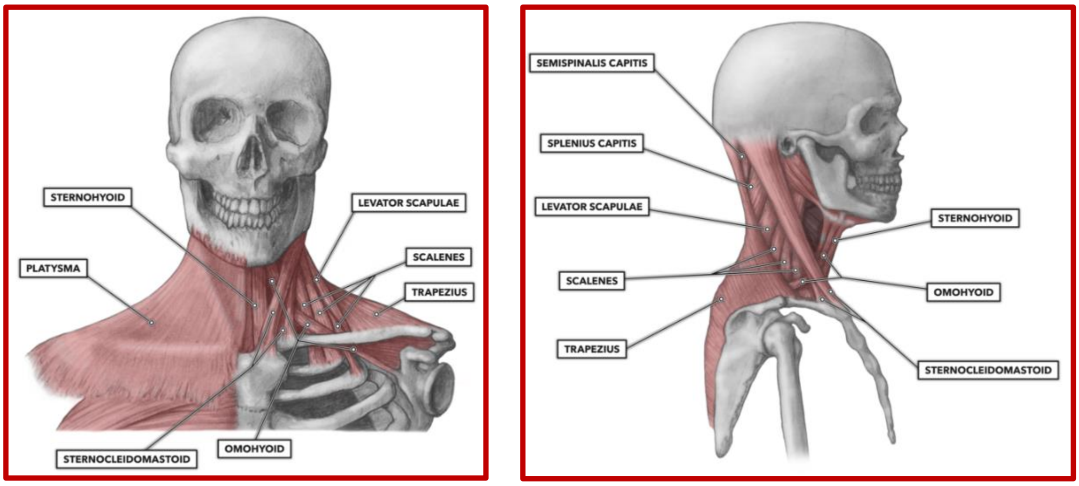
2. STATE OF ART

For the creation of the collar mentioned in this project, it is necessary to understand the context in which the equipment will be inserted. The Collar has the function of protecting the patient's spine more accurately in the neck area, therefore, it is important to understand the functioning of the spine of an introductory one to understand and create the necessary conditions to develop equipment that allows its entire protection.

2.1 Anatomy of Neck and Spine

The neck is composed of a wide variety of vital structures that are cervical spinal cord, vertebrae, vertebral disks, muscles, vertebral ligaments, nerves, blood vessels, pharynx, larynx, trachea, esophagus, thyroid gland, parathyroid glands, and lymph nodes. More precisely the muscles have great importance because they are responsible for head movement, stabilizing the upper region of the body, assisting in swallowing, helping to elevate the rib cage during the inhalation. In addition to all the previously referenced functions, they attach to various bones of the skull, spine, thoracic cage, and shoulder girdle.

Many muscles that make up the neck areas are shown in figure 2.1, but it is important to mention that the Sternocleidomastoid and Scalenes are responsible for certain movements that the person can perform with the head. Both acts together in several muscle actions to allow the lateral neck flexion, neck flexion, and contralateral head rotation.



a) b)

Figure 2.1 Double Figure of the cervical muscles. *(CrossFit 2019)*: a) Frontal View; b) Lateral View.

The spine is formed of approximately 33 vertebrae, which are subdivided into 5 groups related to morphology and location: cervical thoracic, lumbar, sacral, and coccyx vertebrae.

As shown in figure 2.2, the 7 cervical vertebrae that are located between the chest and the skull are mainly characterized by their small size. The 12 thoracic vertebrae are characterized by their articulated ribs. Next are located the 5 lumbar vertebrae that give rise to the skeletal support for the posterior abdominal region and are characterized by their large size. In the penultimate group are the 5 sacred vertebrae fused into a single bone called the sacrum.

Finally, there is the group of vertebrae of the coccyx, which present a varied number, but generally 4.

With a Right Lateral View side, as shown in figure 2.2, the entire spine has a natural S-shaped curve. The spine's overall curve is made up of 4 distinctive and important curves: Cervical Curvature (Lordosis), Thoracic Curvature (Kyphosis), Lumbar Curvature (Lordosis), and finally the Sacral Curvature (Kyphosis). Together, the 4 curves of the spine maintain their strength and flexibility, thus, when the spinal loses its healthy curve, there is a significant loss of strength and flexibility.

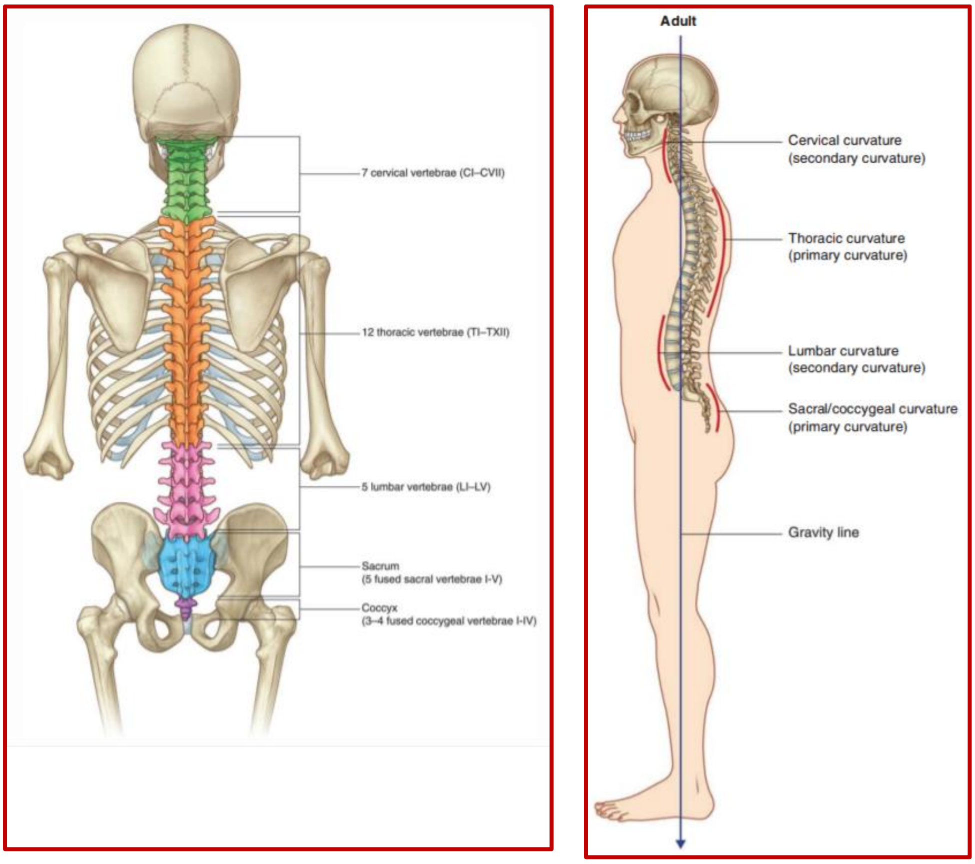


Figure 2.2 Adapted Image from Drake (2015): a) Vertebrae; b) Curvatures of the vertebral column.

In terms of injuries in the cervical zone, according to Cervical Injury, (2021), trauma is the most common cause of cervical injury. Trauma injuries include motor vehicle accidents, falls, penetrating or blunt trauma, sports-related or diving injuries.

In terms of non-traumatic injuries, causes can include compression fractures from osteoporosis, arthritis, or cancer and inflammation of the spinal cord.

Cervical injury can be a result of flexion, extension, rotation, contusion, and compression of the spinal cord.

2.2 Cervical Collars

The Recovery Cervical Collar is a medical device for immobilization with the function of keeping the cervical spine in a neutral and anatomically correct position in the period after surgery or they can provide non-surgical relief if the patient experienced trauma or injury to his neck (from whiplash, for instance), as his shown in the figure 2.3.

Figure 2.3 Lateral X-Ray of the neck with a cervical based on Dilmen, (2011).

Within the group of recovery collars, there 3 major groups: soft, semi-rigid, and rigid collars. The difference between the 3 groups mentioned is directly related to the type of surgery and the time of use. Each type of cervical collar has its specific function. Therefore, for each type of injury or trauma, there is a specific collar for its recovery.

According to Muzin et al., (2007), with the increase in the stiffness of the collar type, the perception of possible movements for the collar patient decreases, as shown in table 1.

Table 2.1 Normal cervical motion and the effects of cervical orthoses, adapted from Muzin et al.,(2007)

	Mean if normal motion (%)		
	Flexion / extension	**Lateral Bending**	**Rotation**
Normal	100.0	100.0	100.0
Soft Collar	74.2	92.3	82.6
Semi-Rigid Collar (Philadelphia)	28.9	66.4	43.7
Rigid Collar (Halo device)	4.0	4.0	1.0

2.2.1 Soft Collar

The soft cervical collar does not truly immobilize the neck, it only limits flexion and extension in the end phase. They are made of foam rubber polyethylene, or sometimes, inflatable cuff.

Figure 2.4 Image of a Soft Collar from Malanga & MD, (n.d.)

The soft cervical collar is mostly used for whiplash injuries and neck sprains. The patient may be worn the cervical for 2 to 3 weeks for correct rehabilitation from a whiplash injury. They also help to provide support for chronic neck pain, especially in older people.

2.2.2 Semi-Rigid Cervical Collar

Semi-rigid models will be the focus of all this work presented.

They provide rigid plastic support in front and behind the patient's neck. It is designed to provide support to the cervical spine by preventing any movement while healing is taking place.

Regarding semi-rigid models, according to Prates, the most common and used models are Aspen, Malibu, Miami, Jackson, Nec Loc, and Philadelphia.

Figure 2.5 Multiple Figure of different types of semi-rigid models according to (Prates, n.d.)

Philadelphia Neck Collar, (n.d.) describes that the Semi-Rigid Collar is used for injuries on the cervical spine, which are: fractures (broken bones), dislocations (bones that move away from the normal position), subluxations (incomplete dislocations), and damage to joints, ligaments, and tendons.

It is very important for the healing to take place, the spine must remain in the correct position and the injury stabilized.

During the recovery period, the patient must be conscient that some activities/movements can injure the cervical spine, for example, physical sports, manual works, lift heavy items. The patient must take other considerations, for a healthy recovery, like keeping his environment clean and without any kind of obstacles, wearing comfortable and practical clothes mainly shoes, and report any skin problem that develops during the use of the collar.

2.2.3 Rigid Collar

A halo device is the most rigid of all cervical collars.

This device remains a useful non-operative option for the injuries of a variety of upper and sub axial cervical spinal fractures.

A halo ring is attached to the skull with four to six pins (only depends upon patient requirements) above the eyebrows at the equator of the skull. The ring is then attached to the halo vest with four metal bars which maintain the fixed position of the head and neck. The halo vest is made of a hard plastic shell with a fleece lining that can be replaced. The vest must fit snugly to prevent motion of the head and neck.

Figure 2.6 Photograph of a halo device from Vita Orthopaedics*, (n.d.)*

The patient must not make any adjustments to the halo ring, vest, or screws. Any adjustments should be made by a certified Orthotist.

2.3 Adverse effects of Cervical Collars

The application of a cervical collar in trauma patients can be lifesaving, however, they can have adverse effects, especially when used for longer periods.

Hollern (2015) describes that current cervical collars have a generic curvature of the posterior cervical spine and chin piece, and therefore do not directly support the spine, allowing for excessive head and neck movement. That type of undesirable can alter the patient's degree of cervical spinal curvature.

Therefore, there is a need for a cervical collar that form fits the user's neck for further support.

Relatively the Philadelphia collar, Lu (2016), relates that there are some issues mainly the adjusting device, therefore the Philadelphia collar has a poor and weak system of fixing and the support is not enough.

One of the biggest adverse effects of Cervical Collars is pressure ulcers. According to Ham et al. (2014), Trauma patients immobilized with a cervical collar are at risk for "C-Collar Related Pressure Ulcers (CRPU). Pressure ulcers are a serious complication and may develop in several hours of using the cervical collar.

A pressure ulcer is a localized injury to the skin and/ or underlying the tissue usually over a bony prominence, as a result of pressure in combination with shear. It is important to refer that the development of humidity and heat underneath the cervical collar will increase the risk of pressure ulcers.

According to Molano Alvarez et al. (2004), Worsley et al. (2018), they confirm the existence of pressure ulcers in patients using cervical collars. Molano Alvarez et al. (2004), found a C-Collar Related Pressure Ulcers incidence of 23.9% in trauma patients diagnosed with spine injuries. Worsley et al. (2018), present research that shows that up to 33% of pressure ulcers acquired in hospitals result from the application of the medical device.

As previously expressed, pressure ulcers are a serious problem that should be treated and above all prevent this kind of injury to guarantee a correct recovery of the patient. For preventing PU, the European Pressure Ulcer Advisory Panel developed evidence-based guidelines. These guidelines recommended implementing a whole of measures to be taken to prevent PU in general but are not specifically directed to the prevention of CRPU.

Specific preventive interventions for CRPU have been described in some studies and comprise pressure relief, regular skin inspection, and skincare. Pressure relief can be promoted by optimizing the diagnostic process of the clear C-spine: early change from extrication C-collar to long-term C-collar and the application of occipital pressure-relieving cushions.

Stage I	Non-blanchable erythema of intact skin. Discoloration of the skin, warmth, oedema, induration or hardness may also be used as indicators particularly on individuals with dark skin
Stage II	Partial thickness skin loss involving epidermis, dermis or both. The ulcer is superficial and presents clinically as an abrasion or blister
Stage III	Full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia
Stage IV	Extensive destruction, tissue necrosis, or damage to muscle, bone or supporting structures with or without full thickness skin loss

a) b)

*Figure 2.7 European Pressure Ulcer Advisory Panel: a) Logotype from (European Pressure Ulcer Advisory Panel et al., 2014); b) Pressure ulcer classification according to EPUAP from (*Figure 1. Pressure Ulcer Classification According to European Pressure..., *n.d.)*

According to Ladny et al.(2020), and others authors already mentioned previously, prolonged use of cervical collars can bring some negative outcomes, including increased risk of aspiration, difficult airways, and impaired venous return secondary leading to increased intracranial pressure (ICP).

Elevated Intracranial Pressure (ICP) is a major clinical concern and may result in poor neurologic outcomes or even death. Cervical collars and ICP is directly related to venous compression followed by impaired drainage leading to brain milieu imbalances. Because of ICP, unleash a new concern related to the optic nerve sheath diameter. Because of elevated ICP, transmitted pressures rapidly displace subarachnoid fluid into the rich trabeculation of the optic nerve sheath, thus increasing its thickness (ONSD), as shown in the figure 2.8.

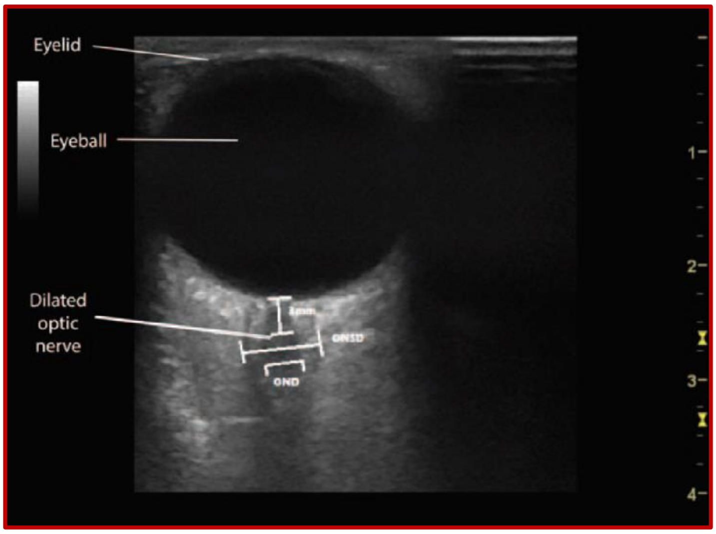


Figure 2.8 View of optic nerve sheath diameter retired from Ladny et al., (2020).

The 5 different cervical collars used for studying the 5 effects on optic nerve sheath diameter are Ambu Perfit, Philly One-Peace Collar, NecLoc Collar, NexSplit Plus, and finally the New Necklite. It is important to refer that the experience was applied in healthy volunteers at 5 and 20-minute intervals respectively.

The increase in ONSD is primarily related to the restrictive ability of the cervical collar around the neck vasculature. The 5 types used in this study were found to be restrictive, but, Philly cervical appears to cause the maximum increase of ONSD and the Necklite cervical collar (this type of collar has a relatively less restrictive nature) was reported to have the lowest change in ONSD.

Table 2.2 Optic Nerve Sheath Diameter adapted from *Ladny et al., (2020): a) Left eye; b) Right eye.*

a)

ONSD Left		
Cervical Collars	Median (Q1-Q2) 5min IQR mm	Median (Q1-Q2) 20min IQR mm
Baseline	3.8 (3.65-3.93)	3.8(3.65-3.93)
Ambu	4.505(4.285-4.61)	4.655(4.41-4.82)
Philly	4.73(4.49-4.895)	4.925(4.65-5.0611)
NecLoc	4.27(4.15-4.395)	4.415(4.27-4.55)
NexSplit	4.705(4.52-4.935)	4.92(4.68-5.115)
Necklite	3.92(3.795-4)	3.995(3.875-4.1)

b)

ONSD Right		
Cervical Collars	Median (Q1-Q2) 5min IQR mm	Median (Q1-Q2) 20min IQR mm
Baseline	3.8(3.675-3.9)	3.8(3.675-3.9)
Ambu	4.5(4.21-4.6)	4.615(4.375-4.805)
Philly	4.705(4.455-4.9)	4.93(4.645-5.075)
NecLoc	4.29(4.14-4.375)	4.38(4.265-4.52)
NexSplit	4.72(4.5-4.92)	4.9(4.67-5.1)
Necklite	3.9(3.795-3.99)	3.995(3.86-4.09)

Many other documents have some references of some adverse effects of the use of the cervical collars witch that interconnect with the adverse effects already mentioned above. For example, according to Prates, (n.d.), there are some known problems usually associated with the use of cervical collars: muscle atrophy, heavy, odor, psychological dependence, pain, lack of hygiene, and discomfort.

Muzin et al. (2007), refers that the use of cervical collars has a difficulty in nursing care and take high costs, besides in general all the adverse mentioned above from other authors.

2.4 Existing Collars

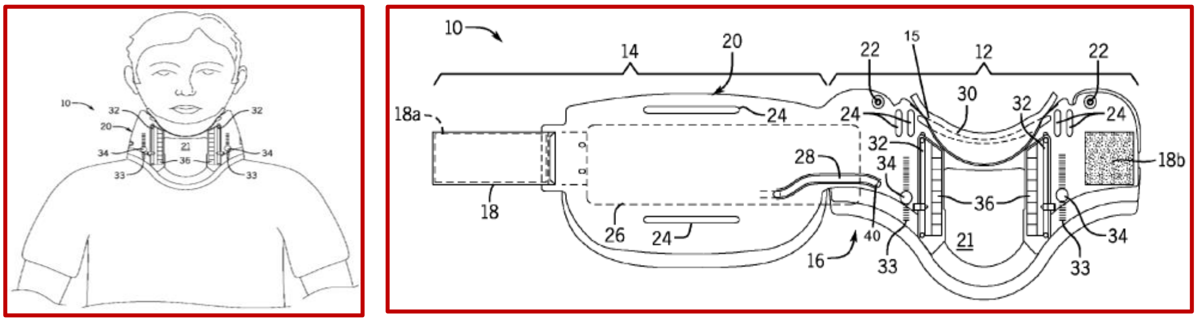
Numerous documents describe methods to overcome the existing disadvantages of traditional cervical collars, such as discomfort and the cancellation of movements that may compromise the correct position of the cervical area.

Therefore, the same documents that describe some of the advantages of the standard collars, propose some solutions to annihilate the problems, using new materials, new collars with different shapes, and even the application of certain sensors strategically placed to improve the entire recovery to the patient.

2.4.1 Inflatable Cervical Collar

(Patent N. US2015190266A1)

According to Hollern (2015), describes a cervical collar is made up of several components: interior, posterior, superior and inferior. The cervical collar may include chin support and an inflatable pocket that can be filled with gas or liquid coupled formed on the posterior and lateral sides of the body.



A) B)

Figure 2.9 Double Figure of the Inflatable Cervical Collar Hollern, (2015): a) Front View of the device in un use and in a closed position; b) Front View showing the outside of the device in an open position.

The collar must be placed all-around of the neck of the patient that allows the chin support to align and supports the chin of the patient.

The function of using the inflatable pocket is to obtain more secure support of the neck to minimize unappropriated movements of the patient, because Hollern (2015) describes that the standard cervical collars have a generic curvature of the posterior cervical spine and chin, so they do not directly support the spine, therefore allowing the existence of excessive head and neck movements that can severely harm the patient´s recovery.

2.4.2 Neck Collar

(Patent N. CN205286651U)

This document requires a cervical collar with various means of adjustment throughout the structure to increase the degree of protection of the cervical area. Lu (2016) describes that this type of neck collar with adjustments was created to eliminate the problems from the generic collars that have insufficient support, few or no adjustment devices in the cervical area.

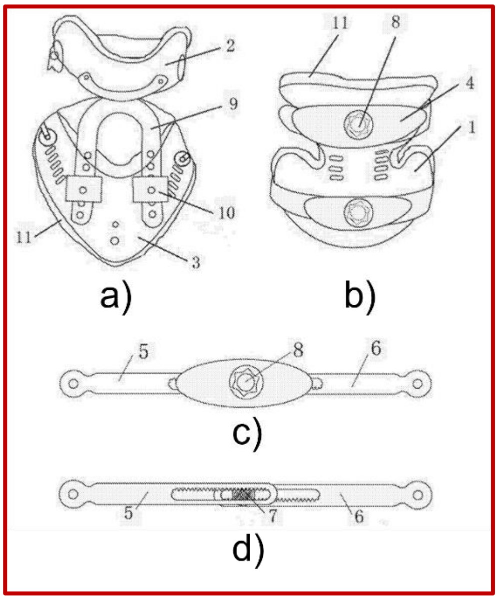


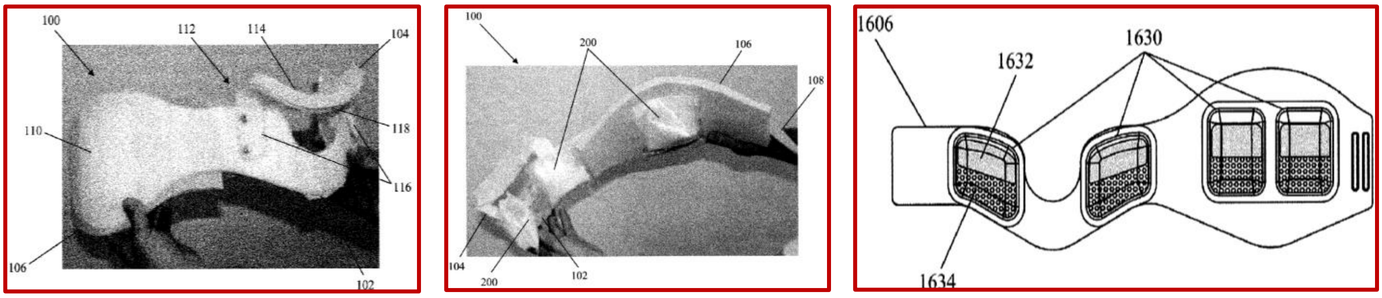
Figure 2.10 Multiple figures of the components of the Neck Collar Lu, (2016)*: a) Schematic view of the front of the utility model; b) Schematic view of the reverse side of the utility; c) Adjustable Connecting means; d) Internal device of structure diagram.*

The collar has neck support with adjustable connections between the jaw and the neck. It has an adjustable connecting device between the lower jaw and the chest support.

2.4.3 Cervical Collar

(Patent N. US2014039365A1)

Maher & Paloian, (2014), describes a cervical collar that has the function of keeping a cervical spine in a neutral position and includes a cooling mechanism for hypothermia therapy for the patient. Although, the collar can be equipped with sensors to measure the body temperature.



a) b) c)

Figure 2.11 Cervical Collar Maher & Paloian, (2014): a) Exterior View of a Cervical Collar incorporating a cooling device; b) Interior View of a Cervical Collar incorporating a cooling device; c) Front View of the Cervical Collar with the cooling chambers

The structure of the collar is divided into several parts that are easily attached and detached. The collar includes an outer shell component that is made up of two parts: the front and the back that ate fixedly attached to the front on one side and which can be removable from the front on an opposite side.

The collar features colling chambers that will be provided therapy in anatomically strategic areas, for example, the carotid arteries (provide blood flow to the brain) and the cervical areas (reduced swelling).

Therapeutic hypothermia is a medical treatment for lowering one's core temperature to, for example, 33º Celsius. According to Maher & Paloian, (2014), that patients at risk for ischemic brain injuries have better results when they are treated with that exact type of therapy.

2.4.4 Cervical Collar with kyphosis adjustment

(Patent N. US2010268139A1)

Garth, (2010), describes a cervical collar with adjustment for cervical kyphosis.

The entire structure provides a mechanism with the function of correcting the cervical spine and with possible adjustment in the relation to the patient's head and neck and includes a member in the front coupled to the neck. The collar provides a lordotic curve correctly by installing a cervical collar on the patient, adjusting it to correctly engage the head and neck, and positioning a member that extends to the rear that will not make any difference at the time of placing and tightening the entire structure of the collar.

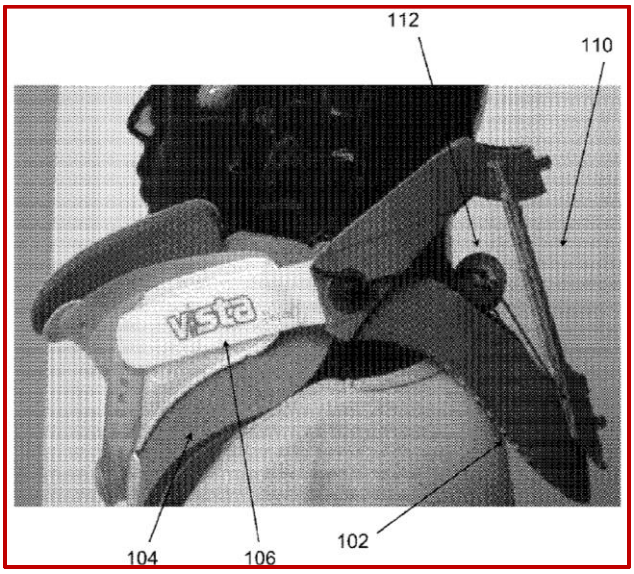


Figure 2.12 Lateral View of an embodiment of a member Garth, (2010).

The collar features at least one sensor that can be used and placed in any optional zone to detect momentary pressure by the collar in the neck to alert if the pressure force is too high.

2.4.5 Novel intelligent Neck Collar

(Patent N. CN209808684U)

According to Gong et al., (2019), describe a smart collar with a hollow and soft structure equipped with several monitored sensors that allow visualizing in real-time the values of each parameter. The sensors on the neck collar allow monitoring heart rate, blood pressure, respiration, blood oxygen saturation, neck support internal pressure, cervical carotid blood flow, and carotid artery blood flow.

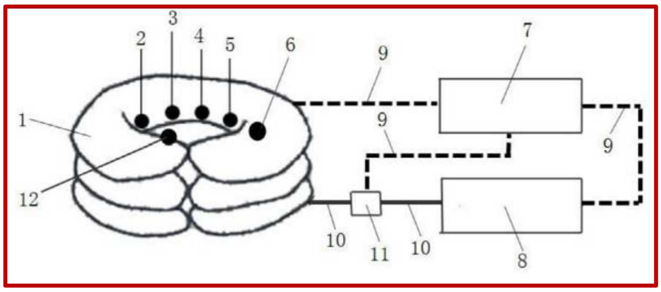


Figure 2.13 Main body of the Novel Intelligent Neck Collar Gong et al., (2019).

The smart controller can communicate with various devices using an internet device.

2.4.6 Intelligent Collar

(Patent N. CN204029122U)

This document describes a smart collar that does not protect the cervical area. Although the collar doesn't have a rigid and strong structure, presents a monitoring system that is important to be referred to. The necklace includes a shell-shaped structure of infrared ceramic powder.

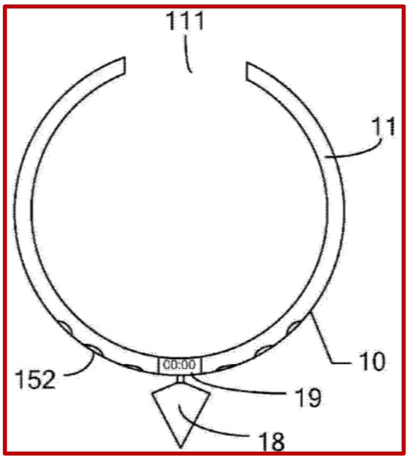


Figure 2.14 Main body of the Intelligent Collar He & Wang, (2014).

He & Wang, (2014), describes a micro control chip is placed in a necklace, and it is connected to a 3D sensor, a watch, an alarm circuit, and a monitor. The 3D sensor is used to monitor the body gestures and the alarm to alert the user that the movements being performed could put at risk the health of the cervical area. The communication interface is made through Bluetooth to have a connection with a smartphone.

3. Tailor made Methodology to Create a Cervical Collar

The recovery cervical collar is a medical device, but as mentioned in the previous chapter, in long used they bring some adverse to the patient.

The idea of creating a new type of cervical collar is to use different techniques, designs, materials, and even the application of sensors to guarantee a correct recovery to the patient and to annihilate as many possible adverse effects in the standard recovery cervical collars.

The recovery cervical collar to be presented in this document is tailor made cervical using techniques and work tools founded in reverse engineering. Therefore, each patient will get a collar different from the other patients because everyone had different physiognomy. The big advantage of a tailormade collar is the perfect fit for each person, therefore, the patient will feel more comfortable and the pressure ulcers and pain in specific zones in the body due to the use of standards collars will theoretically disappear.

The cervical collar will have implemented a type of foam in the borders of the structure. The borders are the zones where is applicated more pressure in the patient, mainly in the zone of the shoulders and jaw. The implementation of the foam only in the borders allows the structure without coating a better airflow, so the patient will feel less pain in the fix zones and be more comfortable with a better airflow inside the collar.

The structure of the entire collar is composed of to separate parts (front and back). The method of assembly is made by tape, and it requires a person to help with the mounting and supervise the entire collar in the patient.

The application of sensors can provide a correct recovery to the patient, and the sensors to be used on the collar are for measuring the pressure and humidity. The collar will be equipped with four pressure sensors and just one humidity sensor. The entire system of the humidity sensor is already equipped with a temperature sensor, thus, it's possible to measure the temperature of the patient in the specific zone when it's located the humidity sensor. The possibility to measure the pressure can alarm the patient about some dangerous movements or even a bad assembly of the collar. Concerning the humidity, can alarm the patient the percentage of humidity, so, with a big value, the collar must be cleaned and dry correctly.

The possibility of controlling the pressure and humidity existent in the collar can prevent the occurrence of pressure ulcers. Big amount of values of pressure will cause ulcers, and a big percentage of humidity will damage the skin that will cause ulcers upon a long time exposed in this humidity environment.

3.1 Materials

For the construction of the Cervical Collar, it will be used Polylactic Acid (PLA), figure 3.1, through the technology of 3D print which will be referred to and explained in more detail later. PLA is a biodegradable thermoplastic of natural origin and renewable sources, such as corn starch or sugarcane. In 3D printing, PLA gained a prominent place for its good printing characteristics, as exposed in table 3.1:

Table 3.1 Table of the characteristics of PLA

Characteristics (PLA)	Easy to print and can be used on any printer;
	Good grip on the printing table;
	Very low contraction;
	High surface hardness;
	High visual quality in print;
	Shiny pieces;
	Good adhesion between layers.

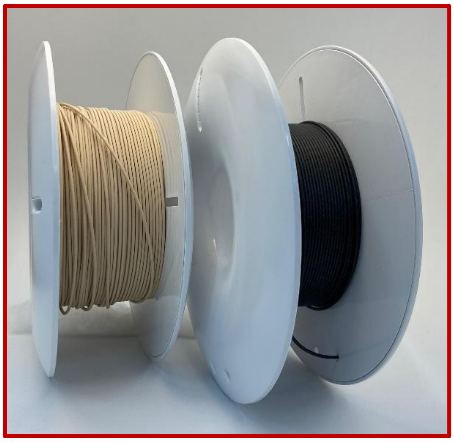


Figure 3.1 Photography of the PLA used to print the Cervical Collar and the external components.

One disadvantage of the PLA material is that has a relatively low glass transition temperature, thus, this problem makes it unsuitable for high-temperature applications.

The physical and mechanical properties of the PLA are shown in the table 3.2:

Table 3.2 Table adapted from Farah et al., (2016), with physical and mechanical properties of the PLA.

Physical and mechanical properties (PLA)			
Properties		Unit	Values
ρ	Density	g/cm^3	1.21-1.25
σ	Tensile Strength	MPa	21-60
E	Tensile Modulus	GPa	0.35-3.5
ε	Ultimate Strain	%	2.5-6
σ	Specific Tensile Strength	Nm/g	16.8-48.0
E	Specific Tensile Modulus	kNm/g	0.28-2.80
T_g	Glass Transition Temperature	°C	45-60
T_m	Melting Temperature	°C	150-162

Given that the collar will be submitted to temperatures between normal values do every day of the patient, the disadvantage mentioned will not be a problem.

After the print of the entire collar, it will be applied coating in specific zones of the equipment. It will be using two types of foams as the figure 3.2 shows. The light orange is a D33 Foam, used for example for mattress stuffing. The second foam is polyester foam, which has softer features than the D33.

Figure 3.2 Photography of the tips of foam to be used on the cervical collar.

Other different materials will be applied on the entire mechanism of the cervical collar which will be referred later, however, the main material to be applied on the main structure of the equipment is the PLA and the D33 and polyester foams.

3.2 Reverse Engineering Methodology

Reverse Engineering is a technology that generates a digital model as a physical model. Beyond the advantage to get a fully digital model with the same measures as the physical one, this type of technology is used to make some new modifications, for example, shape modifications or scale modifications. One of the best advantages of reverse engineering is the possibility to reproduce surfaces or even objects without any documentation available.

Reverse engineering is constituted of four process steps: physical model, equipment, software, and digital model.

Applying the process steps with the recovery cervical collar, all processes are illustrated in figure 3.3:

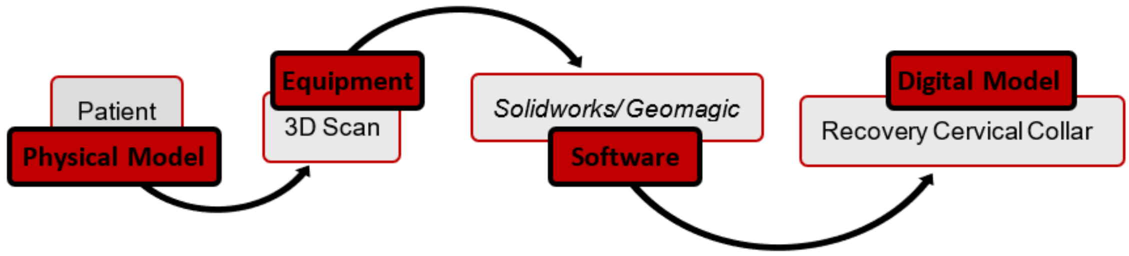


Figure 3.3 Steps from the Physical Model until the Digital Model.

3.2.1 Physical Model

The base of everything on this project is to create a tailormade cervical for each person, therefore, the patient is needed to create the final digital model: the cervical model.

3.2.2 Equipment

Exists on the market, different types of mechanisms/ equipment to obtain the digitalization. The methods of digitalization can be divided into 2 groups: with physical contact and without physical contact. Each type of mechanism has pros and cons, but the environment type, the dimension, and shape of the physical model, and even the costs are the main factors to choosing the proper mechanism.

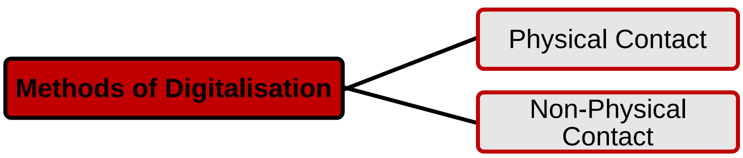


Figure 3.4 Methods of Digitalisation to apply the Reverse Engineering.

This project, its will be used a non-physical contact mechanism for the digitalization of the patient. The base of the mechanism is 3D scanning. This mechanism is a technology for creating high-precision 3D models of real-world objects. The equipment is called a 3D scanner and it takes multiple snapshots of an object.

The specific equipment used for scanning the volunteer is a "Sense™" from the software supplier "3D SYSTEMS®".

"3D Systems®" is a company that designs, manufactures, and sells 3D printers, 3D printing materials, 3D scanners and offers a 3D printing service.

Figure 3.5 3D Scan Equipment "Sense™", used in the project.

With the aid of the figure 3.6, it is possible to see structured all the schemes for the scanning process.

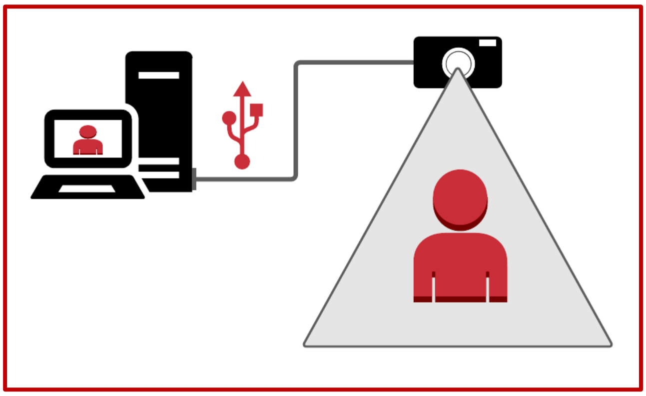


Figure 3.6 Scheme of the entire Scanning process.

The scanning equipment is connected by USB to a computer. For scanning, it is needed to install a program "3D Systems Sense®" to use during the scan. The program will help during the process as far as it's possible to see in live data the scan through the monitor.

Concerning the software "3D Systems Sense®", it is possible to choose the type of scanning: object or body. In this case, its need to scan a body to obtain the first solid model for building the collar, therefore, body. As soon as it's chosen the body scan, it's divided into two more options: the entire boy or just from the chest zone until the entire head. In this case, the second option is more than enough.

The volunteer must be attended during the entire scan process. Must be seated ideally, relaxed, and focused on a distant object to obtain a better-quality scan with the minimum involuntary moves, as shown in figure 3.7, and remove accessories and if possible, shouldn't use clothes in the zones where need to be scanned. The clothes and any accessories will not allow scanning the best surface quality from the skin. The hair must be fixed as best as possible to not influence the scan process.

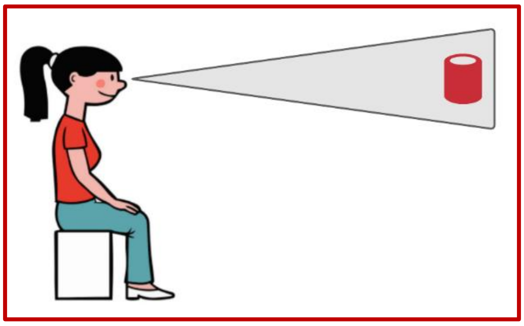


Figure 3.7 Scheme of the correctly positioning of the volunteer.

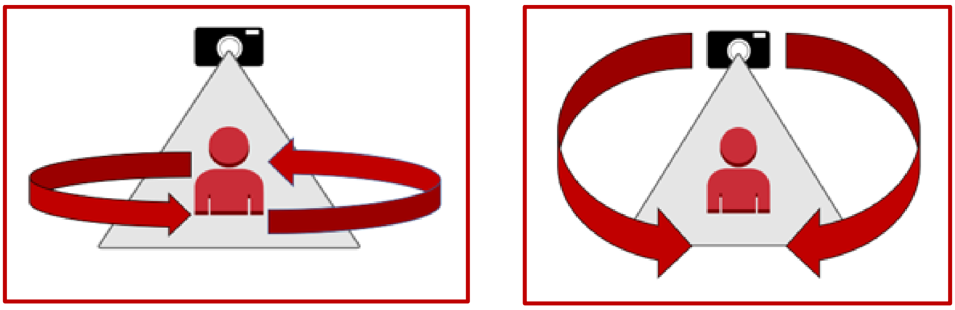
The 3D scan process works relatively slow, and it requires patience from the person who is using the equipment. The person should be steady and not make the whole scan on a fast way. It needs to consider the distance from the scanning equipment and the volunteer to be scanned, the best average distance for the "Sense™" is around 200 mm.

With the software running and the volunteer seated in the best conditions, it is necessary to choose the best way for the scan process.

As shown in figure 3.8, it is possible to understand the two methods for scanning:

In the first method (left picture) the Scan Equipment is fixed and stable and the volunteer will rotate 360º until the complete scan with the aid of a swivel chair or rotating chair (chair that allows the seat to rotate 360 degrees to the left or right).

In the second method (right picture), the volunteer is completely stable, and the equipment must scan around the person.



a) b)

Figure 3.8 Double Figure of the methods of scanning: a) The scan equipment is fixed, and the volunteer rotates; b) The volunteer is stable and the scan equipment scan around the volunteer.

In consideration of all the attention to must concern with all the process, the best method to be chosen is the second one. Thus, it´s the guarantee that the volunteer will be completely steady for the best scan model.

Figure 3.9 shows an example of the layout of the "3D Systems Sense®" software during a scan process. The green color shows the surfaces that are already scanned.

Figure 3.9 Layout of the “3D Systems® Sense” software during a scan process.

3.2.3 Software

After the entire process of the correct and best use of the scanning equipment, a proper scan model is shown at the figure 3.10. The yellow spots show zones where the scanning equipment didn't reach. The neck zone is the most important for the scan, therefore, other zones are not a priority for the best quality scan. For the entire process from the 3D scan until the final printed model of the cervical, the person used as a model will be called Volunteer A.

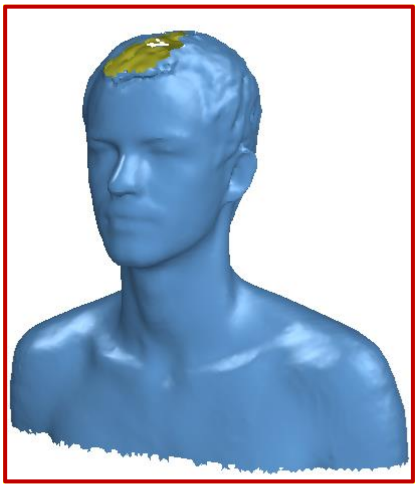
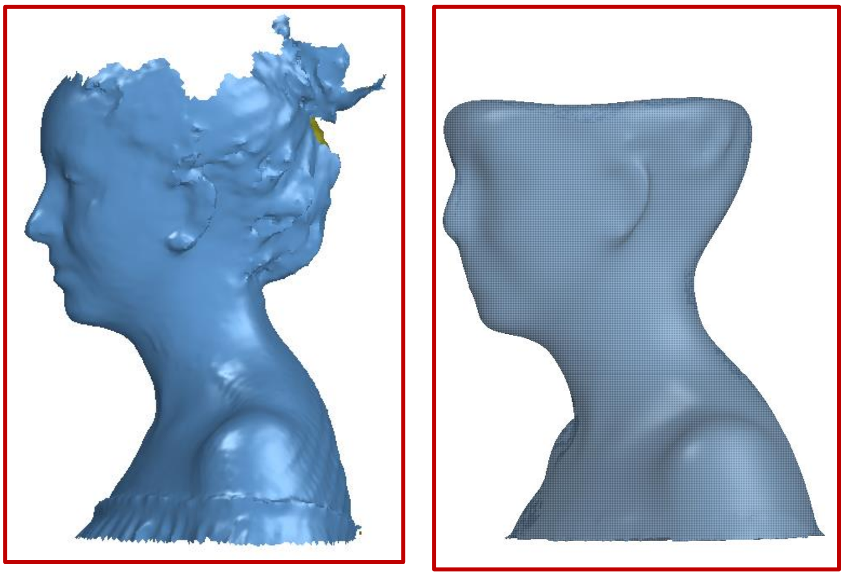


Figure 3.10 Completed Scan of the volunteer A

The software that will be used for processing the scanned model is an add-in for *Solidworks®* (Scan to CAD 3D Software Solution | Geomagic for Solidworks Plugin, n.d.) called *Geomagic®. Geomagic®* is a professional software brand of 3D Systems®.

After the completed scan, it is necessary to start some modifications to improve the quality of the final digital model. With the help of the *Geomagic®*, it's necessary to cover some holes ("Fill Holes"), remove some spikes ("Remove Spikes"), repair a few damages in the surface ("Repair"), soften the surface ("Smooth") and after all these processes build the digital model needed to start the construction of the Recovery Cervical Collar ("Auto Surface").

It is necessary to consider some details about the same modifications mentioned above. The hair will decrease the quality of the print, principally in zones where the scan is important, thus, the hair must be removed from the model to obtain the final digital model, as shown in figure 3.11:



a) b)

Figure 3.11 Double Figure of the volunteer B: a) Lateral View without any modification; b) Lateral View of the scan with modifications.

3.2.4 Digital Model

After using the needed tools from the *Geomagic®* software, the digital model of the needed surfaces to build the cervical collar is shown in figure 3.12.

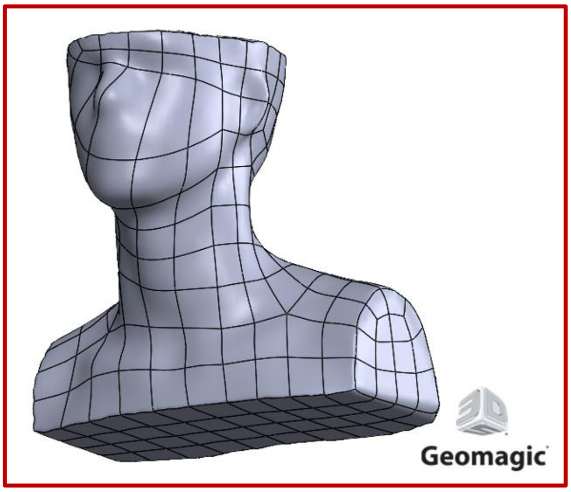


Figure 3.12 Completed Digital Model of the volunteer A using the Geomagic® Software.

To close the chapter Reverse Engineering, the figure below shows the last procedure from the physical model until the digital model, so, henceforth, it only is needed to use the tools from *Solidworks®* to make all the procedures to reach the final collar.

3.3 Cervical Collar Geometry

Upon obtaining the digital model from the volunteer, it is necessary to use the tools from *Solidworks®* to obtain the cervical collar. (3D CAD Design Software | SOLIDWORKS, n.d.)

In this chapter, it is going to be explained and shown all the procedures from the digital model until the final collar. Thereupon to build a final design of the collar, it is necessary to create a set of mechanisms with the purpose of assembly the equipment on the volunteer, thus, the collar must be divided and then apply mechanisms to guarantee the perfect assembly from both divides parts in the volunteer and mechanisms to close the entire collar. All the mechanisms must be as simple as possible and unpolluted to help the volunteer in the recovery time.

During the construction of the collar, some adversities happen. Each person has different physiognomy that distinguishes them from the other people. Because a digital of a persons' body parts is being used, it is sometimes difficult to find geometric points that can be used to build the collar as geometrically as possible.

The same applies to the creation of, for example, planes and axes. Using a model of a part of a body it is not possible just to focus on equal and exact values of distances for all people because age and gender are examples of factors that will influence the size and shape of the collar from person to person.

3.3.1 System of references

The first procedure is to create a system of references with planes and axes to be used in the entire construction.

On the Appendix A it will be explained with detail the creation of the Axis XX and YY.

The first plane being created was the Top Plane, as shown in figure 3.13.

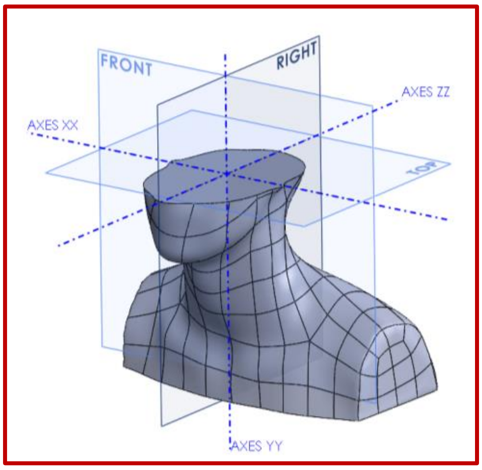


Figure 3.13 System of references created in the Digital Model.

The Top Plane shown in the figure 3.13 is a good example to exemplify the adversity refereed previously. For the creation of the plane, was used the reference the line that crosses the lower part of the nose and the lower part of the ear, as shown in the figure 3.14.

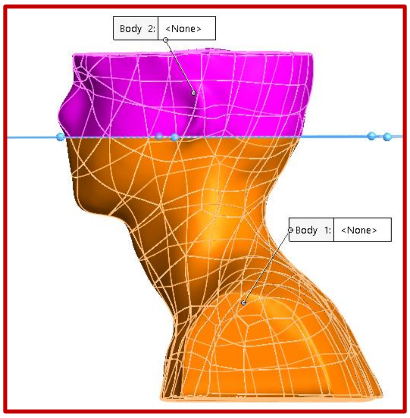
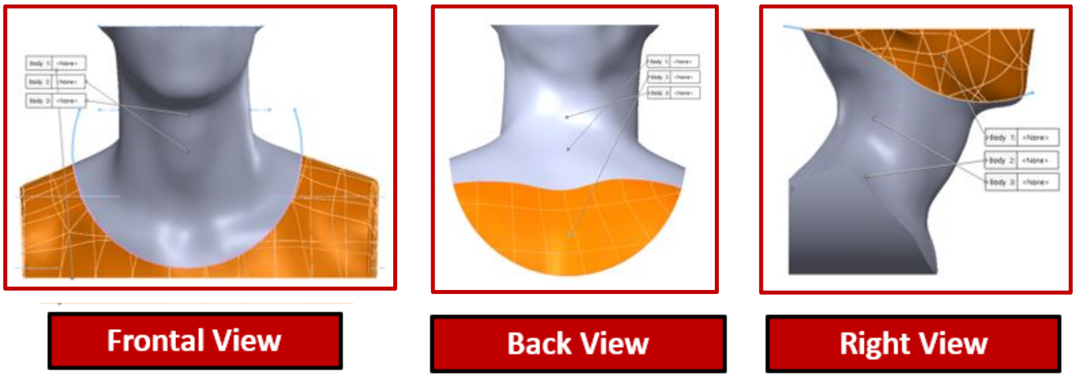


Figure 3.14 Lateral View of the Digital Model to create the Top Plane.

3.3.2 Generalization of the Collar

As mentioned before, one of the best vantages of this type of collar is the tailor made construction, however, it's crucial to create a general system to help the operator to build different collars for a different person in a fast and simple way. It will be measuring some specific dimensions from the volunteer to create relations to build planes and sketches to cut ("Split") the unnecessary zones as shown in figure 3.15. The relation with the specific measurements and the created planes and sketches are the base of the entire optimization.



a) b) c)

Figure 3.15 Multiple View of the Cut the Unnecessary zones of the Digital Model for the volunteer A: a) Sketch and Cut of the Frontal View; b) Cut of the Back View; c) Sketch and Cut of the Lateral View

The system of generalization was created after the building of the first cervical collar (volunteer A).

The relations between the different planes and distances were simplified to values with more preciseness. The dimensions measure from different parts of the volunteer was round for one decimal unit.

In a row, it will be explained with accuracy the different relations created to create a general method.

Frontal View

Starting with the Frontal View, the engineer will need two measurements: "FACE" and "NECK". Using the TOP Plane, it is possible to measure the distance from the edge of the ear to another edge (FACE). The next procedure is to create the LINE ALPHA, using the equation:

$$LINE \ = ALPHA\ FACE \ \times 0.50 \qquad (3.1)$$

The second measure needed from the volunteer is the NECK, using the LINE APLHA.

Another Line must be created using the volunteer 's clavicle as a reference. The LINE BETA must be drawn below the clavicle between the values 20mm and 30mm.

The next process is creating a circle with will be responsible for the front cut. Using the NECK dimension, it was possible to create the next equation:

$$Circle_1 = NECK \times 1.75 \qquad (3.2)$$

The $Distance_1$ its basically the radius of the $Circle_1$, and should be collinear with the Axes YY.

$$Distance_1 = \frac{Circle_1}{2} \tag{3.3}$$

In a row the $Circle_1$ must be cut in a specific zone ("Trim") to prevent the split of necessary zones.

In the figure 3.16, it illustrated a sketch scheme for the cutting in the Frontal View.

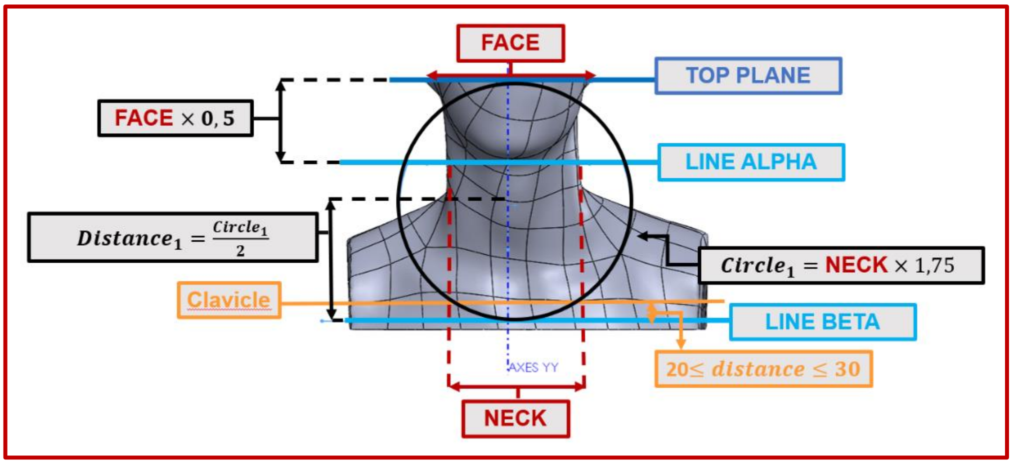


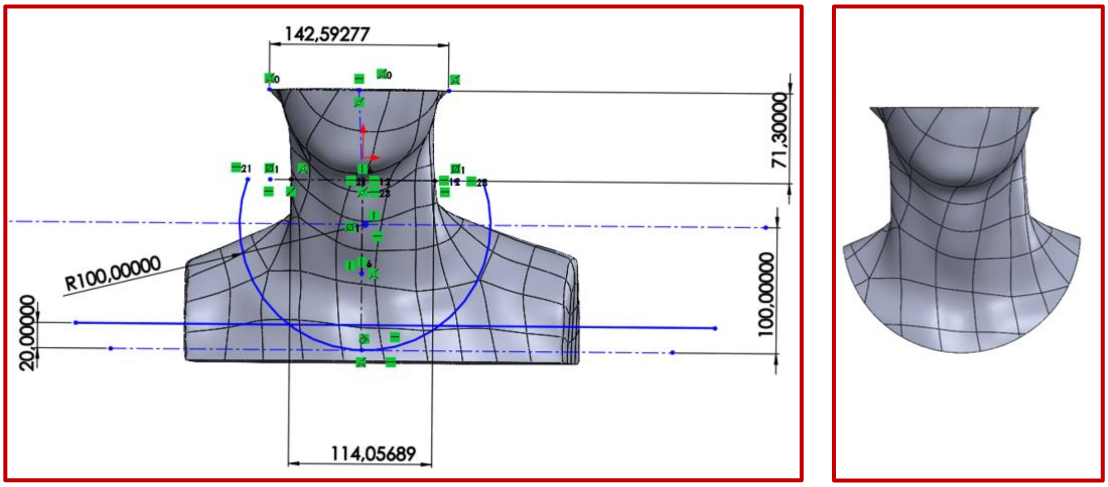
Figure 3.16 Sketch Scheme for the cutting on the Frontal View.

For the construction of the cervical collar for volunteer A, the dimensions needed especially for the Front Cut and equations are represented in table 3.3:

Table 3.3 Dimensions and Equations for the Front Cut.

Dimensions of the volunteer A	Equations
$FACE \cong 142.6mm$	$LINE\ ALPHA = FACE \times 0.50$ $LINE\ ALPHA = 142.6 \times 0.50$ $LINE\ ALPHA = 71.30mm$
$NECK \cong 114mm$	$Circle_1 = NECK \times 1.75$ $Circle_1 = 114 \times 1.75$ $Circle_1 \cong 200mm$
	$Distance_1 = \frac{Circle_1}{2}$ $Distance_1 = \frac{200}{2}$ $Distance_1 = 100mm$

The sketch of the volunteer A and the cut procedure is represented on the figure 3.17:



a) b)

Figure 3.17 Double Figure of the Sketch Scheme for the Cutting in the Frontal View with the dimensions of the volunteer A: a) Sketch and Dimensions of the volunteer A; b) Final cut of in the Frontal View.

Back View

The next procedure is the cut on the back view. Comparatively with the all procedure for the front view, it is a small and easy one.

It is only needed to create a Plane (Back Plane) and use it for the cut ("Split").

The operator will need a measure already used for the procedures on the Front View, the NECK.

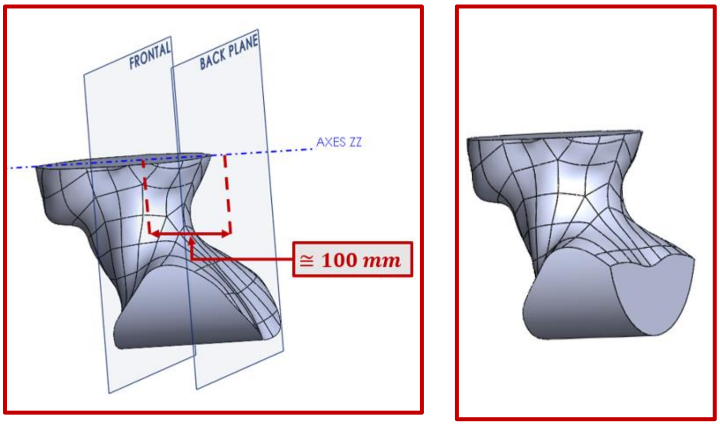
The reference Plane it's the Frontal, and the distance between the Frontal Plane and the Back Plane it's represented by the equation:

$$Back\ Plane = NECK \times 0.88 \tag{3.4}$$

Table 3.4 Dimensions of the volunteer A and the respectively Equation for the Back Plane.

Dimensions of the volunteer A	Equations
$NECK \cong 114mm$	$Back\ Plane = NECK \times 0.88$ $Back\ Plane = 144 \times 0.88$ $Back\ Plane \cong 100mm$

The representation of both Planes and the specific distance between them also the cut procedure is shown in figure 3.18:



a) b)

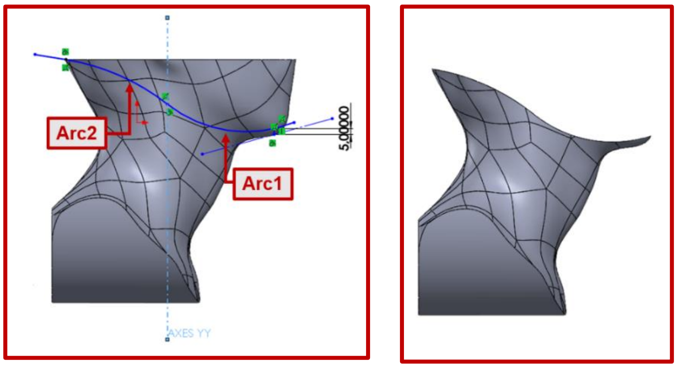
Figure 3.18 Double Figure of Sketch Scheme for the Cutting in the back zone of the Digital Model of the volunteer A: a) Dimension between the 2 planes; b) Final cut in the back zone

Right View

At last, the Right View. This cut procedure requires a bit more attention from the operator. As already mentioned previously, working with non-geometric surfaces and with the different types of physiognomy of each person, becomes a difficult challenge, and the cut procedure needed from the Right View it is a good example.

The cut sketch must cover the inferior zone of the chin, passes under the volunteer 's ear, and finish in the occipital knob.

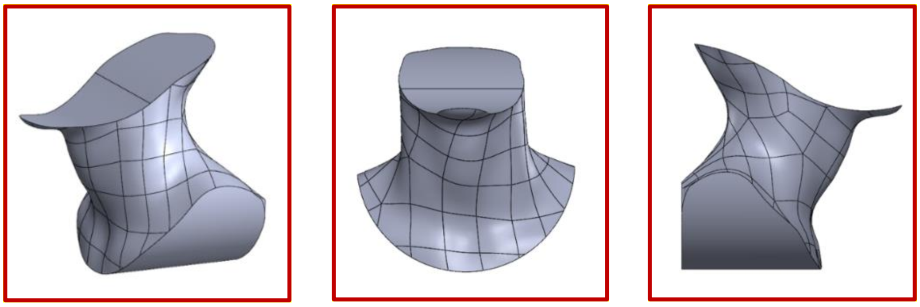
There are no equations needed for this procedure. The sketch it's composed of two Arcs, and they must have a Tangent relation between them and coincident with the AXES YY. The Arc 1 must be located 5mm above the line of the chin.The sketch of the volunteer A and the cut procedure is represented in figure 3.19:



a) b)

Figure 3.19 Sketch Scheme for the Cutting in the Lateral View of the Digital Model for the volunteer A: a) Sketch from the Lateral View; b) Final Cut in the Lateral View.

The final look of the collar upon all the general processes is shown in the figure 3.20:



a) b) c)

Figure 3.20 Multiple Figures of the final digital model of the Collar: a) Overall View; b) Front View; c) Lateral View.

3.3.3 Thickness and Division of the Collar

First, it was created a surface from the entire process of cut and optimization process ("Surface Offset"). Then, the Offset is 1mm to guarantee no total interference between the volunteer and the collar, only in the zones where it will be placed the coating. Another advantage is the possibility of better airflow in the zones without airflow.

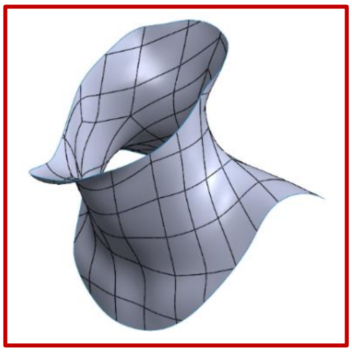


Figure 3.21 Offset from the Digital Model.

After the Offset procedure, it will need to apply a thickness for the entire structure.To have a mean of comparison, standards cervical collars (for example Philadelphia Collar) have an average thickness of $10mm$.

As mentioned before the material chosen for the print of the equipment is PLA, and in consideration of, that is a material with high surface hardness, it will be chosen $8mm$ of thickness for the cervical collar, as his shown in the figure 3.22.

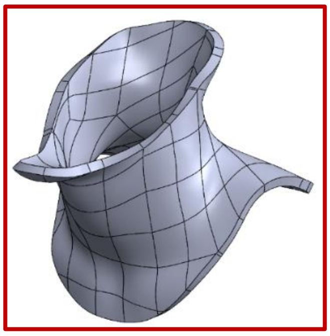


Figure 3.22 Thickness of $8mm$ of the Cervical Collar.

Finally, the last process for the construction of the cervical collar. As mentioned, before it is necessary to create a division of the collar to facilitate the assembly of the collar to the patient.

Initially, the idea was to create divisions with 8 parts of the collar and create adjustments mechanisms to improve a better assembly on the patient's neck, as shown in figure 3.23, but the strength of the entire structure will be smaller, thus, with the movements of the patient the collar will be not able to protect the cervical spine.

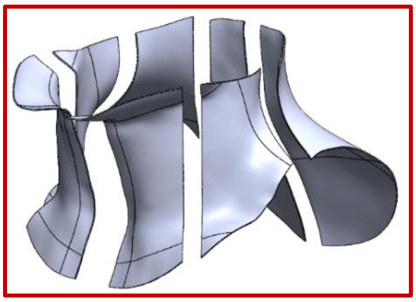
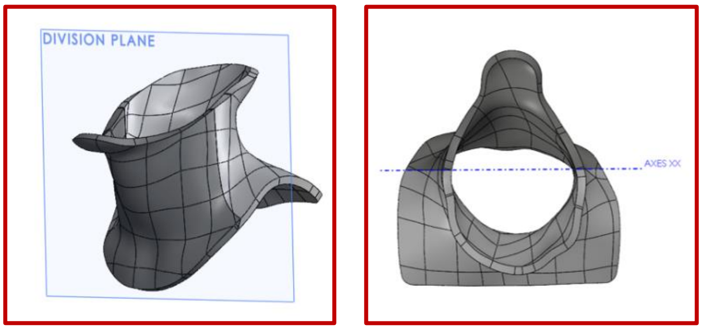


Figure 3.23 Division of 8 parts of the Collar.

Therefore, it was created a division only into 2 parts, to ensure the facility to for the patient to put the collar on and the strength of the entire equipment will resist and protect the patient. To divide the collar, it was created a plane (Division Plane) using the Axes XX as a reference. The division is shown in figure 3.24:



a) b)

Figure 3.24 Double Figure of the division in 2 parts of the Collar: a) Overall View; b) Top View.

3.3.4 Closing Mechanisms

To finish all processes of the construction it is essential to create closing mechanisms to secure the cervical spine of the patient in perfect conditions. The mechanism will be built with the same material of the entire collar and will be added fabric straps on the closings mechanism to guarantee a simple and light system to the patient.

The entire mechanism it's composed of 3 phases: a system composed with an elastic band, cylindrical guides, and a system composed with resistance fabric with Velcro.

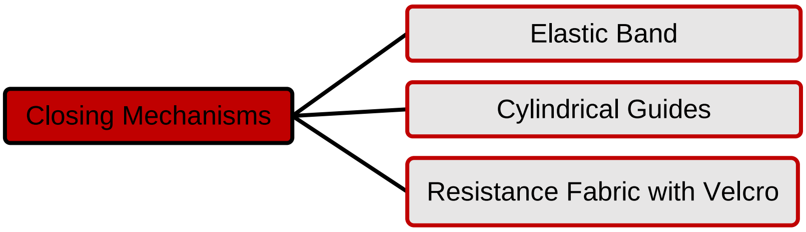


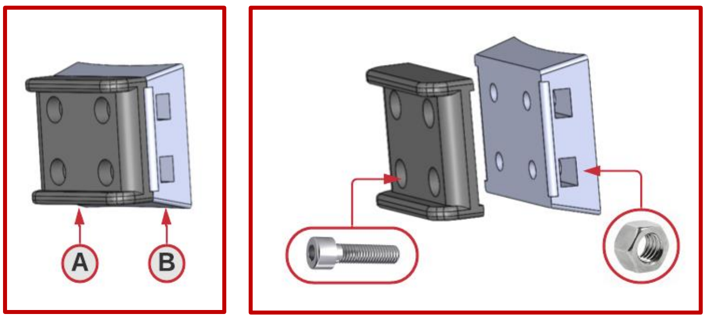
Figure 3.25 Closing Mechanisms existing in the Collar.

Elastic Band System

The elastic band system allows that both divided parts have a simple connection between them, it is light and, most important, doesn't degrade with humidity resulting from for example the rain.

Figure 3.26 Photography of the Elastic Band used in the Elastic Band System.

It was necessary the build a solid part to fix the elastic band system to the collar. The solid component is divided into two parts: one part (Component B) will be assembly to the collar and the other part is an exterior component (Component A) which will be fixed to Component A with hexagon socket cap screws 4x M3 and respectively nuts, as shown in the figure 3.27:



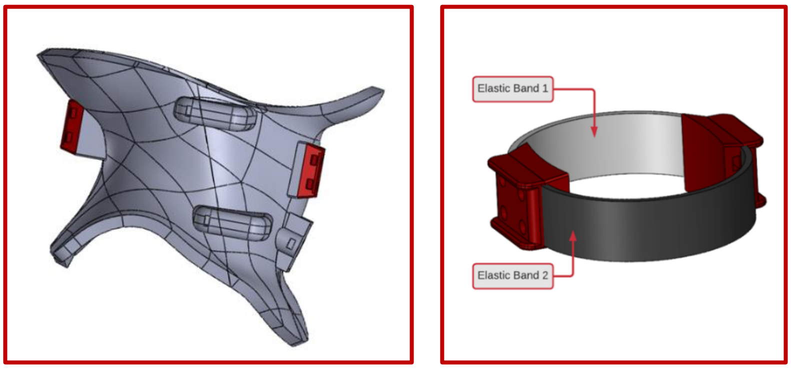
a) b)

Figure 3.27 Double Figure of the Component used in the Elastic Band System: a) Constitution of the component (Component A and Component B); b) Hexagon socket head cap screws and nuts used to fix.

Component A will be placed in Component B with the aid of 4 x hexagon socket cap screws M3 and respectively M3 nuts. The screws in addition to assembly both components, they will guarantee that the elastic band will be completely fixed between both components. The all-external components existing in the system are shown in figure 3.28:

Figure 3.28 Photography of the entire all-external components of the Elastic Band System.

The collar will have 2 entire solid components to fix the elastic system to the collar. One in front of the collar and the other in the back. It needs to place both components in an assembly file using the AXES YY to mate all the entire components to guarantee a geometric position. The entire mechanism will have 2 elastic bands, on each side with the same dimensions. In the case of volunteer A, the dimension of each elastic band is 260mm. That dimension will guarantee sufficient length to apply the force in the collar.



a) b)

Figure 3.29 Double Figure of the 2 solid components assembled to the Collar: a) Lateral View of the assembly of both solid components; b) Overall View of the entire Elastic Band System.

Figure 3.30 shows the appearance of a completed mechanism for the elastic band in the front part of the cervical collar:

Figure 3.30 Photography of the completed mechanic of the Elastic Band System.

On the Appendix B it will be explained with detail the entire components that are part of the Elastic Band System.

To put the collar in the patient must be applied a small amount of force by the operator in that way that the distance between both parts of the collar is enough to introduce in the head of the patient from top to bottom.

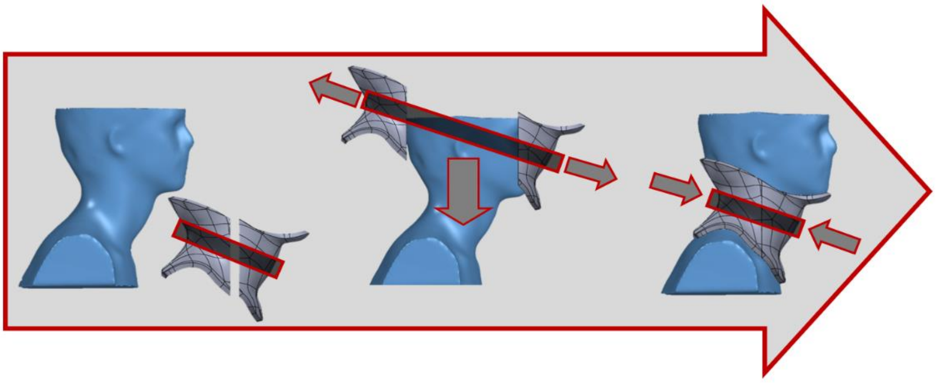
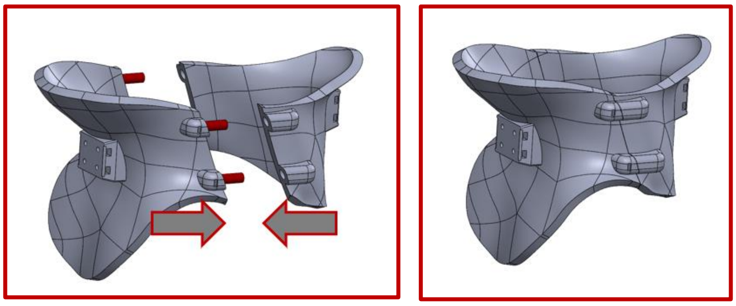


Figure 3.31 Scheme of the steps of the correct assembly of the Collar to the Patient

Cylindrical Guides

The cylindrical guide it's a mechanism to guarantee the perfect assembly between both divided parts of the collar.

The collar will be assembled with four cylindrical guides, two on each divided part of the collar as is shown in figure 3.32:



a) b)

Figure 3.32 Double Figure of the Cylindrical Guides assembled to each part of the Collar: a) Cylindrical Guides movements; b) Collar closed perfectly

The methodology is the same as the Elastic Band Mechanism. All component is created and then assembled to the cervical collar. Figure 3.33 is an example of one of the entire components used to guide de cervical collar's parts. At the moment of the assembly with the collar, the Division Plane of the component must be coincident with the Division Plane of the entire collar to ensure the perfect split of the entire components.

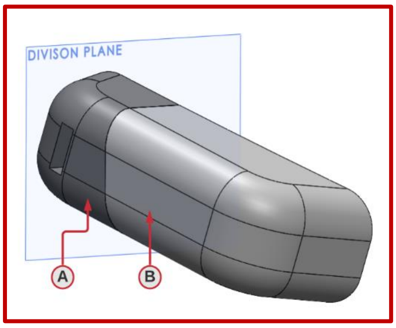
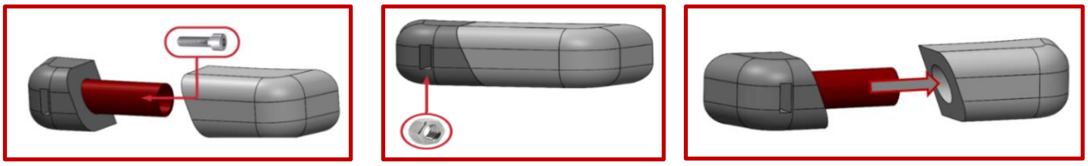


Figure 3.33 1 of the 4 components existing in the entire Collar for the Cylindrical Guides.

For the component illustrated above (figure 3.34), it will need 4 objects: Component A fixed at the back portion of the collar, Component B fixed at the front portion of the collar, 1 cylinder which guarantees the guide mechanism, 1x hexagon socket head cap screw M3 and 1xM3 nut. The screw will fix the cylinder in component A.



a) b) c)

Figure 3.34 Multiple Figure of the function of each component used in the Cylindrical Guides: a) Assembly of the hexagon socket head cap screw M3 with the cylindrical component to one of the solid; b) Final assembly of the components with a M3 nut; c) Correct movement with the mechanism.

The cylinder has a diameter of 8mm and the cavity of Component B has a diameter of 8.3mm because it was applied an Offset of 0.15mm to help a better assembly between both components. With a cavity with the same diameter as the cylinder (8mm), it would be impossible to assembly all the components due to the dimensions being the same.

The all-external components existing in the system are shown in figure 3.35:

Figure 3.35 Photography of the external components of the Cylindrical Guides Mechanism

The figure 3.36 shows the appearance of a completed mechanism for the cylindrical guides:

Figure 3.36 Photography of the completed mechanic of the Cylindrical Guides.

On the Appendix C it will be explained with detail the entire components that are part of the Cylindrical Guides.

Resistance Fabric with Velcro

Lastly, the mechanism will provide a complete fix closing mechanism to the entire cervical collar. It is composed of resistant fabric, slider buckle, and velcro tape. The velcro tape is directly sewn to the resistance fabric in the edge to close the mechanism. The figure 3.37 is shown the components attached to the resistance fabric:

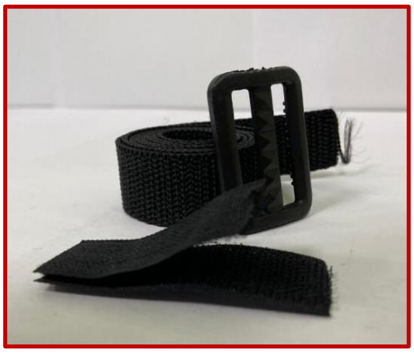
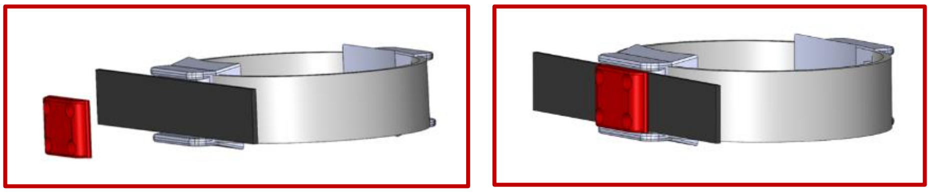


Figure 3.37 Photography of the resistance fabric, slider bucker and velcro tap used in the Resistance Fabric with Velcro mechanism

To assembly the resistance fabric to the collar, it will be using the same screws and the mechanism used for the elastic band plus a new component to guarantee the complete connection (shown in figure 3.38).



a) b)

Figure 3.38 Double Figure of the mechanism of the Resistance Fabric with Velcro: a) New component for the mechanism; b) Correct positioning of the new component.

The assembly between the resistance fabric and the collar is on the backside of the collar, as shown in figure 3.39. The closing mechanism is a guarantee with the velcro already sewn to the fabric resistance.

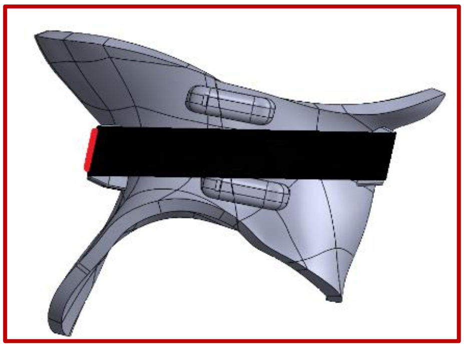


Figure 3.39 Lateral View of the Assembly of the entire Mechanism in the Collar.

The Velcro and the slider buckler will be guaranteeing the entire closing system. After the correct assembly of both divided parts aided with the cylindrical guides, the patient or the assistant (depending only on the patient's health condition) must push the resistance fabric and rotate in the direction of the clock's hands around the patient until fixed on the Velcro. As shown in figure 3.40, there are some different views for the cervical collar with the Resistance Fabric with Velcro system to close the entire equipment:

a) b) c)

Figure 3.40 Multiple Photographs of the completed Mechanism: a) Lateral View; b) Back View; c) Front View

On the Appendix D it will be explained with detail the entire components that are part of the Cylindrical Guides.

3.3.5 Final Finishes

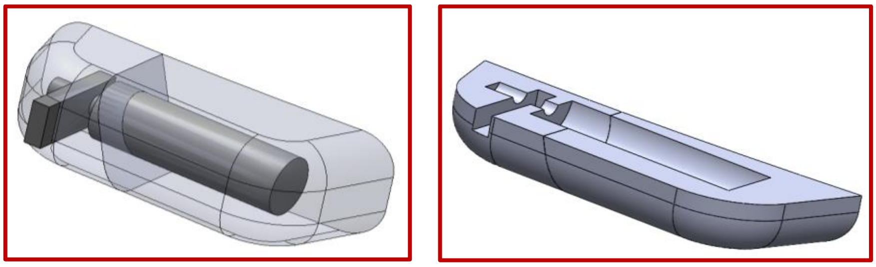
After the construction of the entire components (cervical collar and the closing mechanisms), is required to assembly the entire components correctly. The systems of references mentioned at the beginning of the entire process are of high importance to allow the operator to carry out all the needed assemblies.

The component created to fix the elastic band system and the resistance fabric velcro will be assembled to the collar using the Lateral Plane of both solids as a coincident mate. The exact location in YY and ZZ axes is chosen by the operator, due to the different physiognomy of each person that will create different collars.

Relatively to the components for the cylindrical guide, the Division Plane of both components (components of the cylindrical guide and collar) is the most important coincident mate. The exact location in YY and XX is chosen by the operator for the same reason used in the components above mentioned.

The most important mattes between each component of the entire collar were described above, however, the entire assembly will be described in more detail in the Appendix E.

For all the components with cavities and holes, the operator after the final assembly should create a kind of filling objects. After the assembly of the entire components, the operator will subtract the filling objects guaranteeing with this method, that all holes and cavities are not overlapping with other objects that are part of the entire assembly of the equipment. Figure 3.41 shows one of the components with and without the filling object:



a) b)

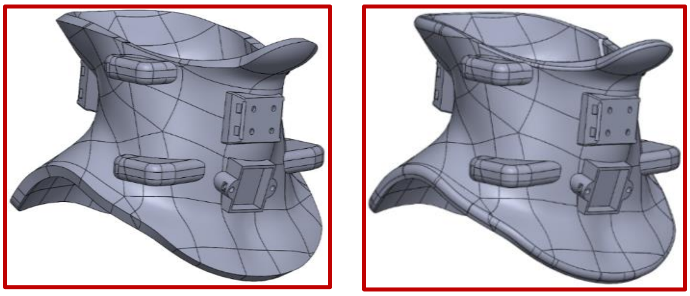
Figure 3.41 Double Figure of the Cylindrical Guides mechanism: a) Component with the filling object; b) Component after the subtraction of the filling object.

On the Appendix E it will be shown a figure with the all-objects inserted in the cervical collar.

During the Assembly of all components, the operator after choosing the right place to assemble the objects should check if they are placed correctly and use the command "Move Face" to guarantee the completed assembly and a better finish.

On the Appendix E it will be shown a figure with the comparison between the collar before and after the command “Move Face”.

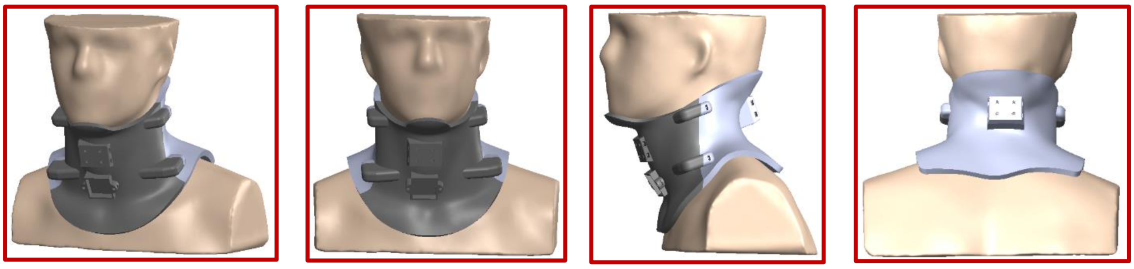
Last procedure, the operator must fillet all edge zones of the equipment. The entire structure must be smoothed so as not to endanger the patient's well-being (Figure 3.42).



a) b)

Figure 3.42 Double Figure of the final model of the Cervical Collar: a) Collar before the fillet operation; b) Collar after the fillet operation.

Finally, the digital model of the collar is completed. The next step is the printing process who has steps that must be followed to obtain the prototype of the collar. The figure 3.43 shows different views of the final digital model assembled in the volunteer.



a) b) c) d)

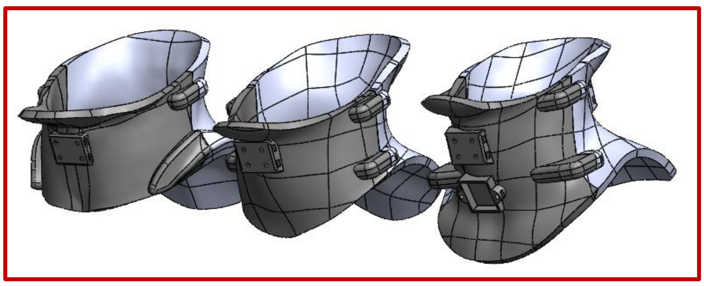
Figure 3.43 Multiple Figure of different views of the assembled of the cervical collar with the volunteer A: a) Overall view; b) Front View; c) Lateral View; d) Back View.

3.3.6 Evolutions of the construction of the Collar

Since the beginning of the entire cervical project, it was necessary to make some modifications during the process. The digital model is a good example of the different modifications. The different evolutions of the cervical collar emerged to improve the rigidity of the structure, closing mechanisms, increase the comfort of the collar for the patient, and mainly to restrict the movements of the patient's neck area to protect the cervical spinal more securely and stably.

On the Appendix F it will be described the first ideas of mechanisms that were devised to put on the cervical collar.

The evolutions of the model of the cervical collar can be divided into 3 collars as is shown in the figure 3.44:



a) b) c)

Figure 3.44 Overall View of the different digital models: a) First version; b) Second version; c) Final Version.

On the Appendix G it will be available figures of the 3 versions of the collar and a brief description of the first 2 models.

3.4 Additive Manufacturing

To obtain the physic cervical collar it will be used the technology of 3D printing. 3D print is inserted in a specific type of prototyping: Rapid prototyping.

Rapid prototyping is a term to designate a set of technologies that are used to build physical objects directly from data sources and it is a manufacturing process using the production of the layer-by-layer component.

It is a technology that offers several advantages in many applications compared to a classic manufacturing process based on material removal (for example milling or turning): there are no limitations for the building of objects relatively complex, the time and cost savings provided by the rapid prototyping is higher, allow the obtaining of parts with the same level of quality as series productions. This technology is the best possible manufacturing process when it needs to produce small batches of parts.

The printer will pre-heat the additive material to the right melt temperature and then the nozzle moves back and forth while dispensing and the additive material (in this case the PLA) layer by layer. It normally adds hundreds or even thousands of layers of material to make a three-dimensional object. All the equipment is composed of guide systems with precise measurements on the 3 main axes to create the object in the right measurements.

One issue of this process is the production speed is very slow, directly depending on the required accuracy and size. Some equipment can’t build big objects due to the limitations of the space available for construction. Precision and the surface finish presented lower quality than the parts obtained by machinery.

All the rapid prototyping is constituted for five basic steps, as shown in the next figure 3.45:

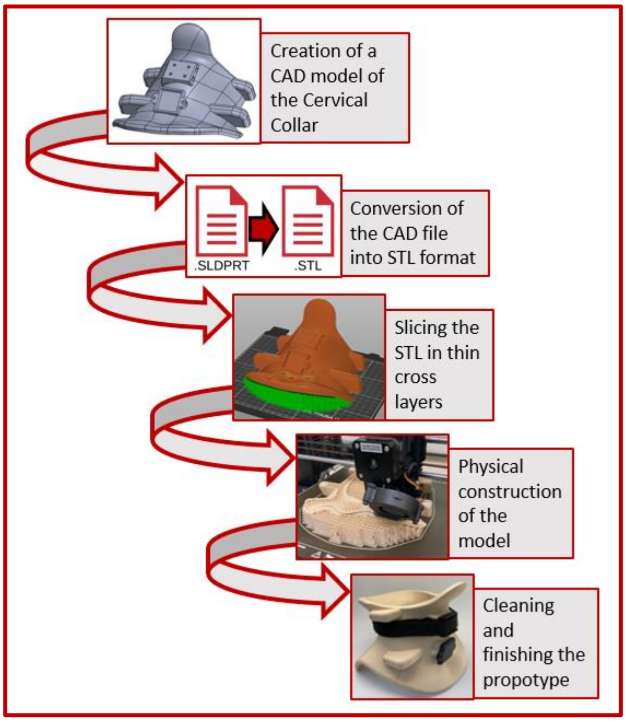


Figure 3.45 Scheme with the 5 steps of the Rapid Prototyping applied to the Cervical Collar.

All the entire 5 steps can be divided into 3 distinguished groups: Pre-Processing, Processing and Post-Processing.

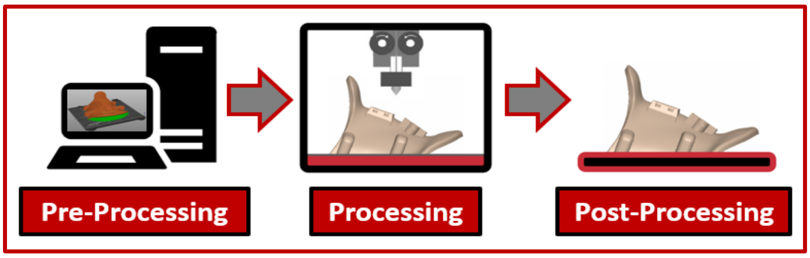


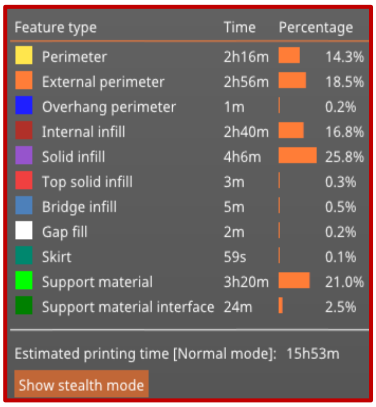
Figure 3.46 Pre-Processing, Processing and Post-Processing applied to the Cervical Collar.

3.4.1 Pre-Processing

The Pre-Processing starts at the moment of the building in the entire Cervical Collar until the simulation on the software before the utilization of the 3D Printer. Thereupon finish the building of both parts of the cervical collar and the external components, it is necessary to save the same files into STL files to open in different software. The software used is the *Prusa Slicer*®, which is an open-source, frequently updated tool that contains all the parameters and options to export the print files for the 3D Printer (Prusa 3D Printer®). (‘PrusaSlicer - Prusa3d.Com - 3D Printers by Josef Prusa’, n.d.)

The program was made for a printer with a 0.6 nozzle with a detailed print (0.15mm each layer) and choose the right filament material (Polylactic Acid).

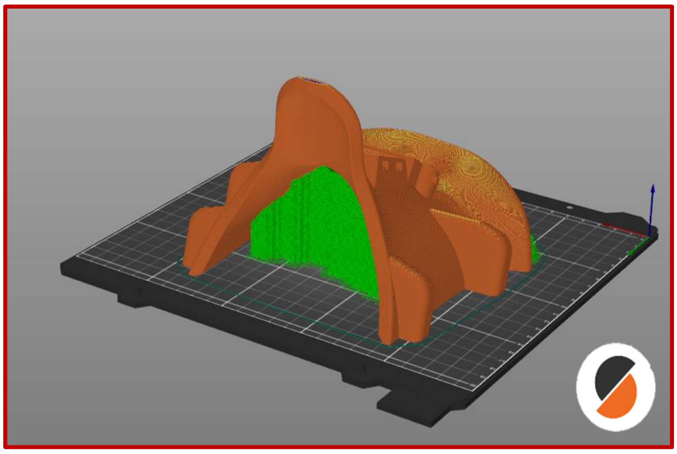
One important step was the creation of supports due to the geometry of each part of the cervical collar. Without the creation of supports, it would be impossible to print the entire cervical collar. The figure 3.47 shows the creation of the support for the front part of the collar. It is possible to see that 21% of the entire print process is only for the supports, due to being a relatively large and tall component.



Feature type	Time	Percentage
Perimeter	2h16m	14.3%
External perimeter	2h56m	18.5%
Overhang perimeter	1m	0.2%
Internal infill	2h40m	16.8%
Solid infill	4h6m	25.8%
Top solid infill	3m	0.3%
Bridge infill	5m	0.5%
Gap fill	2m	0.2%
Skirt	59s	0.1%
Support material	3h20m	21.0%
Support material interface	24m	2.5%

Estimated printing time [Normal mode]: 15h53m

Show stealth mode



a) b)

Figure 3.47 Double Figure of Pre-Processing step with the Prusa Slicer Software: a) Table of the time of Printing of each feature type; b) Image of the sliced Front Part of the Collar using the Software.

On the Appendix H it will be available figures of the Back Part of the Collar and all the external components using the *Prusa Slicer Software*®.

After the building of the supports and checking all the parameters (for example layer height, perimeters, and speed moves), the operator will slice the component and check layer by layer if everything is in perfect condition to export the print files.

3.4.2 Processing

After exporting the print files, it comes the Processing step. After that, the operator must check if the printer is in the perfect conditions: check the plater (remove areas with dirt that make it difficult for the filament material to adhere), lubrification, and put in extruder the right filament material and color to be used.

The 3D Printer starts the printing process with an auto-calibration and then it will start the printing process. 3D Printing is an additive process, and the cervical collar is created by laying down successive layers of material until the equipment is created. As mentioned before, the 3D Printer used for the printing process is an Original Prusa i3 MK3S®, as shown in figure 3.48.

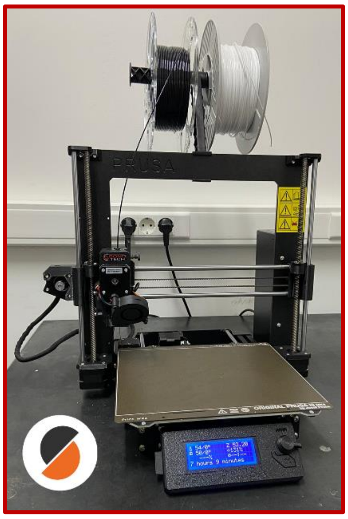


Figure 3.48 Photography of the 3D Printer used to print all the components. (Prusa i3 MK3S®)

The time of the printing process of the front part of the cervical collar is about 15h53m (as shown in figure 3.47 a)) and it will need 249.86g of the filament material (stands for 83.77m of filament).

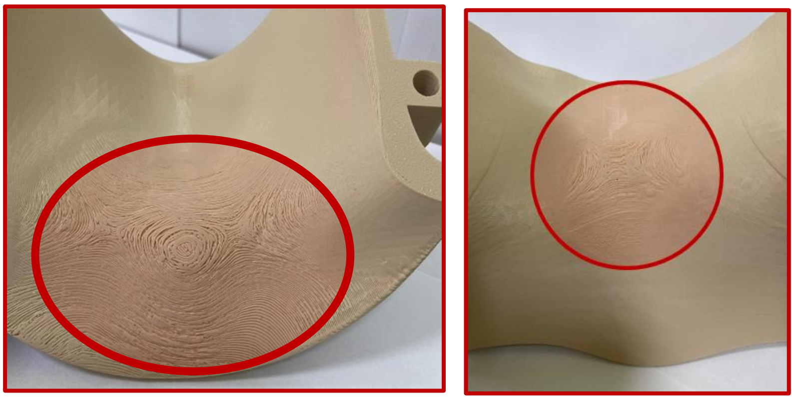
Therefore, the summation of all the components of the cervical collar is 36 hours and 55 minutes, 604.33 grams (stands for 206.62 meters).

On the Appendix I it will be available a table of each STL file about time of printing process and quantity in grams.

3.4.3 Post-Processing

The last process of the entire 3D Print. The parts of the collar are removed from the plater and remove the supports from the parts.

As mentioned before, the parts of the collar have geometries with a certain degree of difficulty, which creates areas with some existing roughness due to the creation of supports. The same roughness zones must be removed with the aid of sandpaper, as his shown in the figure 3.49.



a) b)

Figure 3.49 Double Figure of post Processing steps: a) remove the roughness in the interior of the front part of the collar; b) remove the roughness of the interior of the back part of the collar.

After the remotion of the roughness zones, the printed part is finished. The same process must be done for the other parts of the structure: the other division part and the external components.

After all printed parts, the entire components must be assembled including the closing mechanisms and the entire structure of the cervical collar it's finished.

On the Appendix J it will be available pictures of the collar with all the implemented mechanisms and a photo with all the external components needed for one model.

3.5 Coating

It will be applied coating in the collar to guarantee a better assembly between the patient and the structure. The application of a softer coating only in the fixed zones brings better comfort for the patient.

The D33 Foam will be applied in the borders of the collar namely between the neck and the chin zone (Top View of the figure 3.50) and the zone of the backpack and chest (Back View of figure 3.50). The polyester foam will be applied to the underside of the chin. Due to it is softer properties, the polyester foam will give more comfort to the patient.

a) b)

Figure 3.50 Double figure of the coating of the Collar: a) Top View b) Back View.

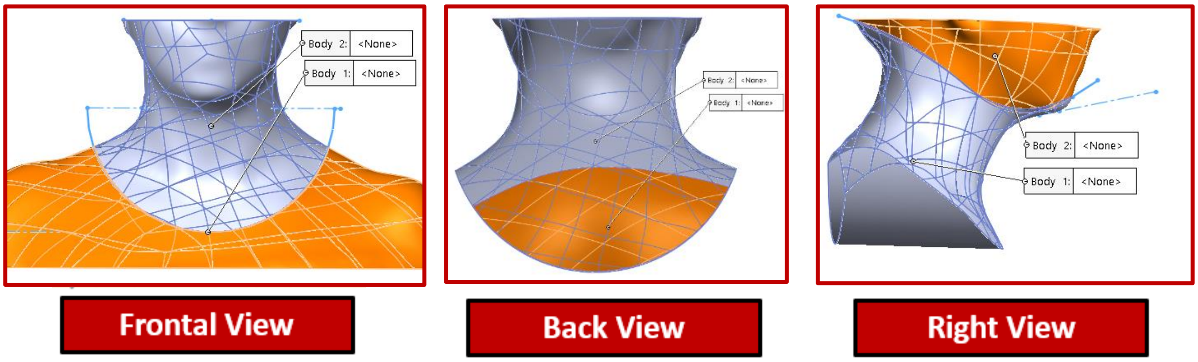
3.6 Examples

As mentioned, although the collar is tailor made, it is necessary to create a general system to help the operator in the construction of cervical collars for different patients and using common reference points.

Using the methodology in the construction of the collar for volunteer A, this chapter will demonstrate the construction of more cervical collars for volunteer B and C. The procedure will from obtaining the digital model by 3D scan until the adjustments to be made at the Frontal, Back, and Right views. From there, the process will be similar from volunteer to volunteer

3.6.1 Volunteer B

The unnecessary zones to cut ("Split"), from the digital model of volunteer B, is shown on the figure 3.51:



a) b) c)

Figure 3.51 Multiple View of the Cut the Unnecessary zones of the Digital Model for the volunteer B: a) Sketch and Cut of the Frontal View; b) Cut of the Back View; c) Sketch and Cut of the Lateral View.

Frontal View

As already explained in the construction process of the collar for volunteer A, the operator will need two measurements: "FACE" and "NECK". The "LINE ALPHA" is obtained with the equation:

$$LINE \;\; = ALPHA\; FACE \;\; \times 0.50 \tag{3.6.1.1}$$

$Circle_1$ is obtained with the equation:

$$Circle_1 = NECK \times 1.75 \tag{3.6.1.2}$$

Next, the $Distance_1$:

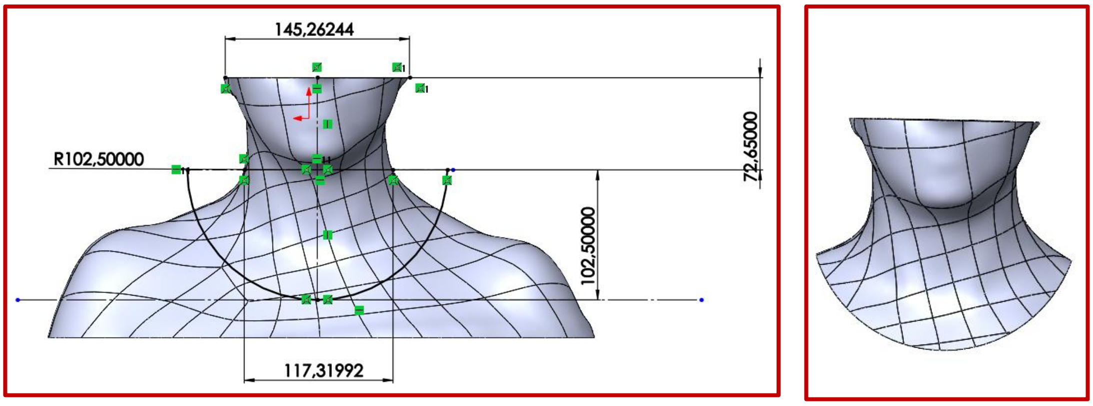
$$Distance_1 = \frac{Circle_1}{2} \tag{3.6.1.3}$$

For the construction of the cervical collar for the volunteer B, the dimensions needed specially for the Front Cut and equations are represented in table 3.5:

Table 3.5 Dimensions of the volunteer B and the respectively Equations for the Frontal View

Dimensions of the volunteer B	Equations
$FACE \cong 145.3mm$	$LINE\ ALPHA = FACE \;\times 0.50 LINE\ ALPHA = 145.3 \times 0.50 LINE\ ALPHA = 72.65mm$
$NECK \cong 117.3mm$	$Circle_1 = NECK \times 1.75\ Circle_1 = 117.3 \times 1.75\ Circle_1 \cong 205mm$
	$Distance_1 = \frac{Circle_1}{2} Distance_1 = \frac{205}{2} Distance_1 = 102.5mm$

The sketch of the volunteer B and the cut procedure for the Frontal View is represented in the figure 3.52:



a) b)

Figure 3.52 Double Figure of the Sketch Scheme for the Cutting in the Frontal View with the dimensions of the volunteer B: a) Sketch and Dimensions of the volunteer B; b) Final cut of in the Frontal View.

Back View

The operator will need a measure already used for the procedures on the Front View, the NECK.

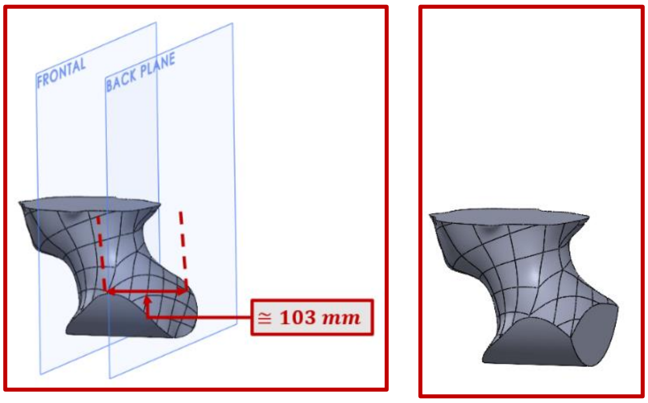
The reference Plane it's the Frontal, and the distance between the Frontal Plane and the Back Plane it's represented by the equation:

$$Back\ Plane = NECK \times 0.88 \qquad (3.6.1.4)$$

Table 3.6 Dimensions of the volunteer B and the respectively Equation for the Back Plane.

Dimensions of the volunteer B	Equations
$NECK \cong 117.3mm$	$Back\ Plane = NECK \times 0.88 Back\ Plane = 117.3 \times 0.88 Back\ Plane \cong 103mm$

The representation of both Planes and the specific distance between them also the cut procedure is shown in figure 3.53:



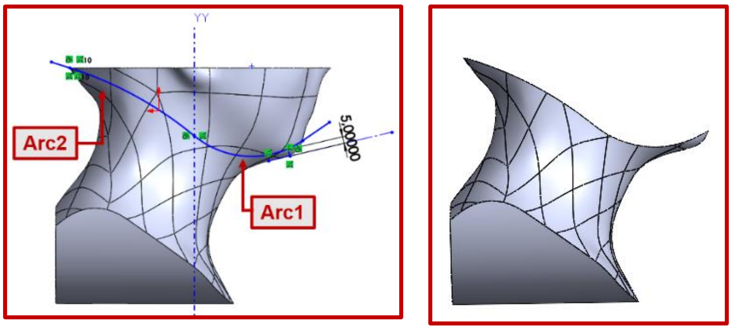
a) b)

Figure 3.53 Double Figure of Sketch Scheme for the Cutting in the back zone of the Digital Model of the volunteer B: a) Dimension between the 2 planes; b) Final cut in the back zone.

Right View

The cut sketch must cover the inferior zone of the chin, passes under the volunteer 's ear, and finish in the occipital knob. The sketch it's composed of two Arcs, and they must have a Tangent relation between them and coincident with the AXES YY. The Arc 1 must be located 5mm above the line of the chin.

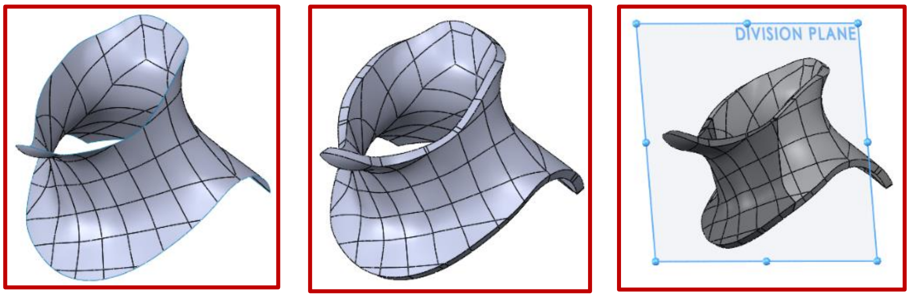
The sketch of the volunteer B and the cut procedure is represented in figure 3.54:



a) b)

Figure 3.54 Sketch Scheme for the Cutting in the Lateral View of the Digital Model for the volunteer B: a) Sketch from the Lateral View; b) Final Cut in the Lateral View.

After all cuts in the different views presented, the operator has to create a "Surface Offset" with 1mm, create a thickness of 8mm and finally divide the collar into 2 parts, as shown in figure 3.55:

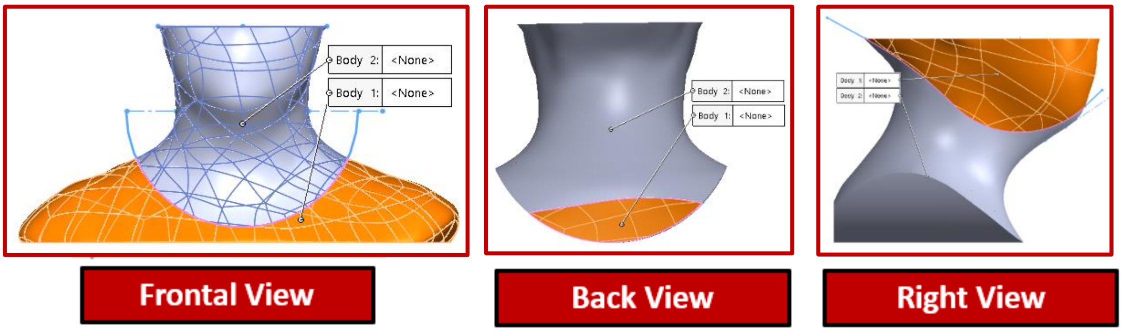


a) b) c)

Figure 3.55 Multiple Figure of different steps for the construction of the collar for the volunteer B: a) Offset from the Digital Model; b) Thickness if the Cervical Collar; c) Division in 2 parts of the collar.

3.6.2 Volunteer C

The unnecessary zones to cut (“Split”), from the digital model of the volunteer C is shown in figure 3.56:



a) b) c)

Figure 3.56 Multiple View of the Cut the Unnecessary zones of the Digital Model for the volunteer C: a) Sketch and Cut of the Frontal View; b) Cut of the Back View; c) Sketch and Cut of the Lateral View

Frontal View

As already explained in the construction process of the collar for volunteer A, the operator will need two measurements: "FACE" and "NECK". The "LINE ALPHA" is obtained with the equation:

$$LINE \ = ALPHA\ FACE \ \times 0.50 \qquad (3.6.2.1)$$

$Circle_1$ is obtained with the equation:

$$Circle_1 = NECK \times 1.75 \qquad (3.6.2.2)$$

Next, the $Distance_1$:

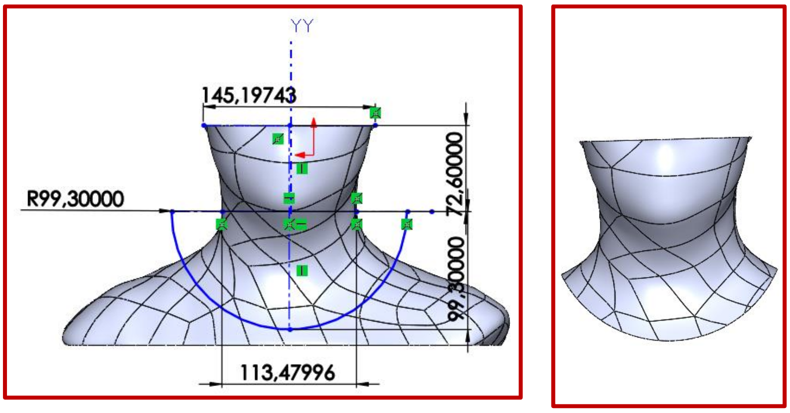
$$Distance_1 = \frac{Circle_1}{2} \qquad (3.6.2.3)$$

For the construction of the cervical collar for the volunteer C, the dimensions needed specially for the Front Cut and equations are represented in table 3.7:

Table 3.7 Dimensions of the volunteer C and the respectively Equations for the Frontal View

Dimensions of the volunteer C	Equations
$FACE \cong 145.2mm$	$LINE\ ALPHA = FACE \times 0.50 LINE\ ALPHA = 145.2 \times 0.50 LINE\ ALPHA = 72.6mm$
$NECK \cong 113{,}5mm$	$Circle_1 = NECK \times 1.75\ Circle_1 = 113{,}5 \times 1.75\ Circle_1 \cong 198{,}6mm$
	$Distance_1 = \frac{Circle_1}{2} Distance_1 = \frac{198{,}6}{2} Distance_1 = 99{,}3mm$

The sketch of the volunteer C and the cut procedure for the Frontal View is represented in figure 3.57:



a) b)

Figure 3.57 Double Figure of the Sketch Scheme for the Cutting in the Frontal View with the dimensions of the volunteer C: a) Sketch and Dimensions of the volunteer C; b) Final cut of in the Frontal View.

Back View

The operator will need a measure already used for the procedures on the Front View, the NECK.

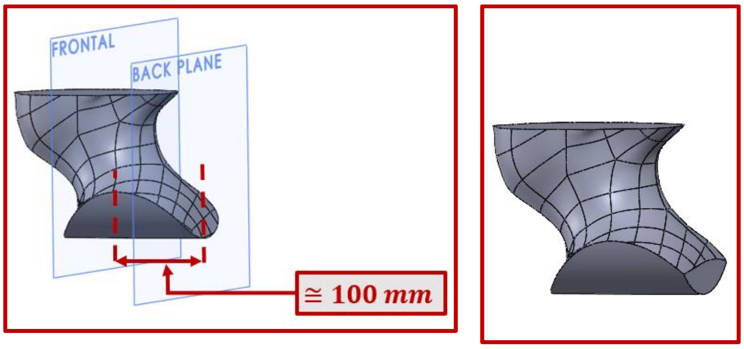
The reference Plane it's the Frontal, and the distance between the Frontal Plane and the Back Plane it's represented by the equation:

$$Back\ Plane = NECK \times 0.88 \qquad (3.6.2.4)$$

Table 3.8 Dimensions of the volunteer C and the respectively Equation for the Back Plane.

Dimensions of the volunteer Patient B	Equations
$NECK \cong 113.5mm$	$Back\ Plane = NECK \times 0.88 Back\ Plane = 113{,}5 \times 0.88 Back\ Plane \cong 100mm$

The representation of both Planes and the specific distance between them also the cut procedure is shown in figure 3.58:



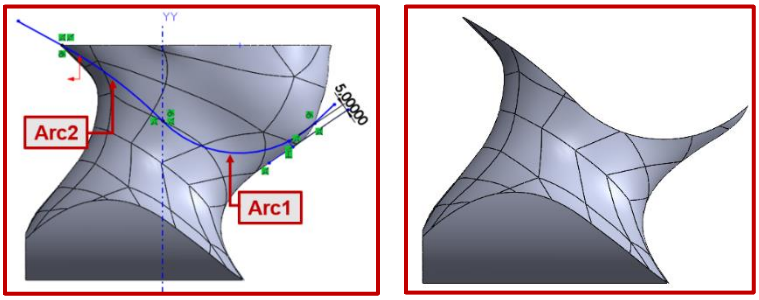
a) b)

Figure 3.58 Double Figure of Sketch Scheme for the Cutting in the back zone of the Digital Model of the volunteer C: a) Dimension between the 2 planes; b) Final cut in the back zone.

Right View

The cut sketch must cover the inferior zone of the chin, passes under the volunteer 's ear, and finish in the occipital knob. The sketch it's composed of two Arcs, and they must have a Tangent relation between them and coincident with the AXES YY. The Arc 1 must be located 5mm above the line of the chin.

The sketch of the volunteer C and the cut procedure is represented in the figure 3.59:



a) b)

Figure 3.59 Sketch Scheme for the Cutting in the Lateral View of the Digital Model for the volunteer C: a) Sketch from the Lateral View; b) Final Cut in the Lateral View.

After all cuts in the different views presented, the operator has to create a "Surface Offset" with 1mm, create a thickness of 8mm and finally divide the collar into 2 parts, as shown in figure 3.60:

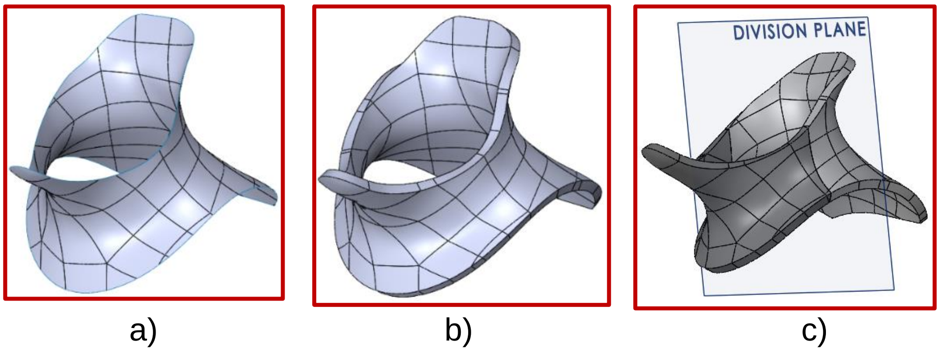


Figure 3.60 Multiple Figure of different steps for the construction of the collar for the volunteer C: a) Offset from the Digital Model; b) Thickness if the Cervical Collar; c) Division in 2 parts of the collar

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4. Cervical Instrumented Collar with Monitoring Sensors

As mentioned at the beginning of the entire project, all electrical assembly including sensors and needed software will be mounted with the aid of Professor Maxim Safronov and Engineer Roman Studensky. The entire process and method applied in this chapter are essentially designed by the collaborators.

The entire chapter 4 encompasses knowledge of sensors, electronics, and knowledge in a programming language. In a very brief way, the chapter reports the various types of sensors to be used, the specific choice of each type of sensor, mounting on the collar, and all the electronic work that includes the correct functioning of the entire device. Then it is necessary to create a program that the user can access through his device and interpret the various values that the sensors return.

The contact point between the sensors will not be directly the skin for the Recovery Cervical Collar, but its behaviour during the time of use of the equipment will be important for the sensors.

In recent years there has been an increase in the research and construction of skin-inspired devices namely electronic devices used in clothing, implants, and electronic skin which us the target of development in wide applications such as healthcare and robotics.

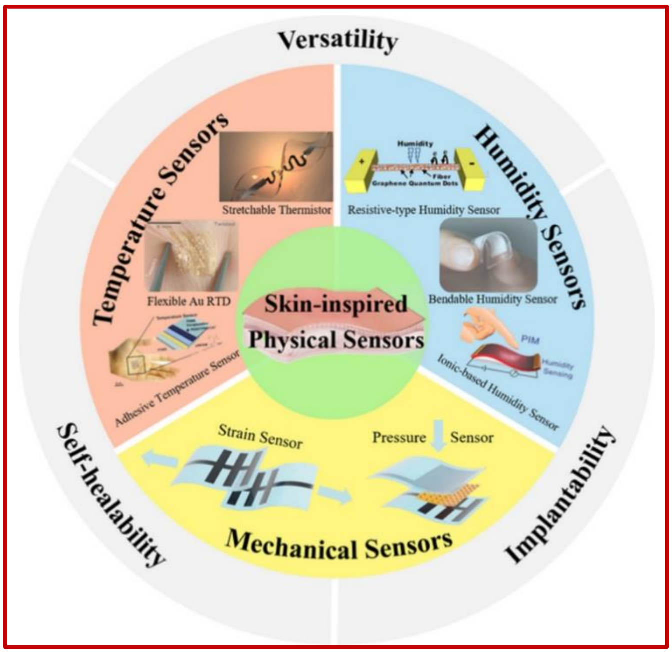


Figure 4.1 Scheme from Li et al. (2020), about type of sensors.

Physical sensors are the basis of all research that can provide important information. Within the physical sensors, there are mainly: temperature, humidity, and mechanical (pressure).

As mentioned above, there are currently systems that can be used in clothing to monitor vital signs, through the term: Wearable Health Devices (WHD). According to Dias & Paulo Silva Cunha, (2018), these devices are part of technology that allows the continuous monitoring of a person's vital signs for a certain period (days or weeks) outside the hospital environment.

They create a connection between various fields of science such as biomedicine, micro and nanotechnologies, materials engineering, and electronic engineering. One of the great advantages of this type of device is to alert in the exact moment, through the vital signs monitored, the different activities that may or may not put the patient's health at risk.

Dias & Paulo Silva Cunha, (2018), refers that the main requirements of this type of technology are low consumption, reliability, and comfort. The type of monitoring can be online or even offline. The type of patient can be healthy or risky, depending only on the type of monitoring. The vital signs that WHD's can monitor are shown in the next table 4.1:

Table 4.1 Vital Signs that WHD's can monitor

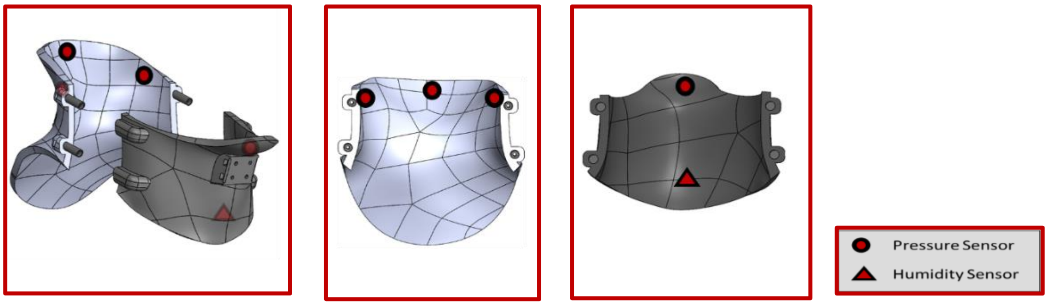
Wearable Health Devices (WHD)	Electrocardiogram
	Heart Rate
	Blood Pressure
	Respiratory Frequency
	Blood Oxygen Saturation
	Blood Glucose
	Perspiration on the Skin
	Capnography
	Body Temperature

Given all the adverse caused by the standard's cervical collars mentioned in chapter 5 (Adverse effects of the Cervical Collars) the technology applied to the sensors in contact with the skin, it's possible to make some conclusions about what type of sensors to use in this specific recovery cervical collar. Pressure Ulcer is one of the main problems existing in the collars, so, healthy skin is essential for a complete health recovery of the patient, thus, will be using pressure and humidity sensors to prevent that kind of ulcers. The pressure sensors will advise the patient about higher levels of pressure values that are not favourable for the spine resulting from for example movements or a bad assembly of the collar. The humidity sensor will advise the patient about higher levels of percentage of humidity, therefore, in those cases, the collar must be removed and cleaned.

Higher values of pressure or even humidity will increase the probability of ulceration.

4.1 Type of Sensors

The recovery cervical collar will be equipped with 5 sensors: 4 pressure sensors and just one humidity sensor, as shown in figure 4.2:



a) b) c) d)

Figure 4.2 Multiple Figures of the Collar with the different sensors equipped: a) Overall View; b) Front View of the back part; c) Back View of the Front part; d) Legend of the different types of sensors.

4.1.1 Pressure Sensors (PS)

In the domain of pressure sensors, there are 3 types of mechanisms: capacitive, piezoresistive, and resistive.

Capacitive PS

Capacitive Sensors are formed by two plates that save opposite charges. Both plates are conductive and separated by a dielectric. A Dielectric is an electric insulator under the action of an external electric field above the limit of its dielectric strength, allowing the flow of electric current.

The sensor mechanism happens when a force is exerted on the sensor, which results in an approximation of the plates resulting in a change in the capacity value. This change in the capacity value will return to the operator the value of the pressure. The next figure 4.3 shows the entire mechanism of a capacitive sensor:

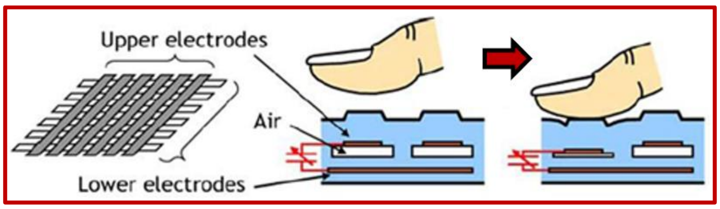


Figure 4.3 Figure adapted from Piezoresistive effect, *(n.d.), dos Santos,(2009) about the functioning of the capacitive sensor.*

Piezoresistive PS

Piezoresistive sensors are based on the piezoresistive effect presented by materials when they are subjected to a force. As shown in figure 4.4, the piezoresistive effect describes the change in electrical resistance that occurs when an external force is applied to a semiconductor. When a force is applied to the area, the sensor experiences a decrease in its value.

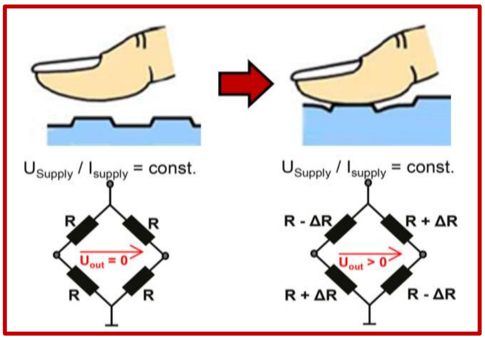


Figure 4.4 Figure adapted from (dos Santos,2009) and Piezoresistive effect*, (n.d.) about the functioning of the piezoresistive sensor.*

Resistive PS

Resistive pressure sensors measure the change in resistance when a resistive material is pressed between two plates. A resistive sensor is a transducer or an electromechanical device that converts a mechanical change such as displacement into an electrical signal.

The figure 4.5 shows the difference between a Resistive Sensor and a Capacitive Sensor:

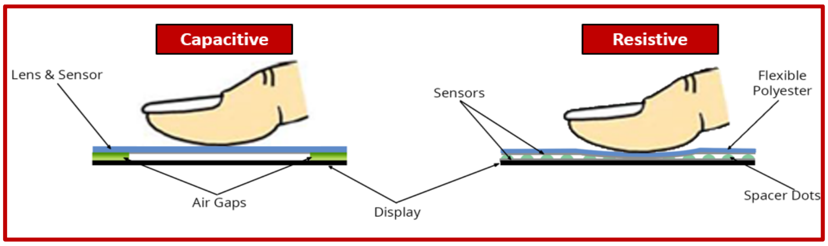


Figure 4.5 Figure adapted from (dos Santos,2009) and ('Touch Sensors', 2018) about the difference between resistive sensor and a capacitive sensor,

4.1.2 PS Application

The Recovery Cervical Collar presented on this project, will be using the Capacitive Sensors. The reasons for the capacitive sensor's choice are more economical compared with the other mechanisms, the method of calibration is simple and effective and for the type of utility, the capacitive mechanism is more appropriate. Figure 4.6 shows the exact pressure sensors to be used on the entire cervical collar.

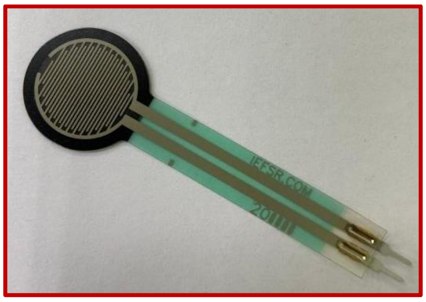
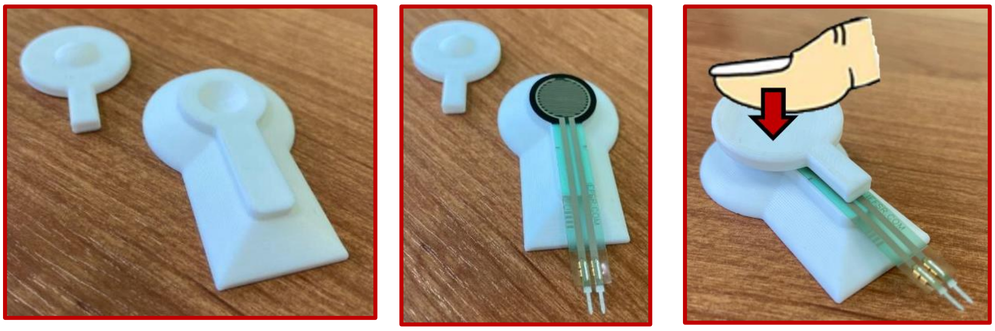


Figure 4.6 Photography of the Pressure Sensor to be used in the Cervical Collar.(FSR 400)

Tests were initially carried out to evaluate the behaviour of the sensor between two parts built and printed using a 3D printer.

The base of the printed component simulates the collar where the sensor will be properly glued and the component that will assemble in the concavity simulates the behaviour of the patient´s chin when the exact moment of making contact with the sensor.

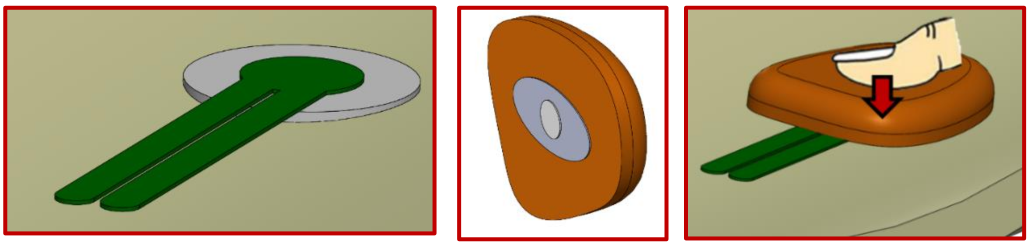


a) b) c)

Figure 4.7 Multiple Figures about the components and methods used to test the pressure sensor: a) components printed; b) Colocation of the sensor in the base; c) Pressing down the top component to test the sensor.

To guarantee the most correct pressure values possible, it was necessary to create a mechanism that allows the collection of pressure values as correct and reliable as possible, so, it is necessary to create a flat base where the sensor must be glued, and a membrane must touch the sensor whenever there is pressure movement. In figure 4.8 it is possible to watch all the components need for the pressure mechanism.

The first step is to create the holes in every zone of the collar to place in these same holes the bases with the flat face. After the base is properly placed and glued to the collar, the sensor is glued to the base. The last step is to glue the contact point between the sensor and the coating. The contact point also has a flat area that must be correctly positioned and in full contact with the zone where the sensor must be pressed to obtain pressure results. To finish, the coating will be glued to the collar.



a) b) c)

Figure 4.8 Scheme with the all components used in the collar to allow the sensor collecting reliable values: a) Fixation of the flat base on the collar and the fixation with glue of the sensor in the component; b) Fixation with glue the contact point in the coating; c) Fixation with glue the coating to the collar.

4.1.3 Humidity Sensors (HS)

Humidity is the presence of water in the air. Water vapor on air can affect processes in industries, and mainly, in this case, can affect human comfort.

In the domain of humidity sensors, there are 3 basic types of sensors: capacitive, resistive, and thermal.

Capacitive HS

The capacitive sensor is composed of two metal plates, or electrodes, separated by a thin layer of non-conductive polymer film, and these sensors use these two electrodes to monitor the capacitance (ability to store an electric charge of a thin metal strip placed between them). The humidity is attracted from the air and when touching the metal plates, it creates a voltage charge. This type of sensor is linear and can measure relative humidity from 0% to 100%.

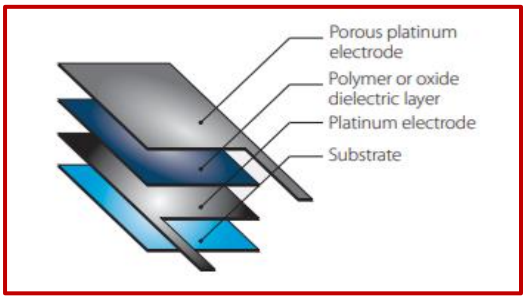


Figure 4.9 Scheme about the composition of the Capacitive humidity sensor from Humidity Sensor What Type Should You Choose?, (2020).

Resistive HS

This type of sensor works on a similar principle to the capacitive sensor because electrical change is measured to produce a value for relative humidity and resistive sensors use a hygroscopic material (humidity absorbing). The difference is that the measurement is of the resistance change in the material instead of the capacitance. The transduction mechanisms of resistive HS involve the changes in conductivity caused by the adsorption of water vapor.

This type of sensor measures the change in electrical impedance of a hygroscopic medium such as a conductive polymer, salt, or even treated subtract.

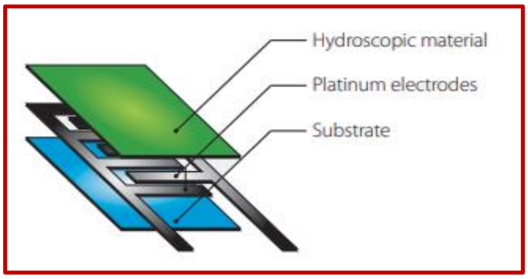


Figure 4.10 Scheme about the composition of the Resistive humidity sensor from Humidity Sensor What Type Should You Choose, (2020).

Thermal HS

This type of sensor is also known as the absolute humidity sensor as they measure absolute humidity. They measure the thermal conductivity of both dry air as well as air with water vapor, and the difference between the individual thermal conductivities can be related to absolute humidity.

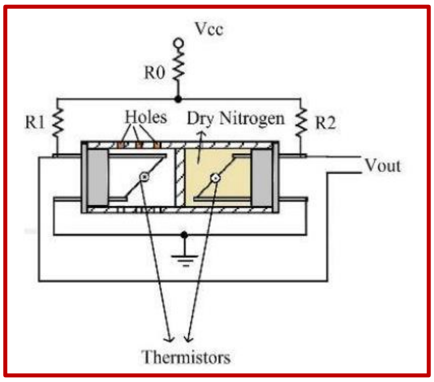


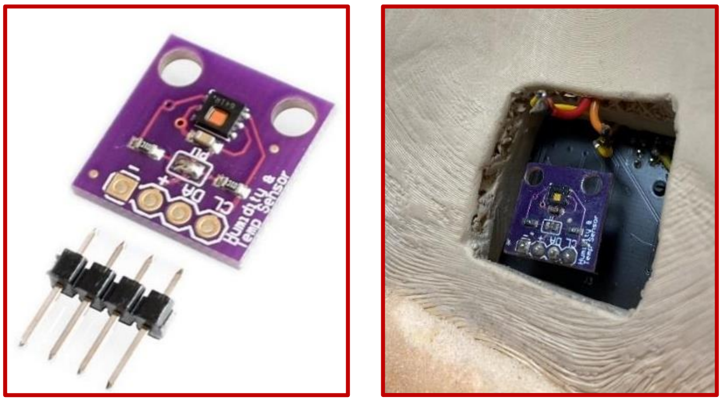
Figure 4.11 Scheme about the composition of the Thermal humidity sensor from Humidity Sensor What Type Should You Choose?, (2020).

4.1.4 HS Application

The Recovery Cervical Collar presented on this project, will be using Thermal Sensors. The specific name of the sensor is HCD 1080 and presents some advantages that justify the choice: it will be contactless the long-term use of the collar allows the sensor not to deteriorate quickly. By using a mechanism where there was contact between the device and the patient's skin, the skin itself makes the mechanism break down easier and faster compared to a contactless system. In addition to the patient's perspective, a contactless mechanism brings more comfort.

The HCD 1080, as shown in figure 4.12, it also has a temperature sensor, so it is possible to measure the humidity level and the temperature in the indicated place. Another advantage of the sensor is its excellent measurement accuracy at very low power.

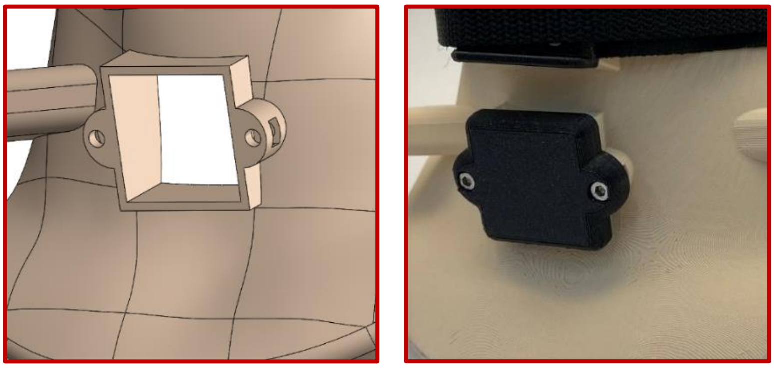
The humidity sensor will be applied in the front zone of the neck, and for that, was necessary to create a small box in the front of the collar to apply the sensor and a hole between the sensor and the skin of the Patient. The sensor will not be in touch with the skin, but it will be close enough to measure the temperature and humidity close to the skin.



a) b)

Figure 4.12 Double Figure of the HCD 1080: a) Photography of the sensor; b) Photography of the implementation of the mechanism in the collar device.

The front box created specifically for the sensor will be open in the front to improve the access in case of a future repair, however, was designed a cover to close the box during the use of the entire collar.



a) b)

Figure 4.13 Double Figure of the box specially created to the humidity sensor: a) Figure of the box in the Solidworks®; b) Photography of the cover created to protect the humidity sensor.

4.2 Electrical Assembly

Initially of the entire process of electronic components, it is necessary to decide the most viable option to place the components that will mainly ensure the energy of the collar. As is shown in figure 4.14, there are 2 ways to guarantee energy to the collar: the first option is to create a component separate from the collar connected by wires and which can be placed wherever the patient wishes (pockets, backpays, among others). The second option is to attach the component to the collar. The chosen and most viable option will be the energy system directly assembled to the collar. The patient will not have to worry about having to transport the component, however, there will have to be the care to create the entire equipment as light and as little large as possible so as not to interfere with the patient's health.

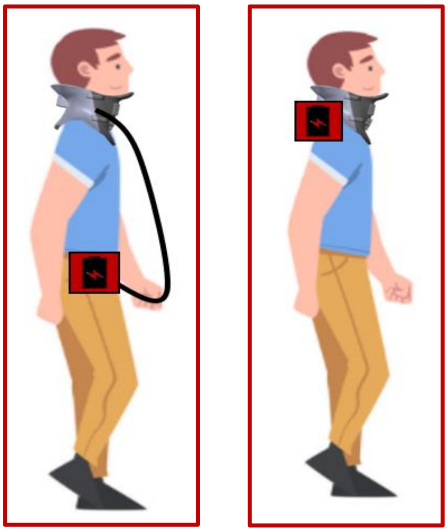


Figure 4.14 Double Figure of the options to create the energy component: a) Connected with wires; b) Directly assembled to the collar.

4.2.1 Power Unit

The first step to be taken is choosing the power unit to place in the cervical collar. There are some options on the market, so it is necessary to choose the ideal device taking into account some parameters.

Battery life is a decisive factor in choosing the right slide, but, weight and volume must be taken into account. Power bank would be a good choice as it has enough life to sustain the collar during the hours of use, however, it is high weight and volume would be a problem as the patient would have to support the battery during the entire day and thus put it at risk your health, since it was decisive to place the battery on the collar itself and not from distance with wires.

The primary lithium-thionyl chloride battery could be a good choice to put in the collar system, have some benefits like high voltage response, stability during most of the lifetime of application, wide operation temperature range (-60° to +85°C), easy integration into compact systems and superior resistance to atmospheric corrosion.

The Coin lithium CR2450 provides long-lasting reliable power in various devices, like car remotes, watches, and even medical devices. Usable in a wide range of temperatures (-30° to +60°C) and have high leak protection.

There was also the possibility of using a lithium battery used especially in a smartwatch. This type of component was immediately discarded because it will increase the overall complexity of the entire power unit system.

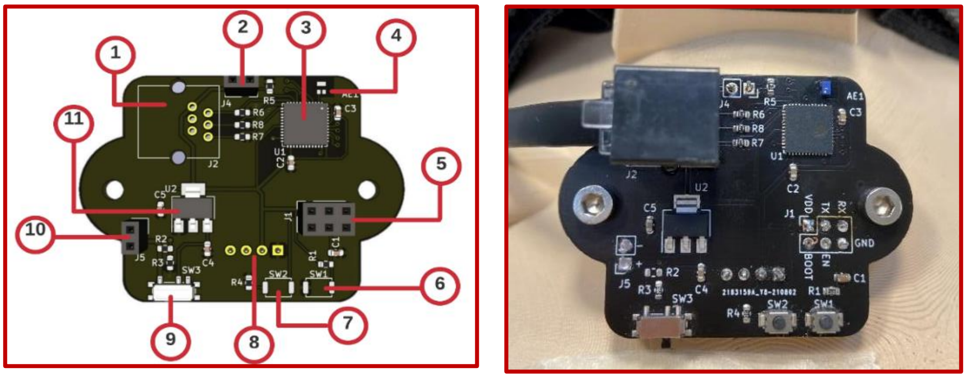
The right choice for the power unit is the 9V battery as is shown in figure 4.15. They are used in many applications requiring a greater amount of power than other devices. The range temperature is -18° to +55°C and principally it is a strong, long-lasting battery. The main reason for choosing this component compared to other possibilities is the capacity of using it for the same type of battery, disposable or rechargeable, as both components have the same voltage.

Figure 4.15 Photography of the 9V battery for the power unit of the entire system.

4.2.2 Printed Circuit Board

PCB briefly is used to mechanically support and electrically connect electronic components. In this case, the PCB will allow to receive of the values of the different sensors and send them to the mobile phone of the user through Bluetooth.

As is shown in figure 4.16, this PCB is constituted by: (1) sensors connector; (2) Front sensor connector; (3) ESP32-PICO-D4 chip; (4) Antenna; (5) Debug connector; (6) Reset button; (7) User button; (8) Humidity sensor connector; (9) Power switch; (10) Power input connector; (11) Voltage regulator.

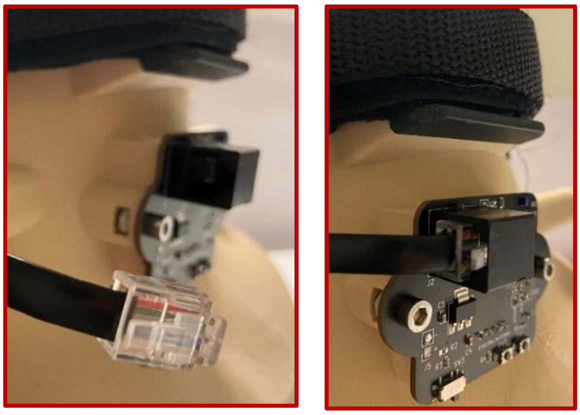


a) b)

Figure 4.16 a) Constitution of the PCB; b) Photography of the implementation of the PCB in the collar device.

4.2.3 Connector RJ45

As the entire collar structure is split into two parts, it would be speculative to predict that the existing sensors on the equipment would also have to be split. Therefore, it is necessary to implement a mechanism that after fixing the device to the patient, it is also possible to connect all sensors. The rear part of the collar will be equipped with the side and rear sensors, and the front part will be equipped with the rest (front pressure and humidity sensor). After placing the collar on the patient, the patient must connect the rear sensors to the PCB on the front with the aid of an RJ45 connector, as shown in figure 4.17.



a) b)

Figure 4.17 Double Figure of the implementation of the connector RJ45: a) Photography of the connector RJ45 dismounted to the front part of the collar device. B) Photography of the connector RJ45 mounted to the front part of the collar device.

4.3 Interface creation and development

4.3.1 Interface

All the values of the sensors will be displayed to the user on his device, therefore, it will be necessary to create an interface to create the connection between the user and the values of the sensors. All the interfaces will be created using the *MIT App Inventor*®. This application is the vantage to be easy and intuitive even for operators that don't are familiarized with programming languages. (*MIT App Inventor | Explore MIT App Inventor*, n.d.)

This program allows the users to drag and drop visual objects to create an application that can run on Android devices.

The user of the collar will have to install the application TMCCIS (Tailor Made Cervical Collar Instrumented Sensors) on his device as is shown in figure 4.18:

Figure 4.18 Figure of the Application TMCCIS.

After the user successfully installs the application, should turn on the device of collar and then open the application TMCCIS. After starting, the application itself provides a short tutorial with the right steps to follow, as is shown in figure 4.19.

First, the user must search pressing the bottom "Scan" to be able to find the device. If it is not possible to find it, the user must rectify the battery health and restart the application. After the application finds the device, the user should press the bottom "Connect".

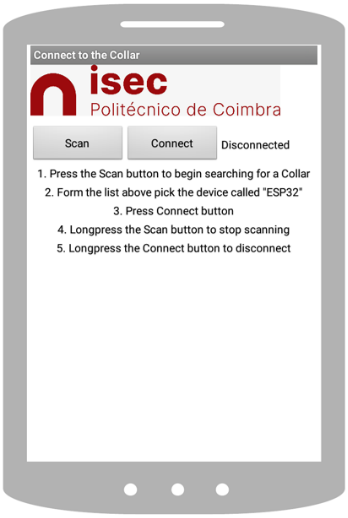
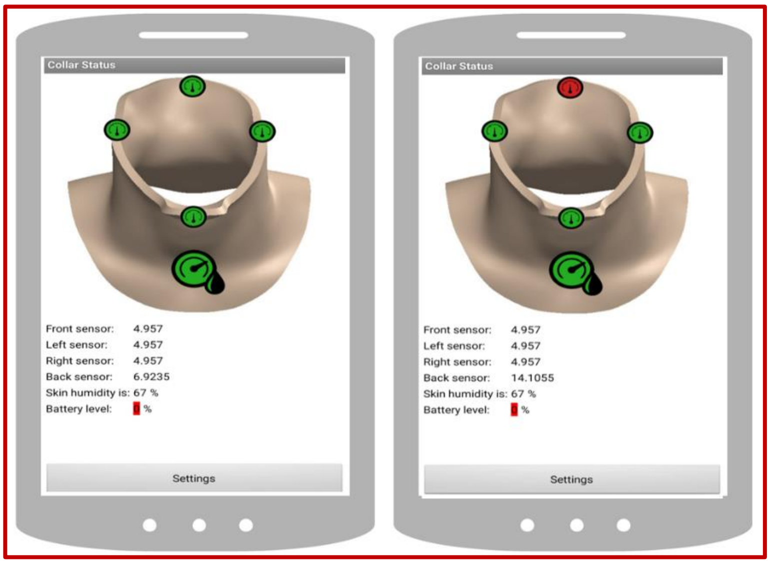


Figure 4.19 Figure of the first page of the application TMCCIS.

The main page of the application is right after the user presses the bottom "Connect". The program will show an image of the collar with 5 icons (4 related to pressure sensors and 1 related to humidity sensor). Below the collar, it will be displayed the values in newtons of the pressure to which the sensors are submitted and the percentage of humidity in the sensor area. If the values of all sensors are in the normal range, the icons for each sensor will be displayed with a green color. If there is a sensor with too high pressure or humidity values, the icon will turn to red color. With this change of icon colors, the user will know in real-time whether the temperature or the activity that he is being subjected to, may or may not, decrease the health and stability of the cervical area.

In figure 4.20 it is possible to watch 2 different main pages. Figure a) indicates the default values (values that the patient is submitting but which do not present any problem for health, as the values are within the correct range). Figure b) it is possible to watch the back sensor detected an effort above normal, changing the color of the sensor itself in the application figure and the value of the effort.



a) b)

Figure 4.20 Figure of the main page of the application TMCCI: a) Default Values of the sensors; b) Change of color and value of the Back Sensor when a effort is applied.

4.3.2 Sensors Calibration

After the correct installation of the program on the mobile phone that will be used to monitor the pressure and humidity values in real-time, it is first necessary to calibrate the implemented sensors.

To calibrate the pressure sensors, it is necessary to use objects with the right weights. Using, for example, an object with a weight of 1kg, it should be placed on top of the covering where a sensor is applied. Then, another object with a different weight must be used on the same sensor. With the values obtained, it is possible to create an equation that allows the operator to return the force applied at the moment in Newtons.

$$y = 0.0285x + 4.957 \tag{4.3}$$

To complete the pressure sensor calibration, the operator must introduce the line of code into the program wish is visible in the figure 4.21:

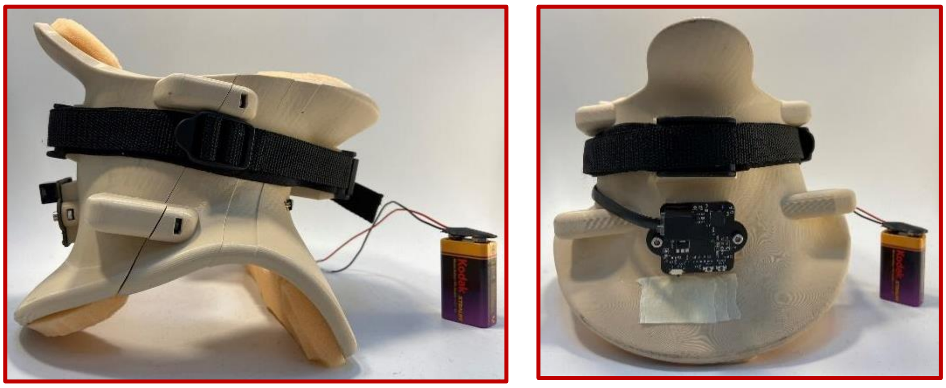
Figure 4.21 Scheme of the code implemented on the MIT App Inventor® to calibrate the pressure sensor and return the values of pressure in newtons.

Regarding the sensor humidity sensor, the device itself has a self-calibration digital system, so it was not necessary to carry out any type of calibration.

4.4 Functional Prototype of Instrumented Collar

It was not possible to test the equipment on the patient, however, through tests using weights, it was possible to test the pressure sensors. The values obtained were as expected, however, there were some differences in value from sensor to sensor which is related to the contact zone or the way they were bonded to the cervical neck.

The figure 4.22 shows the final prototype of the Tailor made cervical collar instrumented with sensors.



a) b)

Figure 4.22 Final Prototype of Instrumented Collar

5. Discussion and Conclusions

The project presented involved the development of a methodology to obtain a personalized cervical collar and the implementation of a specific group of sensors to monitor some vital signals and prevent lesions through the use of the collar. Two main conclusions can be present concerning the developed work:

1. Tailor made methodology

As explained and tested, the proposed methodology shows an easy way to develop and implement a tailor-made based cervical collar perfectly adapted to each patient. The possibility of using one of the reverse engineering processes allow creating a necklace adapted for each user, thus eliminating the uncertainties generated by necklaces on the market.

2. Sensor Monitoring System

The application of sensors and the possibility of monitoring some vital parameters in a personal device allows the user to have more security as they can predict if the applied movement will endanger the cervical spine's stability. Also, the skin's health can be considered, thus reducing the probability of having ulcers.

Future work

Although the results obtained show a good path, they are based on developing a prototype, which, as expected, needs improvement. Thus, work is planned to be implemented in the future, which is described:

To improve the characteristics of the cervical collar, certain factors need to be corrected. The present cervical collar's weight is about 450g. Therefore, it is heavier compared to existing necklaces on the market (the necklaces weigh between 100 and 200g). That said, it is necessary to reduce the collar's weight to increase the patient's comfort when using it. There are two possible solutions: to reduce the density of the material deposited in the construction without endangering the rigidity of the collar; Optimize the structure, removing material in areas where it is not necessary for the system and the healthy recovery of the patient;

- The structure must be improved at an aesthetic level to be more presentable and also to protect the implemented electronic components better;

- The process of constructing the necklace using the *Solidworks*® tool can be improved to make the production of the necklace more intuitive and faster for the operator;

- The collar must present an improved geometry, namely the increase of the collar's contact area in the patient's jaw area, as the current model allows a slight free lateral movement of the neck, which is undesirable for correct recovery of the cervical region of the patient and can be optimized;

- Regarding the electronics, the battery system of the equipment needs to be improved to increase the life of the device as much as possible;

- Concerning the values registered by the sensors, they must be improved to be as reliable as possible. Improving the contact zone of pressure sensors and increasing the number of humidity sensors per device can be a viable solution. In a future perspective, it would be essential to have a test accompanied by professionals with medical knowledge to correctly measure and calibrate the values of all sensors. In this way, the sensors implemented in the collar go beyond the exact ranges of values to alert the patient in case there is movement or excessive humidity that can put at risk the health of the cervical spine.

Finally, it is important to mention that with all the elaboration of this project, knowledge was acquired using *Solidworks®* tools, 3D Printer and even the 3D Scan device. All the experience of carrying out mobility in Russia, also allowed the development of the ability to speak, communicate in English and learn the alphabet and some quick forms of communication in Russian.

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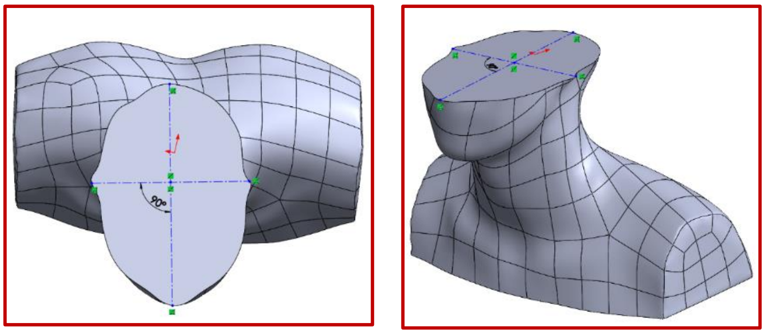
Appendix A

Creation of the Axix XX and YY

The first procedure is to create a sketch using the Top Plane as reference. It is a challenging procedure, because it is not easy to find to exactly geometrical zones of the head of each person, so, both Axes are drawn as geometric as possible and perpendicular to each other, as shown in the figure A.1. After that procedure, the entire systems of references it will be built in base of the drawn sketch.



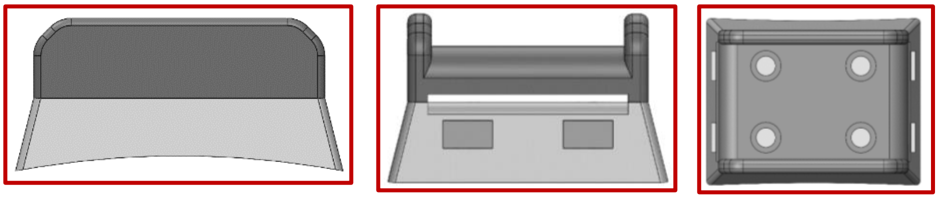
a) b)

Figure A.1 Creation of the Axix XX and YY.

Appendix B

Component to fix the elastic band

The entire component is divided in 2 solids, one of them it will be directly assembled to the collar, as mentioned in the figure A.2. It is possible to visualize a concave zone to facility the assembly the component to the collar. Both components present fillet on the edges to prevent cuts in the elastic band and the resistance fabric.



a) b) c)

Figure A.2 Multiple Figure of the entire component needed to fix the elastic band: a) Front View; b) Right View; c) Top View.

The 4 nuts will be collocating in the 4 cavities created with the dimensions $6{,}2 \times 3{,}5\ mm$ as shown in the figure A.3. These dimensions had already an offset from the dimensions of the nuts ($5{,}8 \times 2{,}5\ mm$) to facility the assembly. The figure A.3 shows too the offset created from the initial dimensions of the nut.

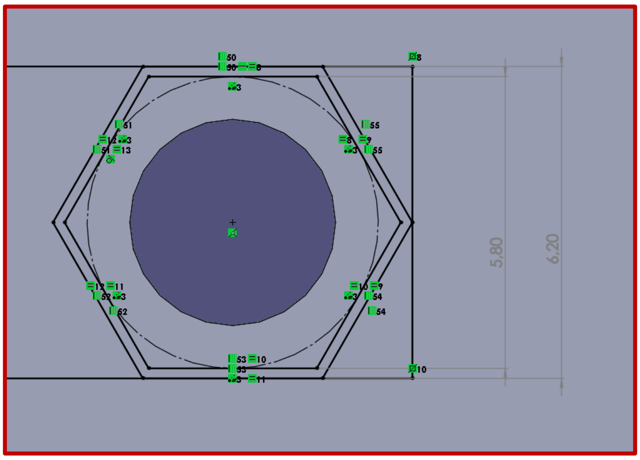


Figure A.3 Offset created for the nut.

There is a gap space of $1mm$ of height between both components. In this specific space is relative to the elastic band as is shown in the figure A.4.

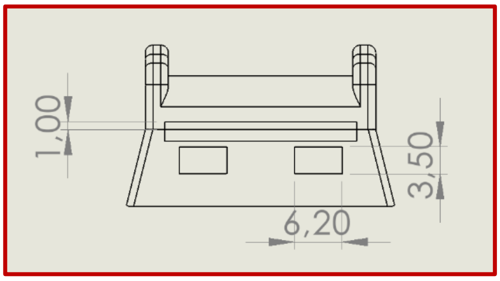


Figure A.4 Dimensions of the space for the Nutt and the gap for the elastic band.

The external component is important because it will support 2 mechanisms: Elastic Band and Resistance Fabric with Velcro. The Elastic Band will be assembled in the bottom of the component, specifically in the gap mentioned previously.

a) b) c)

Figure A.5 Multiple Figure of the external component to support 2 mechanisms: a) Right View; b) Front View; c) Top View.

The Elastic Band has 1mm of height and 20mm of width, thus, the mounting to the solid component is made with the hexagon socket head cap screws 4x M3 and 4x M3 nuts as is shown in the figure A.6.

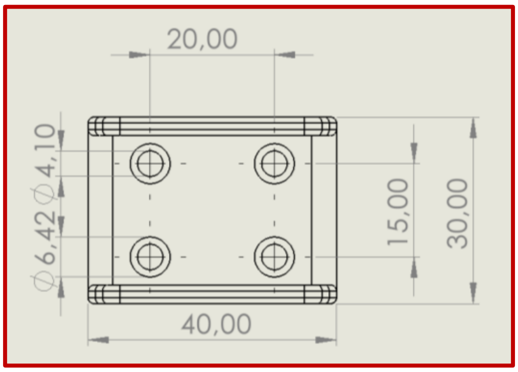
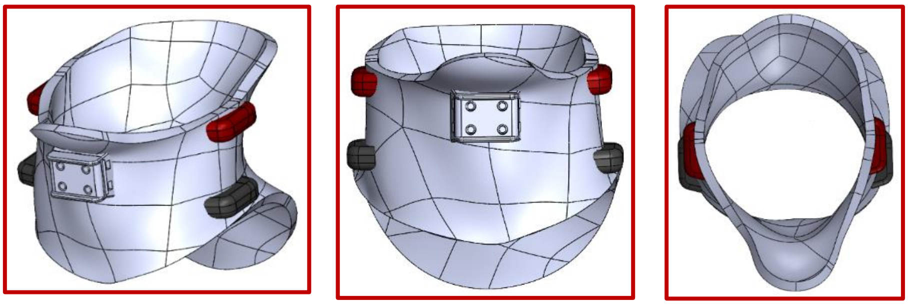


Figure A.6 Dimensions of the External component to fix the Elastic Band.

Appendix C

Components of the cylindrical system

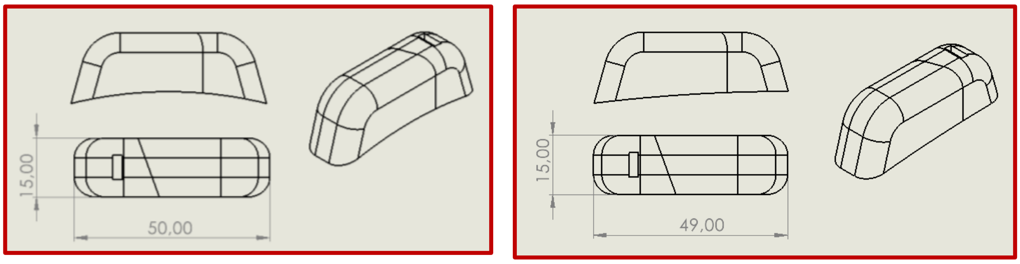
The cylindrical guides mechanism can be divided in 2 groups: Superior components and Inferior Components, as shown in the figure A.7 in different colours. The Superior components are coloured with red, and the Inferior are coloured with grey.



a) b) c)

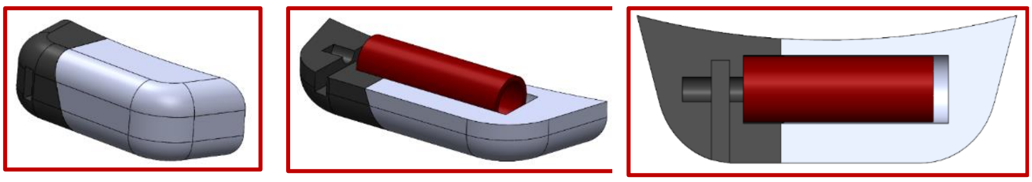
Figure A.7 Double Figure of the 2 different components of the cylindrical system: a) Overall view; b) Front View; c) Top View

Both systems are similar with only differences relatively to the concave zone to facility the assembly the entire component to the collar and the length, the Inferior Component is $1mm$ smaller to the Superior component for the same reasons mentioned about the concaves zones.



a) b)

Figure A.8 Dimensions of the length and thickness of the 2 types of cylindrical mechanisms for the Right side: a) Superior Component; b) Inferior Component.



a) b) c)

Figure A.9 Multiple Figure of one of the components of the Cylindrical Guides: a) Overall View; Overall and Cut View with the pine assembled; c) Top View with the pine assembled.

Appendix D

Dimensions of the component to fix 2 closing mechanisms

As mentioned previously, the external component shown in the figure 7.6, will support 2 mechanisms: Elastic Band System and the resistance fabric with Velcro. Thus, it will need to mount the resistance fabric only on the back part of the collar. It will be necessary to remove the screws used to assembly the elastic band system, place the resistance fabric and finally assembly the new component design, as shown in the figure A.10, to fix the entire system.

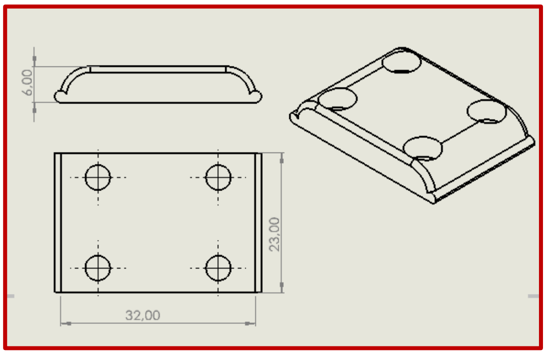
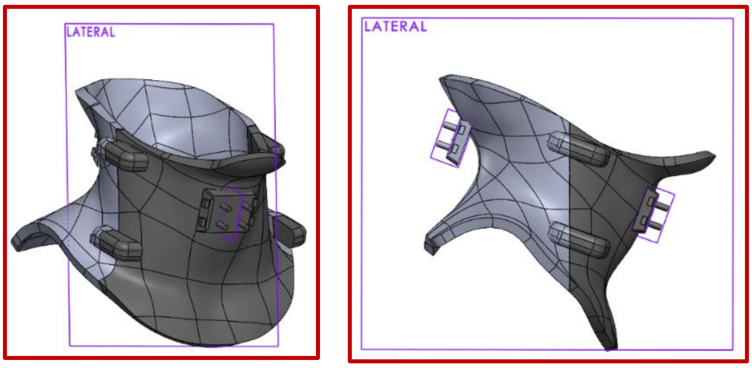


Figure A.10 Dimensions of the component to fix the entire Resistance Fabric with Velcro System to the component used to fix the Elastic Band system

Appendix E
Final Finishes of the collar

The Finishes steps of the digital model is the correct assembly of the entire components, remove the filling components and create solid components to guarantee the completed assembly and a better finish.

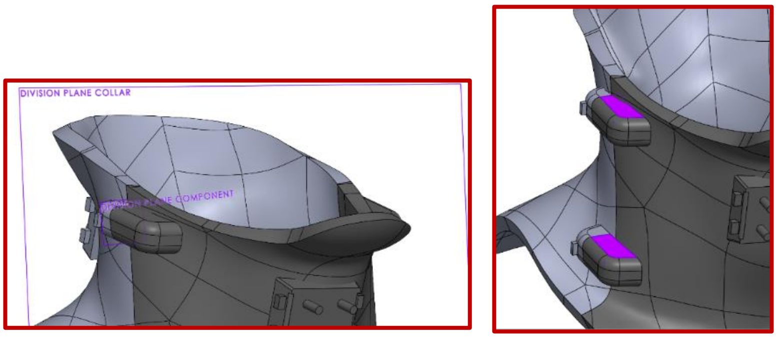
Relatively to the components to fix the Elastic Band and the Resistance Fabric Velcro, the operator should use the Lateral Plane of the Collar with the Lateral Plane of each component and create a coincident mate. The 2 components should have a parallel mate between them and the exact location on the YY Axe is at the discretion of the operator.



a) b)

Figure A.11 Double Figure of the mattes created between the 2 components for the fix of 2 closing mechanisms and the cervical collar: a) Mate created between the Collar and the components; b) Mate created between the 2 components.

The next assembly are the 4 cylindrical guides to the collar. The operator will use the Division Plane of the components and the Division Plane of the collar and make a coincident mate to guarantee in the moment of the division, all the components will be divided in the exact zone. After that, all 4 components must have a parallel mate between them. The exact location in the YY and XX Axes is at the discretion of the operator.



a) b)

Figure A.12 Double Figure of the correct assembly of the Guides system components to the collar: a) Mate created between the guides system to the collar; b) Mate created between the guides system components.

Next step is to remove the filling objects created. The next figure A.13 shows the Collar Cervical with the all-filling objects:

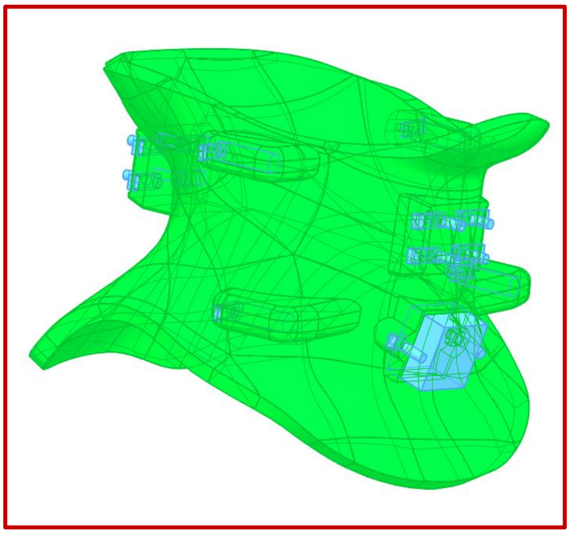
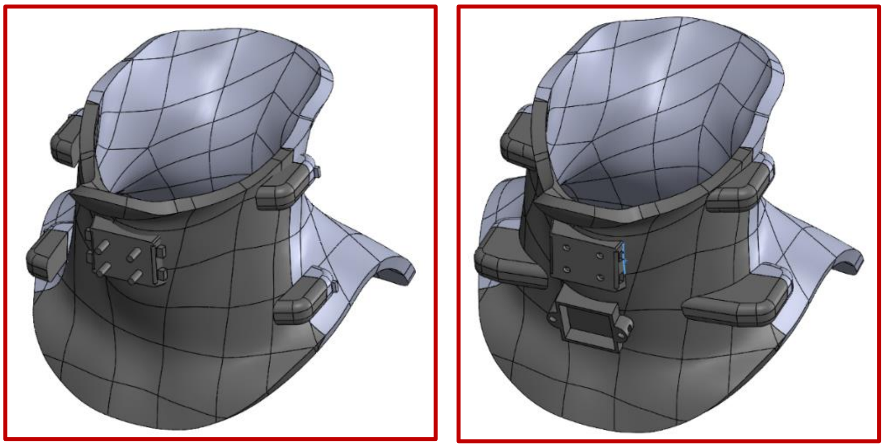


Figure A.13 Cervical Collar with the all-filling objects (blue colour).

Final step of the digital model is to guarantee the perfect assembly between the all the components and also give a better finish to the entire collar using the command “Move Face”. This command creates solid bodies that will connect the entire components until the surfaces of the collar ensuring that there are no empty spaces between them. The figure A.14 shows the difference between the collar with and without the command “Move Face” applied:



a) b)

Figure A.14 Double Figure of the difference of the application of the command “Move Face”: a) Collar before the application of the command; b) Collar after the application of the command.

Appendix F
Closing Mechanisms

During the construction of the model of the collar, some mechanisms have been changed to improve the entire collar both for comfort and ease of use for the patient, as well as to improve the stiffness of the collar, as already referenced.

Closing Mechanisms

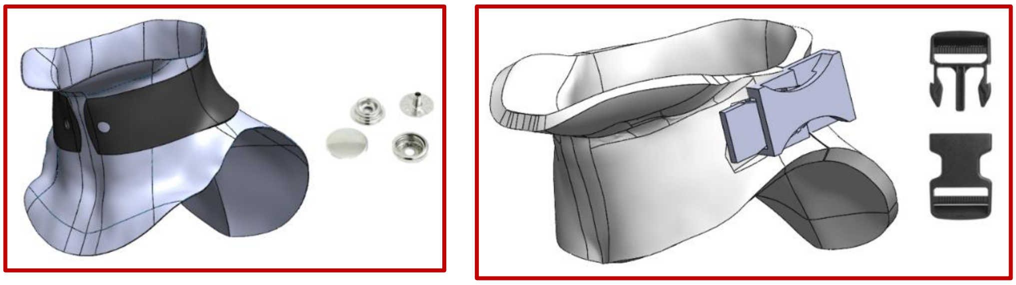
In the first models, the idea of using wide elastic straps was used, in which fixation point would be made through the use of pressure buttons (very used in clothing) in the holes designed at the endos of the elastics.

However, the mechanism did not have continuity in the project, as the fixation system would not have as much force for closing the collar compared to the system used in the last model (Fabric Resistance with Velcro).

There would also be disadvantage of having to create a hole in the collar to place one of the components of the pressure button, which could damage the structure at the closing moments.

One other mechanism to closing the collar was idealized using a buckle system (typically used to close backpacks). The perception quickly emerged that the system would not be the most appropriate because it occupies a lot of volume that in some way would be inconvenient for the patient or even because the closure is not completely reliable.

The figure A.15 shows the initially idealised mechanisms:



a) b)

Figure A.15 Double figure of Closing mechanisms initially idealised: a) Elastic Straps with pressure buttons; b) Bucle system.

Over time, the need arose to create a system that could perfectly align the 2 divided parts of the collar. Before reaching the last mechanism used to guide the parts (cylindrical guides), the use of smaller pins was initially conceived and placed inside the thickness of the equipment. It was then necessary to rethink the mechanism and increase the size of the cylinders to ensure a perfect assembly of the parts.

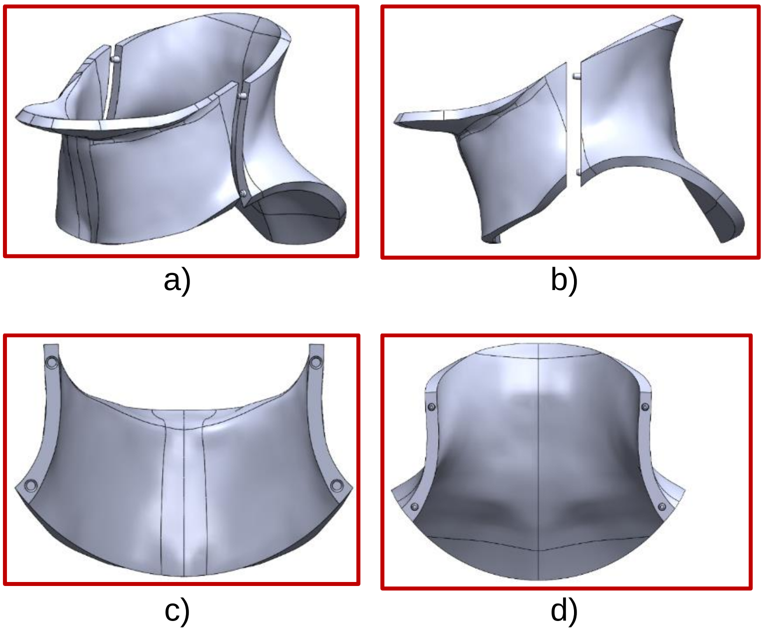


Figure A.16 Multiple Figure of the initially guide system created: a) Overall view of the collar with the guide system; b) Lateral View of the collar with guide system; c) Back View of the Front Part of the collar; d) Front View of the Back Part of the collar.

Appendix G

First and Second Models

First Model:

The first of the digital was created without using the technology of 3D scan, therefore it is a completely different cervical collar compared with the other versions. It was used a human model from the GrabCad ((*James (Human Body for Scale)* | *3D CAD Model Library* | *GrabCAD*, n.d.)). The process of the building the collar starts at the moment when the operator identifies the surfaces of the model's neck area for the construction of the collar and with the help of *SolidWorks*® tools uses the same steps used in any collar using 3D scanning technology. The only difference is the use of a model created by the author and not using a model taken from a physical object (in this case the volunteer). In the figure A.17 is shown the used model and some assemblies between the model and the first model of the collar.

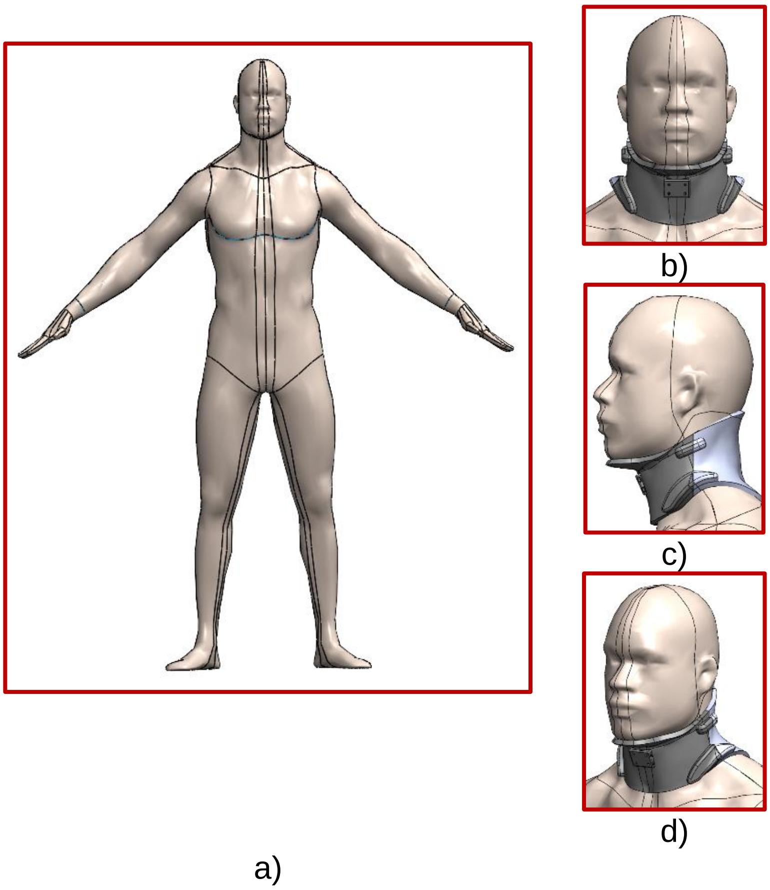
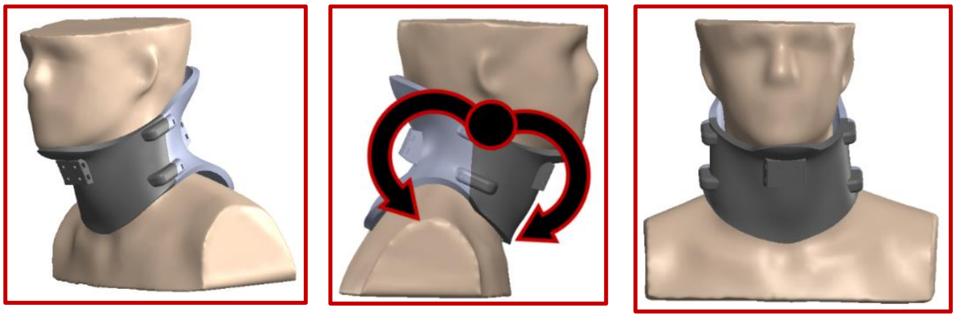


Figure A.17 Multiple Figure of the model used and the first digital model of the collar(James (Human Body for Scale) | 3D CAD Model Library | GrabCAD, n.d.): a) Front View of the model of the Human body used; b) Front view of the collar; c) Lateral View of the collar; d) Overall view of the collar

Second Model:

The second model it was already applied the 3D scan technology to obtain the digital model from the volunteer, therefore, this model has similarities compared to the final model.

After the construction and successive printing of the model, when placed on the volunteer, a problem was noticed that quickly had to be corrected. The model had to be extended in the chest and back areas, because the volunteer was able to flex and deflect the head in an exaggerated way, given that, there was a need to increase the contact area on the chest and back in order not to allow the movements mentioned.

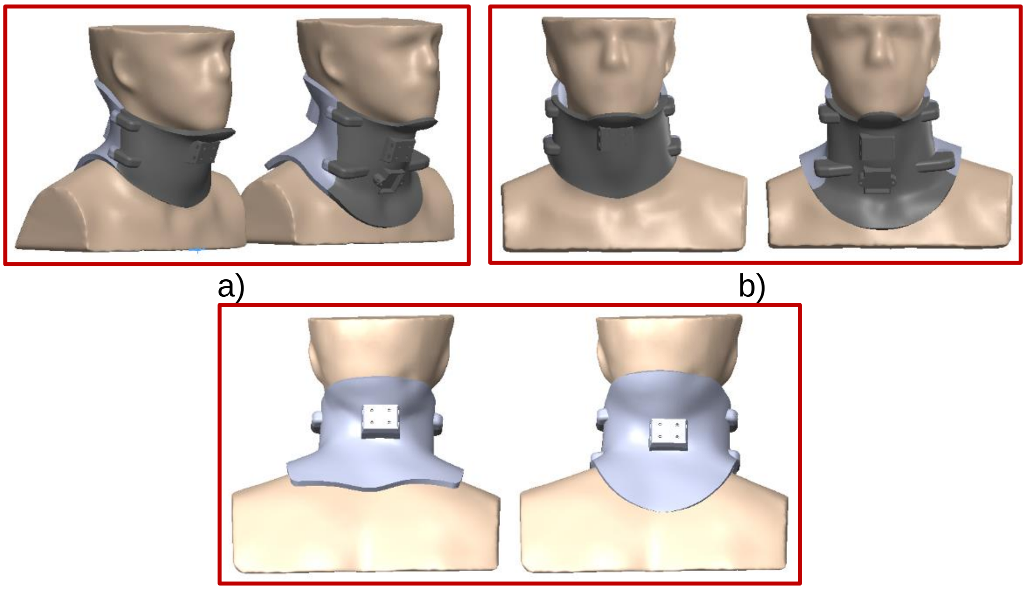


a) b) c)

Figure A.18 Multiple Figure of the Second Model with the volunteer: a) Overall View; b) Lateral View and the Deflection and flexion movements of the volunteer; c) Front View.

Final Model:

The entire process of the construction is already explicated during the project, however, it is important to show the final model and compare with the model previously developed. The figure A.19 shows the second model and the final model where the changes, made in the chest and back are explained.



a) b) c)

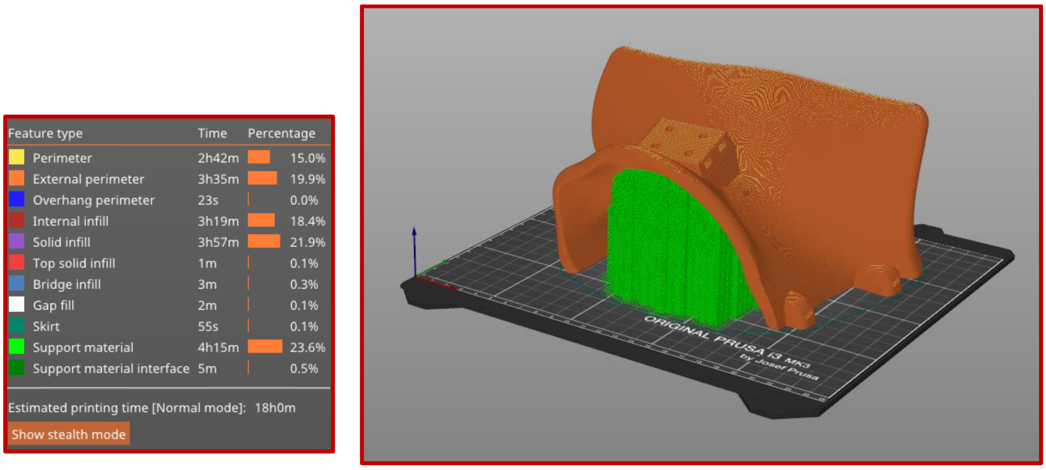
Figure A.19 Multiple Figures of the comparison of the second model and the final assembled on the volunteer: a) Overall view; b) Front view; c) Back view.

Appendix H

Pre-processing of the Back Part and external components

The program was made for the same printer used for the printing of the Front Part (0.6 nozzle with a detailed print ($0.15mm$ each layer) using algo PLA as material.

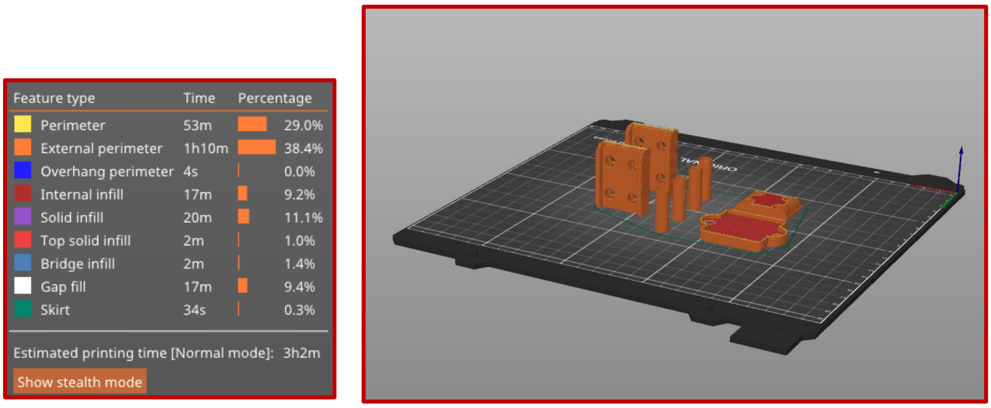
As is shown in the figure A.20, it was necessary to create supports due to the geometry of the Back Part:



a) b)

Figure A.20 Double Figure of Pre-Processing step with the Prusa® Slicer Software: a) Table of the time of Printing of each feature type; b) Image of the sliced Back Part of the Collar using the Software.

For the external components it was used the same characteristics of the print, but as expected, it is a fast process comparing with the two prints of both parts of the collar, as it is shown in the figure A.21:



a) b)

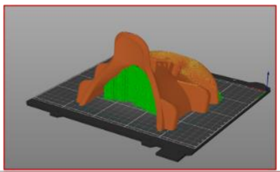
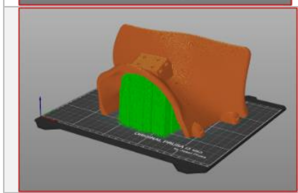
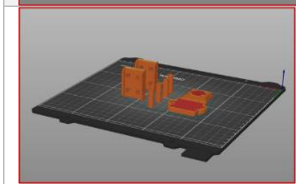
Figure A.21 Double Figure of Pre-Processing step with the Prusa Slicer Software®: a) Table of the time of Printing of each feature type; b) Image of the sliced external components of the Collar using the Software

Appendix I

Table with parameters of the components of the collar to be printed

The table A.1 shows the time required, grams and meters of material required for each component to be printed: Front Part, Back Part and External Components. In the final part of the table, it also presents the total of each parameter.

Table A.1 Table of some parameters of each and total components of the collar to be printed.

	**Front Part**	Time	15H:53m
		Meters (m)	87,77
		Grams (g)	249,86
	**Back Part**	Time	18H:00m
		Meters (m)	108,90
		Grams (g)	324,80
	**External Components**	Time	3H:2m
		Meters (m)	9,95
		Grams (g)	29,67
TOTAL		Time	36H:55m
		Meters (m)	206,62
		Grams (g)	604,33

Appendix J

Views of the Collar and External components

In the A.22, is shown different views of the collar printed and assembled with the all components used for the closing mechanisms:

a)

b)

c)

d)

Figure A.22 Multiple Figure of the Collar and the External Components: a) Overall View of the front; b) Overall view of the back; c) Lateral View; d) External components needed for one cervical collar.

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