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MESTRADO EM ENGENHARIA MECÂNICA

Development of a Novel Pre-Hospital Cervical Collar with a Pressure Measuring System

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Coimbra, Maio de 2022

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Development of a Novel Pre-Hospital Cervical Collar with a Pressure Measuring System

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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Dedications

I want to dedicate and thank all the participating parties that allowed directly or indirectly to the execution and completion of this project. With some risk of not mentioning someone, on the following lines I desire to express my sincere thanks:

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ABSTRACT

Cervical Orthosis is a medical device for cervical treatment, post-surgery recovery, and immobilisation in emergency scenarios. Its main function is to protect the cervical region to prevent further damage, in emergency scenarios, and to immobilise or provide support for a surgery recovery or treatment of a health condition. In every case, the cervical orthosis is a structure that transfers the weight from the head and natural gravitational efforts to the shoulders or adjacent areas, protecting the cervical column.

There are two types of cervical collars, the Hard Cervical Collars, and the Soft Cervical Collars. The Hard Cervical Collars are applied in situations of higher immobilisation as they present better movement restriction (right after surgery, or in emergency scenarios). The Soft Cervical Collars are usually used during treatment or recovery from surgery as an element of transition between the higher support provided by the Hard Collars and the normal life of a patient (full recovery).

According to what was found on the State of Art, namely regarding problems reported in several articles, was verified a big margin for improvement on these devices. There was also verified a lack of technological improvements on the emergency focused Cervical Collars, and for that reason, an Emergency Cervical Collar for Adults was developed.

This project was developed in Polytechnic Institute of Coimbra, Portugal, in cooperation with Penza State University, in Russia. It comprises a Mechanical Section where a structure was designed from sketch, aiming to prevent diagnosed problems of the state of art, and an Electronic Section where a Pressure Measuring System (for assessing fastening pressures) and a Respiratory Rate Monitoring System were developed as a technological improvement.

The document describes the several steps for which the work passed through to accomplish the prototype produced with Additive Manufacturing. Due to the high potential of immobilisation achieved with the device, it was named Neck Protection Structure (NeProS).

Keywords: *Cervical Orthosis; Emergency Cervical Collar; Medical Devices; Additive Manufacturing*

RESUMO

As Órteses Cervicais são equipamentos médicos para tratamento cervical, recuperação pós-cirurgia, e imobilização em situações de emergência. A sua principal função é a de proteger a região cervical para evitar danos acrescidos, nos cenários de emergência, e para imobilizar ou providenciar suporte na recuperação de uma cirurgia ou no tratamento de uma condição médica. Em todo o caso, as órteses cervicais são uma estrutura que transfere o peso da cabeça e dos esforços gravitacionais durante movimentos para os ombros ou áreas adjacentes protegendo, assim, a Coluna Cervical.

Os Colares Cervicais podem ser divididos em dois grupos, Colares Cervicais Rígidos e Colares Cervicais Esponjosos. Os primeiros são normalmente aplicados em situações em que é necessária uma maior imobilização (após cirurgia, ou em cenários de emergência médica), uma vez que apresenta maior restrição de movimentos. Por outro lado, os Colares Cervicais Esponjosos são habitualmente utilizados durante um tratamento, ou durante a recuperação de cirurgia, como um elemento de transição entre o Colar Rígido e a vida normal do paciente.

Atendendo ao que foi encontrado na literatura, nomeadamente em relação aos problemas reportados por diversos autores, foi identificada uma vasta margem para melhoria destes equipamentos. Foi também identificada uma falta de melhorias tecnológicas para Colares Cervicais direcionados para a vertente de emergência médica, e por este motivo, foi desenvolvido um Colar Cervical de Emergência para aplicação em adultos.

Este projeto foi desenvolvido no Instituto Politécnico de Coimbra, em Portugal, numa cooperação com a Universidade Estatal de Penza, na Rússia. A solução proposta apresenta uma vertente Mecânica onde uma estrutura foi desenvolvida de raiz, com o objetivo de evitar alguns dos efeitos adversos identificados no estado de arte, e uma vertente eletrónica, onde um Sistema de Medição de Pressão (para avaliar pressões no momento de aplicação do colar), e um Sistema de Monitorização da Respiração, foram desenvolvidos como melhorias tecnológicas.

O presente documento descreve as diferentes etapas de desenvolvimento do projeto até ao culminar de um protótipo produzido recorrendo a Fabrico Aditivo. Devido ao elevado potencial de imobilização observado, a estrutura foi batizada de Neck Protection Structure (NeProS).

Palavras-Chave: *Órtese Cervical; Colar Cervical de Emergência Médica; Dispositivos Médicos; Fabrico Aditivo*

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Abbreviations

2D	Two-Dimensional
3D	Three-Dimensional
ABCDE	Airway; Breathing; Circulation; Disability; Exposure
ABS	Acrylonitrile Butadiene Styrene
App	Application
ASTM	American Society for Testing and Materials
CAD	Computer-Aided Design
CHAMU	Circunstâncias do acidente /Accident Circumstances; Historial de Doenças e/ou Gravidez / Disease and Pregnancy History; Alergias / Allergies; Medicação Habitual / Usual Medication; Última Refeição / Last Meal;
CNC	Computer Numerical Control
CODU	Centros de Orientação de Doentes Urgentes (Guiding Centres for Urgent Patients)
CSIC	Cervical Spine Immobilisation Collar(s)
FFF	Fused Filament Fabrication
FDM	Fused Deposition Modelling
ICP	Intracranial Pressure
INEM	Instituto Nacional de Emergência Médica
MIT	Massachusetts Institute of Technology
PSU	Penza State University
PCB	Printed Circuit Board
PVC	Polyvinyl Chloride
PLA	Polylactic Acid
SCI	Spinal Cord Injury
STL	Standard Triangle Language
TBI	Traumatic Brain Injury
PETG	Polyethylene Terephthalate Glycol
NeProS	Neck Protection Structure

1. Introduction

The Cervical Orthosis, commonly known as Cervical Collar, is a device for complete immobilisation of a patient with suspected injury to the cervical column and to the spinal cord, that has been considered a signal of good practice in the emergency scenario since it began to be applied worldwide on the mid-1960s. The restriction of movement offered increases the stabilisation of the patient in situations where the additional movement of the cervical spine can cause irreversible damage to the spinal cord beside the initial injury caused by a trauma accident.

In recent years, numerous articles like the ones from Carrison *et al*. (2015), Stone *et al*. (2010), and Damiani (2017), have described and proven that the constant immobilisation with this kind of device shouldn't be a must as it presents harmful conditions to the patients and sometimes worsening their vital parameters. Since the protocols remain and this orthosis is still in use, its evolution and improvement are essential to reduce bad effects and to find better and more recent compatible technologies and solutions. By also understanding the procedure since the approach to the victim, its immobilisation, and transport to the assigned medical facility creates the opportunity for solving necessities during that period and implementing it on the cervical orthosis turning the device versatile.

The market offers different kinds of solutions that solve individual known problems from the literature. But there isn't any versatile option that solves several problems on just one device.

This project aims to understand the function of the vertebral column, in specific of the cervical region, interpret its needs for immobilisation when in an emergency, prize the harmful effects detected on the state of art, and work with it to find a possible structure that can be considered an improvement in this type of devices. The project also intends to implement a pressure monitoring system and a respiratory monitoring system that assists the paramedics' work when applying the cervical collar by controlling the pressure of fastening and saving them time when evaluating or re-evaluating the patient's condition. The respiratory monitoring system also alerts the paramedics when the condition worsens and life is compromised, due and based on the airway.

The developed device present in this work, designed Neck Protection Structure (NeProS), was developed in cooperation with Polytechnic Institute of Coimbra (School of Engineering – ISEC), in Portugal, and Penza State University (PSU), in Russia.

The 3D modelling and production of the mechanical system were implemented in the Applied Biomechanics Laboratory of ISEC. Concerning the production method and taking into consideration that a prototype will suffer several changes during its development and testing process, 3D printing is the most reasonable solution. The costs associated with this kind of process are low when compared to the remaining ones. This is a very versatile method due to the possibility of producing highly complex features relatively quickly. The technology used for printing was fused filament fabrication, a layer deposition method.

As for the electronic components, implementation of sensors, app creation and interface design process, this took place at Penza State University, in the framework of an ICM Erasmus Mobility.

The document is presented in 6 chapters that are organised according to the engineering design process adopted in this project. The first chapter and its subchapters collect information through the literature, present the state of the art concerning cervical collar devices, the needs and constraints of this kind of device, and are also identified immobilisation methods. The following chapters and subchapters, display the 3D modelling from the first to the final model (printed version), the production of the concept and the implementation of the electronics, as well as the time and costs associated with the production method in use. After the production of the first fully assembled prototype, a chapter with first trials is presented. During this chapter are identified the major needs of it, required improvements and corrections, and a report, concerning parameters' evaluation and further suggestions, is filled by the volunteers and the immobilisation performer. The document is finished with suggested future works and conclusions. All the 3D modelling processes are supported with appendices for a better understanding of each model because the exposure of all the detailed features in the main document would result in extensive text.

2. Cervical Collar

The main purpose of applying a cervical collar is a complete immobilisation of the head and neck to reduce possible movements (rotation, flexion, lateral flexion, and extension - Figure 1) and keep a perfect alignment of the body at the neutral position according to the axis nose, belly button and feet. This type of structure offers head support by transmitting any effort from the neck to the shoulders or adjacent areas.

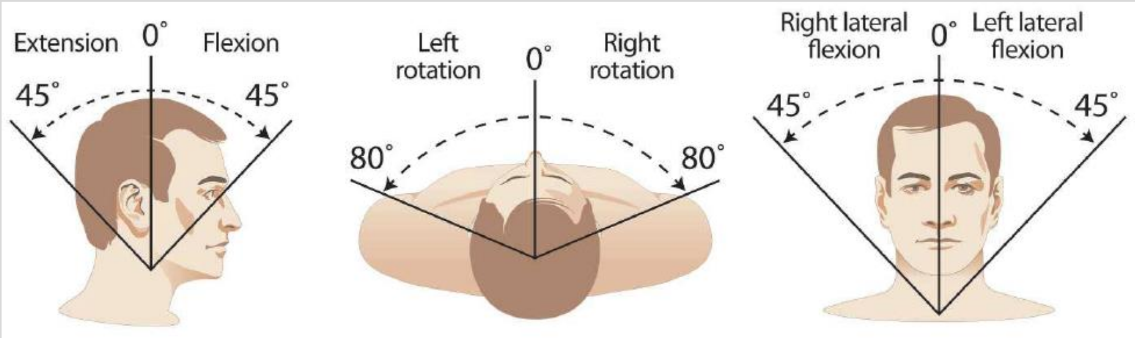


Figure 1 – Cervical Spine Range of Motion. Adapted from *Carrison et al. (2015)*

The pre-hospital/emergency cervical collar is usually applied to trauma victims. It aims to restrict, as much as possible, the additional movement of the cervical spine since this can result in severe and irreversible damage apart from the initial injury caused by the trauma accident.

Once the neck is attached to the body, a cervical collar only secures it, not fully restricting or fully preventing the patient's further movement. Even if the cervical spine would be completely immobilised with the help of external devices, movement underneath it would cause the patient to move and, as a consequence, the cervical spine. So, it is impossible to immobilise the cervical spine without a complete immobilisation of the patient.

To ensure a complete understanding of cervical collars, this chapter presents information considered relevant in the context of the work carried out. So, firstly a revision concerning the vertebral column and spinal cord is presented, followed by the trauma mechanisms on it that require the application of a cervical collar for immobilisation. Afterwards, the trauma victims' approach is also described. Finally, an extended revision concerning the cervical collar systems that can be found in the market, as also in the open literature, is presented and discussed.

2.1 – Vertebral Column and Spinal Cord

The Vertebral Column and Spinal Cord are part of the skeletal system. Even though the skeleton is associated with bones and death, the skeletal system is a live and dynamic tissue capable of self-healing after injuries, growth, and adaptation to different applied pressures. It is composed of conjunctive tissues like ligaments, cartilages, and tendons.

The Vertebral Column is an extended composition with 33 irregular bones (26 in adult life), designated vertebrae, and located on the medium line of the posterior part of the body. The top part of the vertebra's body articulates with the precedent. The bottom part of each articulates with the following vertebra having in between the intervertebral disc (a pulposus nucleus mainly composed by water and proteoglycans involved by a ring of collagen fibres) allowing the column to be semi-flexible, and in combination with its natural curvature, to create a robust structure. The intervertebral disc actuates like a hydraulic system distributing the weight from one vertebra to another, preventing its collision/friction and allowing movement. (Jones, 2020)

The Vertebral Column is divided into 4 regions. Following the direction head-feet, those regions are the following:

- Cervical Region – 7 vertebras, matching the neck region;
- Thoracic or Dorsal Region – 12 vertebras, matching the dorsum;
- Lumbar Region – 5 vertebras, matching the lumbar;
- Sacrococcygeal Region – 5 vertebras, matching the sacrum, and 4 vertebras, matching the coccyx. These two groups separately merge from newborn to adult life, forming the two major groups, sacrum, and coccyx.

The different regions described above can be observed in Figure 2 - Right.

Also, in Figure 2 – Left, is presented the general shape and constitution of a vertebra. There, it is possible to see the body - that as mentioned articulates with the bodies on the vertebras positioned before and after; the vertebral arc and hole - that when in a group with the remaining vertebras will compose the spinal canal (where the spinal cord will pass); and the apophysis which function is also the articulation (with the remaining vertebras or with other bones). Regardless of these common characteristics, each vertebra presents its own identity and is distinguishable from the others due to its proper position and function particularities. (Jones, 2020)

Following the direction head to feet, a progressive increase in the volume of each vertebra is observed, directly increasing the strength of the structure. Concerning its curvature (anteroposterior direction, on the left in Figure 2 - Right) there are two types: primary or posterior (present on a newborn), and anterior or compensatory (acquired when the child begins its development like holding their head and standing up). The primary curvatures are located on the thoracic and sacral region, and the compensatory curvatures, on the cervical and lumbar ones. (Kisner & Colby, 2005)

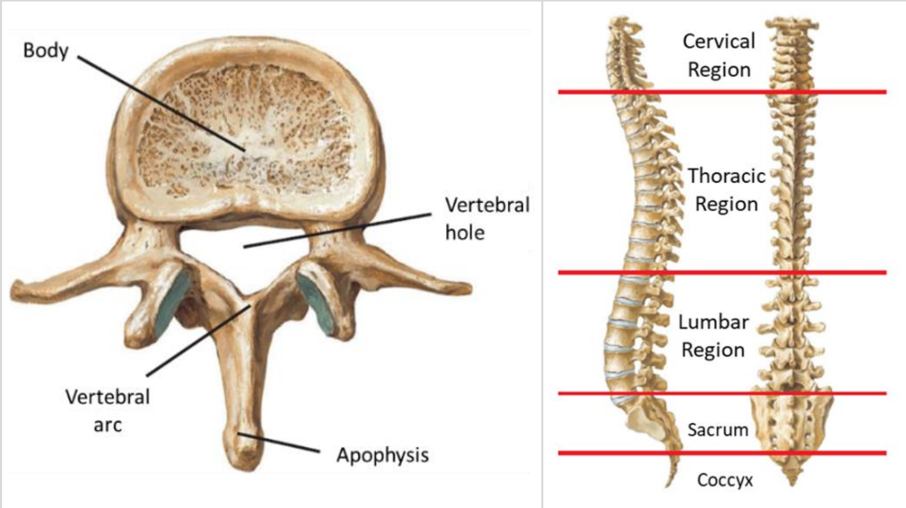


Figure 2 – Vertebral Column Composition. L2 Vertebra (Left). Adapted from *Valente et al., 2012(b):17*; **Column' Regions (Right).** Adapted from *Valente et al., 2012(b):17*

There are also three lateral curvatures that can't even be compared to the anteroposterior ones because they are much less pronounced. These may vary much more from person to person and, when present in a high level of deviation, is clinically called scoliosis. (Figure 3) (Kisner & Colby, 2005)

The curvature is balanced anterior and posteriorly, and every deviation on one region is compensated on the other. This flexibility and balance on the spinal column are essential to support gravity and external forces effects. (Kisner & Colby, 2005)

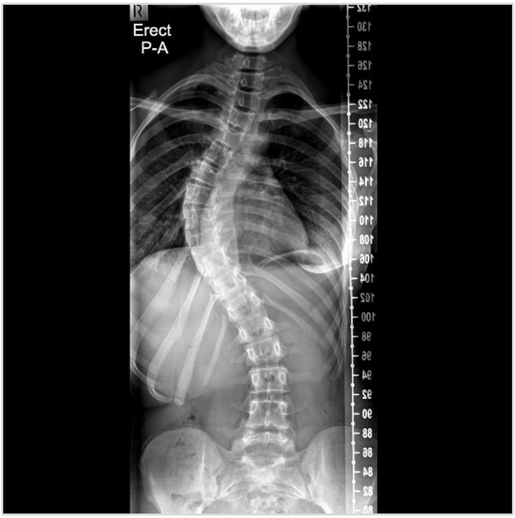


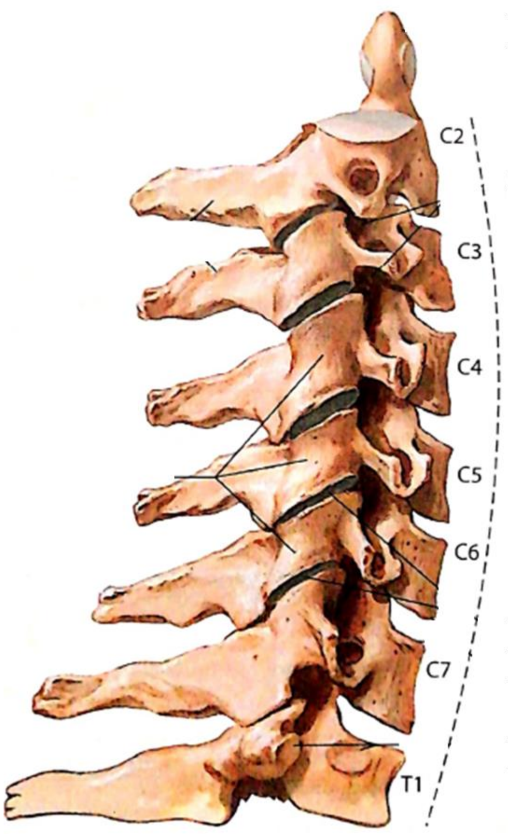
Figure 3 – X-Ray of a Patient Suffering from Scoliosis. Adapted from *Gaillard, n.d.*

Besides the bones, compositions of muscles and ligaments are essential to keep the biomechanical functions of the Vertebral Column.

This bone structure has a crucial role in the static and dynamic of the motor functions participating in the entire body locomotion, head, thorax, abdomen, shoulders, and superior members support, and offer connection to the inferior members. Its involved structure allows the protection of the spinal cord and every vertebral nerve that passes through it.

In the case of this project, the focus is on the cervical region, and it is important to have the consciousness that when affected above cervical vertebra number three (C3), it is almost certain death for the patient. (SpinalCord.com Team, 2020)

Figure 4 shows the different injury levels on the cervical spine and their common effects on the patients' life or mobility. There are eight levels of possible cervical injury and those are separated into two groups, Higher Cervical Injuries and Lower Cervical Injuries. The Higher Cervical Injuries are the most severe and most of the time result in death. Nevertheless, the survivors are most likely to need 24-hour care for the rest of their life and may not be able to breathe without assistance. For the Lower Cervical Injuries, they can cause full paralysis of all members but in this case, the survivors may be able to breathe on their own. The spinal cord injury is identified by the vertebra that involves it. On the table is mentioned a C8 level of damage that doesn't match a vertebra but is related to the spinal cord root that is present on the vertebral column between C7 and T1. (SpinalCord.com Team, 2020)



C1	**HIGH CERVICAL NERVES**	Are the most severe but also the rarest of the injuries and can lead to full paralysis. Most often leads to death
C2		
C3		When not fatal, complete damage of the nerves on this level usually leads to full paralysis or quadriplegia
C4		
C5	**LOW CERVICAL NERVES**	Paralysis on torso, legs, wrists, and hands
C6		Paralysis on legs, torso and/or hands, inability to control nerves that control wrist extension and inability to control bladder and bowel function
C7		Some ability to extend shoulders, arms, and fingers but the strength to move the last two may be compromised
C8		Leads to paralysis of the legs, trunk, and hands but the shoulder and arm movement is kept

Figure 4 – Injury Levels and their Most Common Consequences. Adapted from *Cleland, 2005*

The spinal cord itself is a column of nerve tissue that connects the base of the skull and the lumbar region of the cervical column. It is part of the central nervous system and is responsible for the transmission of nerve signals from and to the brain. Those transmissions concern mainly the movements, motor coordination, reflexes, and sensorial functions. (Dafny, 2020)

The care with the cervical column injury is justified by the importance of preventing a secondary neurological injury post-trauma (injury to the spinal cord and subsequent death of neurological cells) that may interrupt the "flow" of communication between the brain and the body.

2.2 – Trauma Mechanisms that Require Immobilisation with a Cervical Collar

Awareness of the different types of traumas is important to reduce response times of the emergency teams, the effectiveness of the victim's treatment and to create alternatives to improve treatment or stabilisation. For this reason, knowing and understanding the mechanisms of the injury and principal procedures for their treatment, creates possibilities for improvement of the involved equipment.

The National Institute of Medical Emergency (INEM) is the most important Portuguese organisation to assist accident victims (on the road, work…), and sudden illness ones. They have a variety of equipment and a large fleet of ground and aerial vehicles promoting quality pre-hospital assistance. Between the mission, vision and values of this institution, the deep knowledge of the medical emergency area, credibility and efficiency are its highlights. The institution's expertise gave a source to a wide literature with free access, used for personal's training and to instruct the society.

In the present section, it is approached the injury mechanisms that have as procedure the immobilisation with a cervical collar during the pre-hospital assistance, techniques on how they are applied and the reported problems of this equipment's reviews.

2.2.1 – Spinal Cord Injury (SCI)

The SCI is, in most part, a result of car accidents. According to Valente *et al*. (2012a), the main age range affected by this kind of injury is young adults.

Any damage on the cervical column, which protects the spinal cord, can interrupt the communication between the brain and the rest of the body. This interruption can cause trouble to breathe or even cause respiratory arrest, and loss of motor or sensorial function below the damaged area. (Valente *et al*., 2012a, p.29)

So, the victim's approach becomes the crucial point to prevent future injuries or worsening of the existents being very important to prevent its movement and keep a perfect alignment of the spine. Non-complete immobilisation or a wrongly executed one can lead partial damage to become a full one. (Valente *et al*., 2012a, p.29)

In terms of actuation on this kind of trauma, the Portuguese protocol follows the ABCDE doctrine, beginning with the primary evaluation. The team must always think and act in accordance with it. After this, the protocol describes the necessity of ensuring the victim's stabilisation, column alignment, and immobilisation of the cervical spine, being the cervical collar application mentioned. Later, it describes a sequence of actions (Annex 1) until the patient's transportation to the hospital. (Valente *et al*., 2012a, p.29)

2.2.2 – Paediatric SCI

The anatomical differences between adults and children allow the second ones to absorb more energy and so reduce trauma risk. Nevertheless, the protocol procedure is like the one used on SCI, and the use of the cervical collar as an immobilisation method remains. There are, however, some principles to keep, like the ones present in Annex 2. (Valente *et al*., 2012a, p.46)

2.2.3 – Traumatic Brain Injury (TBI)

The TBI is one of the most important trauma mechanisms for mortality or morbidity, especially on the opposite sides of the age range (<5 and >70 years), and young adults (15-24 years). (Valente *et al*., 2012a, p.25)

As the name announces, TBI stands for Brain injuries and despite some neurons getting irreversibly damaged, the others may partially assume their functions. On the other hand, as the neurons are not replaceable and the damage to the system is permanent, the injuries are mainly disabling. (Valente *et al*., 2012a, p.25)

The most common problems developed when in a TBI are cerebral oedema and intracranial bleeding. (Valente *et al*., 2012a, p.25)

The protocol states that if the victim has a suspicious TBI, it should be approached like an SCI victim, which means that it should be immobilised with a cervical collar (Valente *et al*., 2012a, p.27), but there are exceptions. When there is a deviation on the trachea, the traction of the neck (alignment of the neck on the neutral position) is not recommended so there isn't a cervical application.

According to Gante (2017), around 15% of the TBI's have SCI associated.

2.2.4 – Burns

Burns are injuries in the skin or adjacent tissues and can be caused by a variety of events. Being the skin the exposed element to the burners it is usually the most severely damaged. Besides that, the remaining organs and systems can also be damaged or profoundly altered, leading, sometimes, to the victim's death. (Valente *et al*., 2012a, p.71) In some cases, the burns are consequences of explosions or accidents with deceleration or projection. In this type of accident, it is common to result in SCI or TBI injuries, so it is mandatory to immobilise with a cervical collar.

Regarding the protocol, the victim's first approach is made to protect both intervenients. It is essential to identify the agent that is causing the burn and to move it away or, in the alternative, move the victim away from it. (Annex 3) Ensuring safety conditions, the next steps are the Primary Evaluation followed by head immobilisation in a neutral position. On the next protocol's step, it is given special attention to airway clearance as some patients may need ventilatory support. The remaining protocol can be consulted on Annex 4. (Valente *et al*., 2012a, pp.74-75)

2.3 – Trauma Victim's Approach

The victim's approach is one of the most important skills to develop by the emergency team. To be efficient, the team must establish an approach plan and the treatment's sequence after the general evaluation of the victim's physical condition, answers and complaints, and local observation. In trauma situations, only 20% of questioning and local observation is necessary (to know the victim's history and understand the incident), and 80% of physical evaluation. In non-trauma emergencies, these percentages turn over. (Valente *et al*., 2012b, p.49)

As per Valente *et al*. (2012b, p.49), the process stages that characterise the victim's approach are:

1. Preparation (Beginning on the call reception at CODU – Centros de Orientação de Doentes Urgentes/Guiding Centres for Urgent Patients);
2. Local and Safety Evaluation;
3. Primary Evaluation;
4. Secondary Evaluation;
5. Victim's Transportation (To the most adequate treatment facility, the fastest possible and performing frequent victim's re-evaluation).

This **preparation** starts when CODU receives an emergency call. According to the number of victims and severity of the injury, CODU activates the necessary means. Sometimes, the victim's relative information concerning its condition is wrong. The injury mechanism (sudden disease or trauma incident) can be the opposite of the initially communicated, so the emergency team must be prepared for any scenario because many of the emergency calls are made by general citizens without any formation in the medical area. (Valente *et al*., 2012b, p.49)

The **second stage** of the protocol has particular importance because **safety** is related to all the parties on the scene (victims, emergency team and thirds that might be on the local). It is important to understand if the scenario does not require any special needs from special teams or law forces, as well as check the presence of flammable elements or structures that may collapse. Concerning the **local evaluation**, its characteristics are of extreme importance for accident interpretation. Understanding the local helps presuppose the involved kinematic which allows suspecting around 90% of the overall victim's injuries. (Valente *et al*., 2012b, p.50)

Once ensured the safety of the operation, the team can proceed with the victim's evaluation.

On the **Primary Evaluation**, it is important not to worsen the victim's condition as well as identify the critically injured ones for prioritised assistance. As soon as the teams arrive at the location, it is possible to get some information concerning the loss of blood (exsanguination) and if the victim is conscious, moving, and communicable. In the case of exsanguination, there is a prevalence for immediate control of the bleeding. On the other hand, if the victim is conscious and communicable the condition can worsen so she might be evaluated anyway. The next step is to follow the ABCDE doctrine, an abbreviation that stands for the different elements that need to be evaluated. They are written in normal performance order: (Valente *et al*., 2012b, p.51)

A. Airway (Airway clearance and cervical spine analysis);
B. Breathing (Ventilation and/or oxygenation);
C. Circulation (Ensure blood circulation with all bleeds controlled);
D. Disability (Motor function evaluation);
E. Expose/Environment (Temperature Control).

Any of these parameters that may constitute a threat to the victim's life must be solved or stabilised before starting the next step of the evaluation. This sequence is merely indicative and there can be a simultaneous evaluation of the parameters. The estimated time for the evaluation goes from 60 to 90 seconds, but when performing medical procedures this time might be longer. (Valente *et al*., 2012b, p.51)

After the primary evaluation and the patient's stabilisation, there is the **Secondary Evaluation**. This stage consists of vital signs evaluation, collection of information and detailed observation of the victim's body. The vital signs must be monitored and registered. Within every 5 minutes the patients should be re-evaluated, in case of being a critical victim, or every 15 minutes, for a non-critical one. (Valente *et al*., 2012b, p.71)

The vital signs that are evaluated and monitored are:

- Ventilation;
- Pulse;
- Arterial Pressure;
- Temperature;
- Oximetry (only when necessary);
- Pain (through numeric scale).

Ventilation is a mechanical function that allows input or output of air on/from the lungs, renewing life essential gases. The mechanism that allows air circulation is characterised by thoracic movements, which constitutes the ventilatory cycle where inhale (air entry to the lungs) and exhale (air exit from the lungs) are the stages. (Baptista, 2008, p.33)

The parameters that should be evaluated to characterise the ventilation and some reference values/results are shown in Figure 5.

Heart contraction results in a blood wave that flows on the arteries resulting in a **Pulse**. It is measured through palpation of any artery (usually carotid or radial artery). The parameters that characterise the pulse are equal to those who characterise ventilation and are shown in Figure 6. (Baptista, 2008, p.34)

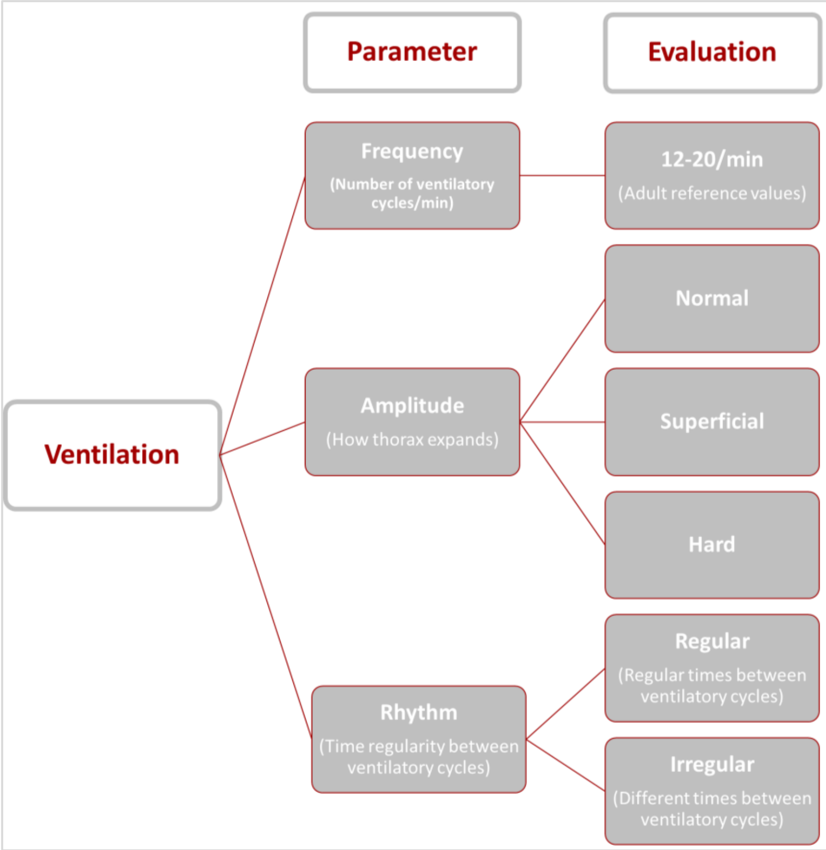


Figure 5 – Characterisation of Ventilation Evaluation

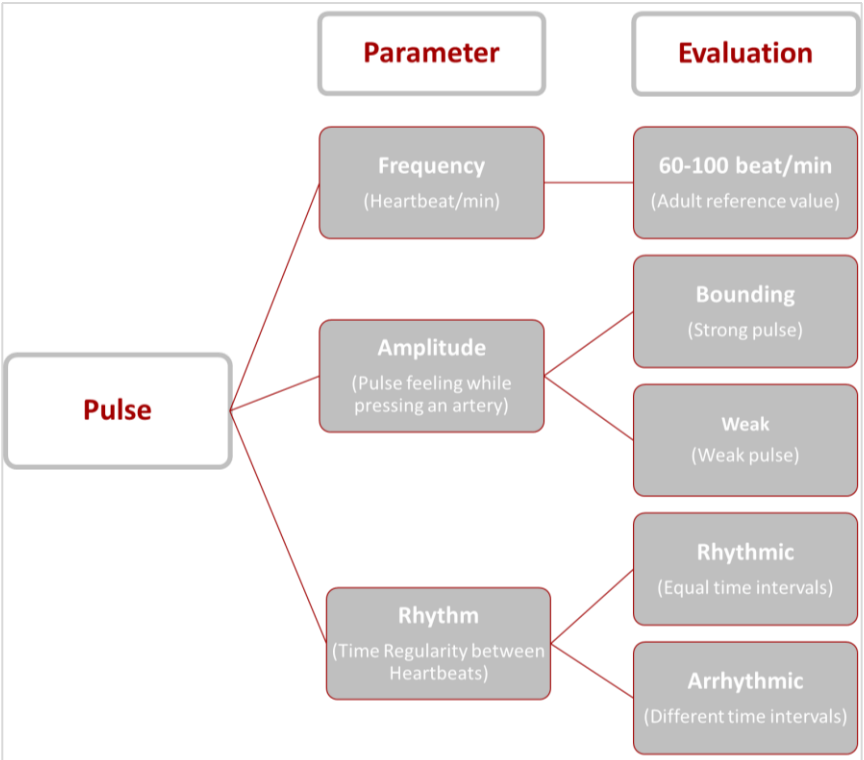


Figure 6 – Characterisation of Pulse Evaluation

Arterial Pressure is the pressure that the blood exerts on the artery's walls. There are two usual values on its measurement. Those values are related to the cardiac cycle and are the main indicators of cardiac function and blood debit. The maximum value is the systolic pressure and the minimum one is the diastolic pressure. To proceed with its measurement, specific equipment such as a sphygmomanometer and stethoscope is necessary. (Baptista, 2008, p.35)

For **Temperature** evaluation, the initial method is by touching and comparing the victim's skin temperature with the medical staff, trying to understand if the skin is hotter, colder or at the same temperature. When colder, it might be hypothermia, when hotter, it might be fever or hyperthermia. (Figure 7) This method is subjective, and the evaluation must be repeated with a thermometer. (Baptista, 2008, p.37)

	NORMAL	HYPOTHERMIA	HYPERTHERMIA
ADULT	35.5ºC to 37.5ºC	<35.5ºC	>37.5ºC

Figure 7 –Temperature Reference Values

Concerning the information that must be obtained from the patient, this procedure is only performed when the victim is conscious and with a sense of reality to give information about the principal complaints (**pain** evaluation), and to answer some protocolary questions. CHAMU is the Portuguese acronym for those questions: (Valente *et al*., 2012b, p.71)

- **C**ircunstâncias do acidente (**Accident circumstances);**
- **H**istorial de doenças e/ou gravidez (**Disease and/or pregnancy history**);
- **A**lergias (**Allergies**);
- **M**edicação habitual (**Usual medication**);
- **Ú**ltima refeição (**Last Meal**).

When the victim isn't conscious or conscious but disoriented, this information can be collected through family, witnesses or others that might know relevant information. (Valente *et al*., 2012b, p.71)

The **Secondary evaluation** ends with a segmented observation of the body through palpation, auscultation and impacting (when possible) by the sequence body and neck, thorax, abdomen, basin and perineum, superior and inferior members and, to finish, back and posterior surfaces. (Valente *et al*., 2012b, p.71)

The algorithm for the secondary Evaluation can be consulted in Annex 5.

In the last, a hospital facility is assigned by the CODU for the victim's **transportation,** or, in particular cases, aerial support is activated, or the team waits for other actions that CODU thinks to be the best option for the victim's treatment. During transportation, the victim's vital signs and the conscious are monitored, and any significant changes must be immediately communicated to CODU. (Valente *et al*., 2012b, p.76)

2.3.1 – Spinal Immobilisation

The pre-hospital spinal immobilisation was implemented in the mid-1960s due to the damage risk that an unstable vertebral column presents to the spinal cord and the neurological condition after a trauma. (Purvis *et al.*, 2017)

Despite the low evidence and research in pre-hospital care about the benefits of immobilisation at the time, the fear of worsening a spinal injury, the fear of missing a spinal injury by not taking any attitude on the pre-hospital scenario (like spinal immobilisation), and the fear for any sue, were some of the reasons why this method was accepted and started to be implemented worldwide during decades. (Carrison *et al*., 2015)

However, in the most recent years, the method and its benefits have been questioned. According to Purvis *et al*. (2017), that in his article reviewed about 36 documents relating to the subject of pre-hospital spinal immobilisation, the reliable evidence evaluated reported that there are “numerous side effects, with no proven benefit”, and that recent meetings defined new guidelines to minimise the potential complications associated with the method (immobilisation with cervical collar and spinal board).

Also, authors like Benger & Blackham (2009) and Carrison *et al*. (2015) describe the several side effects from the application of the cervical collar. In the case of the first one, he even suggests that “alert, stable and co-operative trauma patients do not require mandatory immobilisation of the cervical spine” and that instead, a position of comfort for the patient may be more appropriate.

Even knowing that there are a lot of side effects due to excessive application of spinal immobilisation and cervical collars, its use remains on the protocols meaning that, since its use cannot be replaced, the priority is to minimise its negative effects and try to reduce its consequences.

2.3.2 – Immobilisation Techniques

As for techniques, there are techniques of extraction and techniques of immobilisation of trauma victims with vertebral column injury suspicion.

For immobilisation, the decision of which kind of technique should be applied will depend on the supposed injuries usually related to the incident mechanism. Thereby, the techniques using a cervical collar and spinal board will depend on the situations presented in Chapter 3.2 and summarised here: (Valente *et al*., 2012c, p.15)

- Closed Trauma, any injury that threatens the patients’ life (ABCDE doctrine);
- Loss of mobility or sensibility after the accident;
- Neck or vertebral column deformity;
- Change in consciousness after the accident;
- Situations that the mechanism suggests a high transfer of kinetic energy.

The application of the cervical collar presupposes that the head manual stabilisation is ensured.

The manual head stabilisation consists of keeping the patient's cervical spine aligned by the line nose-belly button (neutral position) until the victim is completely immobilised. (Figure 8) On the other hand, this procedure can't always be performed causing the nullity of cervical collar usage. The paramedic should immediately stop the movement of the head and neck to the neutral position every time that a neck muscle spasm is verified, there is an increase in pain, the neurological conditions worsen, and once the ventilatory function gets compromised. (Valente *et al.*, 2012c, pp.15-16)

			
Lateral approach with victim seated in a vehicle	Posterior approach with victim seated in a vehicle	Anterior approach with victim standing-up	Approach with the victim in dorsal decubitus

Figure 8 – Different Approach Positions to the Victim's Manual Head Stabilisation. Adapted from *Valente et al. (2012c, p.15-16)*

When the first stage of immobilisation is verified, the cervical collar is then applied.

According to Valente *et al.* (2012c, p.19), and according to the available models of cervical collars on the Portuguese pre-hospital scenario, the instructions demand the collaborative action of two paramedics (or medical emergency staff) and the guidance through the manufacturers' instructions for a correct device application.

One of the paramedics initially ensures the manual stabilisation in a neutral position leaving the cervical region with free space to ease the second paramedic operation. The second element should then proceed with the choice of collar size by measuring the distance between the mandible' angle and the neck base of the patient and compare it with the appropriately sized collar. The collars that have height adjustment mechanisms incorporated skip this step. After this step, the manufacturers' instructions should be followed and the element responsible for manual stabilisation should keep it until the cervical collar is properly applied. (Figures 9 and 10) (Valente *et al.*, 2012c, p.19)

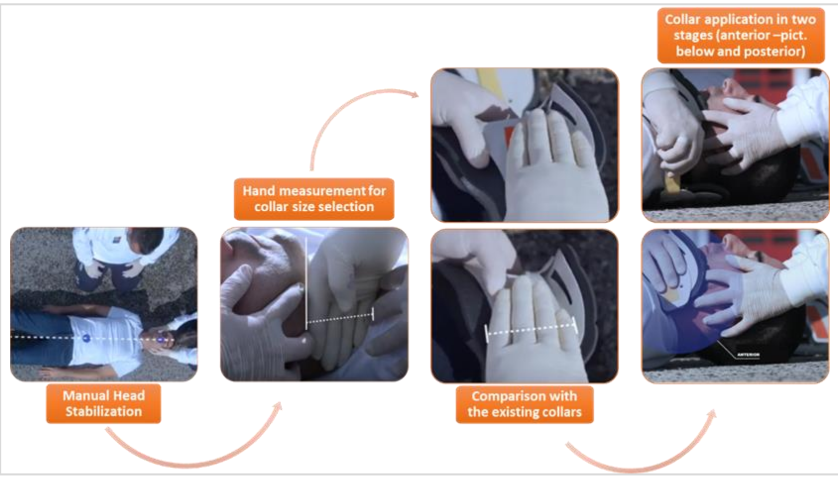


Figure 9 – Application of a 2 Pieces and 4 Support Points Cervical Collar. Adapted from *INEM (2019)*

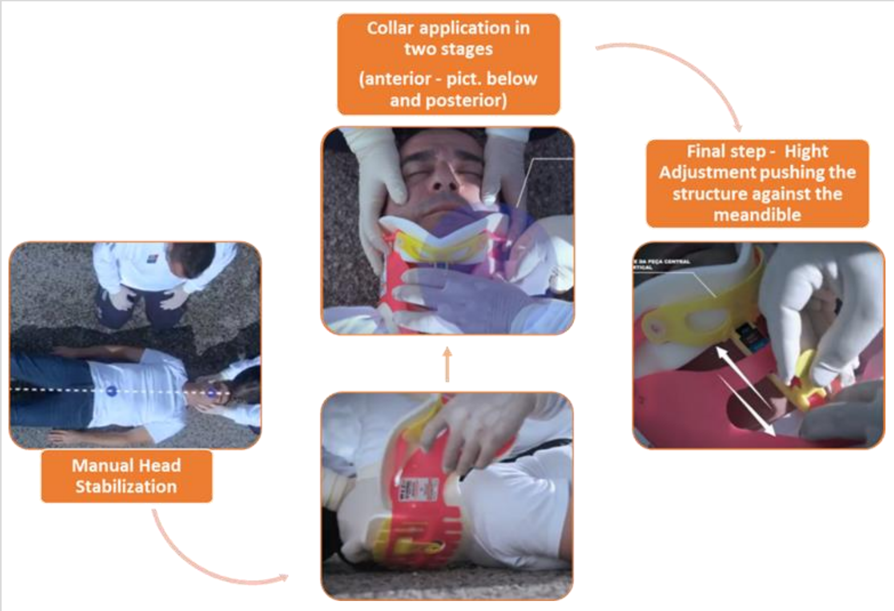


Figure 10 – Application of a 1 Piece and 4 Support Points Cervical Collar. Adapted from *INEM (2019)*

During both processes, all the abrupt, uncoordinated, and unnecessary movements should be avoided since they might worsen or provoke neurologic deficit.

Usually, the application of the cervical collar is followed by a transition to a spinal board for transportation (in the case of the patient not being already on the spinal board). In the case of expected travel exceeding 60 minutes, the vacuum stretcher should be used in combination with the spinal board. (Valente *et al*., 2012c, p.61) In all cases, when the patient is immobilised in a spinal board, their removal and transfer to another element should be done as soon as possible due to the bad effects known and caused by long periods of usage.

2.3.3 – Achieving the Neutral Position and Ideal Position for Immobilisation

The neutral position was defined by Schriger *et al*. (1991) as the "normal anatomic position of head and torso that one assumes when standing looking straight ahead". On the top view, like on the Manual Head Stabilisation presented in figures 9 and 10, the neutral position (in that case, the alignment of the nose-belly button) is achieved, but there isn't any consideration for the movement to a neutral position on the anterior-posterior plane.

Taking into consideration the normal curvatures of the vertebral column and the anterior-posterior plane there is needed an occipital offset to ensure the correct alignment and protection of the cervical spine. Both Schriger *et al*. (1991) and Benger & Blackham (2009) determined and verified that the pre-hospital spinal immobilisation (cervical collar and spinal board) would place the patients in relative cervical extension.

So, to achieve the neutral position on this plane, Schriger *et al*. (1991) on his research assessed the occipital offset required to achieve the neutral position. For that, one hundred healthy volunteers with no history of back disease were immobilised and its head position was levelled by adding padding below. The method used for checking the neutral position was merely visual as it is the one used in the prehospital environment, but as this method isn't the most rigorous, this amount of padding/occipital offset was not considered. Instead, the research performed by De Lorenzo *et al*. (1996) was considered because the method used was radiologic (magnetic resonance imaging), a more reliable and accurate method. On the other hand, the group of study was almost 20% of the one evaluated by Schriger *et al*. (1991) (19 healthy volunteers). In this method, instead of padding the head for increasing the occipital height, various degrees of flexion and extension were applied to the patient's head in increases of the equivalent to 2 cm.

The results from De Lorenzo *et al*. (1996) support a recommendation for immobilisation in a position of neck flexion with the occipital raised around 2 cm. The results from Schriger *et al*. (1991) recommended occipital padding in the range of 0 to 9.5 cm and an average increase of 3.8 cm.

For effects of this project and due to the more rigorous research and experiment verified by De Lorenzo *et al*. (1996), the accepted height increase for the occipital is 2 cm.

2.4 – State of Art – Cervical Collar Devices

The state of art will be focused on the different categories of cervical collars and the existent open literature. The search for patents was performed on the website **worldwide.espacenet.com** including the terms "cervical collar", "trauma cervical collar", "pre-hospital cervical collar", "emergency cervical collar", "intelligent cervical collar" and "cervical collar with sensors" and in every search result, the first 100 patents were opened and viewed. The selection for this state of art included the reading of the abstract and patent's figure observation, being chosen, during the first sorting, the ones that presented relations with trauma immobilisation and pre-hospital scenario. The second and final sorting defined the most relevant documents and selected the widest variety of cervical collar structures and their locking and fastening mechanisms. Some patents were also chosen because they represent the development of cervical collars present on the market (like Necklite and Lubo).

2.4.1 – Types of Cervical Collars and its Production Materials

The cervical orthosis, also known as cervical collar, is a medical device used for treatment, post-surgery recovery, and immobilisation in emergency scenarios. It is a device well known for immobilisation since the 1960s and has undergone changes and improvements that nowadays can categorise it as Soft Collars or Hard Collars. (Figure 11) As for proper designation, the orthosis should have in its designation the part of the body it is supporting (for example cervicothoracic orthosis, cervical orthosis, …). (*Cervical*, n.d.)

The most common shape of the cervical collar is an encircling band supporting the chin and settling on the chest, on the frontal portion, and supporting the occipital region while settling on the shoulder and back, on the back portion.

Concerning its type, the Soft Cervical Collars are a transition device. Its purpose is to gradually help the patient to support its head. It is considered a transition device because its application takes place between the immobilisation with a Hard Collar (applied due to injury, or after a surgery) and the full recovery of a patient. As for Hard Collars, they are used for the treatment of spinal conditions such as spondylosis, post-surgery, and for emergency purposes in which the restriction of movement is highly needed. Comparing both types, the Hard Collars present higher movement restriction than the Soft ones. (Hawkinson *et al*., 2019) The main difference between these two types of orthoses is their production material. In the case of Soft Collars, it is common to see the use of foams (ex: polyurethane), on the other hand, for Hard Cervical Collars, the materials used are more in the range of hard plastics (ex: ethylene) but also integrating soft elements for comfort and contact with the skin.

	
Soft Cervical Collar Adapted from *Bodymedics*, n.d.	Rigid Cervical Collar Adapted from *Eclipse*, n.d.

Figure 11 – Soft and Rigid Cervical Collars

The materials used in the collars' production have changed and followed the industrial evolution changing from materials like leather, heavy plastic, or metal, to lighter and cheaper materials.

The need for this change came from problems verified on medical procedures such as the incompatibility of metal components with x-rays, due to storage and handling performance - as heavy and bulky devices are often difficult for such activities -, and obviously due to production cost. On the other hand, these collars provide a reasonably successful immobilisation of the patients' heads. Such cumbersome materials can be found on devices dating back to the first developed and published patents, namely from Smith *et al*. (1957) and Monfardini (1962), for example.

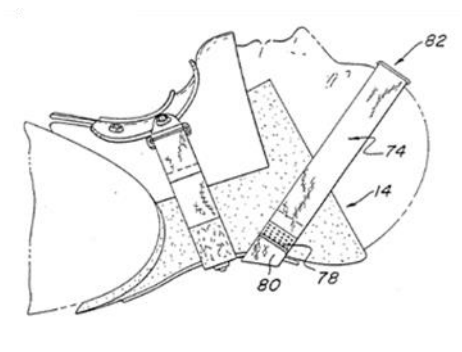
As a result of those needs, the use of stiff lighter weight plastic materials for structure in combination with closed-cell foams became a common practice in the cervical collars industry. These collars can be bent and encircle the patient's neck providing support at a lower cost. Some examples of these modern materials' application can be found on the patents exhibited in the following state of art subchapters.

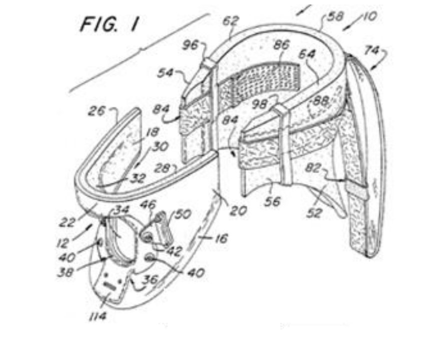
2.4.2 – Patent. US 4,886,052 A – 12/12/1989

Calabrese (1989) presents an invention of an emergency cervical collar whose principal characteristics are its production materials and its unusual fastening strap that goes around the patient's forehead. The author claims that the device can better fit and reliably immobilise a patient on land or water without having to continuously lift the patient's head to ensure proper alignment. This is achieved due to the collar's design. (Figure 12)

The collar is a two-piece device presenting two U-shaped components (front and rear) that thanks to their end portions present an adjustable overlapping relation allowing to fit several neck diameters (in combination with its preformed soft material) and self-alignment. This structure prevents the flexion and hyperextension of the patient's head, and for further stability and reduction of lateral movements and rotation, a strap around the patient's forehead is applied and adjusted. That strap is connected to the rear part of the collar.

Concerning its materials, the cervical collar is made of a "soft, flexible, lightweight material which is non-toxic, water-resistant and buoyant in water, for example, a closed-cell polymeric plastic material such as polyethylene or polyurethane" being possible a thinner outer layer made of a rigid polymer such as polyethylene. On the chin support, a material like Moleskine is adhesively applied and for fastening materials, Velcro is the one used.





Immobilisation with the cervical collar	Anterior and Posterior Parts of the Collar

Figure 12 – Cervical Collar Applied and Exhibited with Parts Separate. Adapted from *Calabrese (1989)*

2.4.3 – Patent. US 4,987,891 A– 29/01/1991

The invention presents a disposable cervical collar with low production cost. According to the author, this design achieves higher stability to the head and neck and prevents some of the disadvantages known on the collars used at the time. (Figure 13)

The materials used in its construction are a foam plastic material, that constitutes most of the collar, a solid plastic sheet on the front part of the collar, overlying most of that region and partially reaching the wing portions providing additional strength, and some materials not described for the fastening mechanisms.

Its shape is like the common shape of cervical collars, an encircling band with the common support regions. A particularity of this cervical collar is its "wing portions" (which allow the circumferential adjustment on the patient, around the neck) that are bigger than usual, covering the ears to prevent rotation and lateral flexion movement, increasing stability.

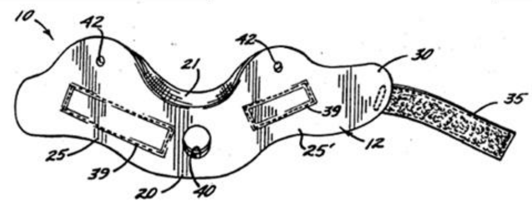
	
Immobilisation with the Cervical Collar	View of the Cervical Collar Opened

Figure 13 – Cervical Collar Applied to a Patient and Exhibited Flat. Adapted from *Gaylord & Dean (1991)*

2.4.4 – Patent. US 5,060,637 A– 29/10/1991

Schmid *et al*. (1991) present an inexpensive one-time use cervical collar. According to the author, the reuse of a collar has associated risks like dirtiness or contamination during use. The possibility of salvaging a structure or not, considering all the risks associated, represents the biggest motivation for this invention.

Following the concept, the collar is formed by a one-piece encircling band adapted to be used around the patients' neck and providing the necessary anatomical support for protecting it. (Figure 14)

The materials used were corrugated plastic for the encircling band, also known as "core board" which is formed from polypropylene and presents a structure construction similar to a conventional corrugated cardboard, and a flexible plastic material (non-determined) creating a flexible strap for fastening. Besides these materials, the author also mentions that the collar can be produced with corrugated cardboard, however, preferably, with polypropylene. As a result of these materials, the collar is compatible with x-rays and similar imaging procedures.

The principal characteristic of this collar is the way it is constructed. The plastic material is corrugated, and its internal structure presents "opposing surfaces interconnected in spaced apart relation by transverse webs which effectively define unidirectionally extending cells or compartments", a structure similar to the one observed on conventional corrugated cardboard. It is also important to notice that when producing the models, the internal cells should be oriented vertically to allow strength on the structure. This kind of structure allows weight reduction on the collar and so the use of materials and its production cost.

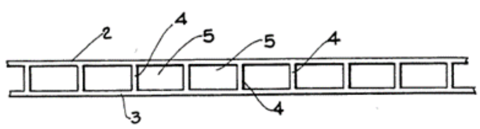
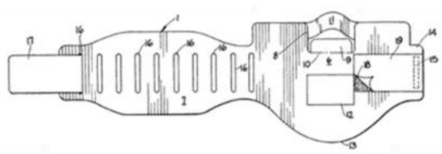
	
Structure Profile	View of the Encircling Band

Figure 14 – Structure Profile and Collar Exhibited Flat. Adapted from *Schmid et al. (1991)*

2.4.5 – Patent. US 5,083,553 A – 28/01/1992

The cervical collar is presented as a two portions device (anterior and posterior) and has attached, or not, as in an alternative embodiment presented, a chin support member. The parts can be moved between them, which allow for the collar to be stored almost flat in a relatively small space, being this aspect one of the main objectives of this invention as the storage on emergency vehicles is low. The cervical collars that can be stored flat but that are built-in one long piece (instead of two as in this structure) is considered by the author to be relatively long, making storing difficult. (Figure 15)

Concerning the materials used for the collar’s production are used hook and loop material (Velcro), stiff, flexible plastic sheet for the chin support and for the anterior and posterior portion (for strength). On the contact with the patient, soft closed-cell plastic is used. As for the material of the pin, anything was referred to.

The stiff and flexible material used on the chin support in combination with the pins and their mate on the guiding slots, allow for this part to be moulded to form the chin support shape and also be stored flat.

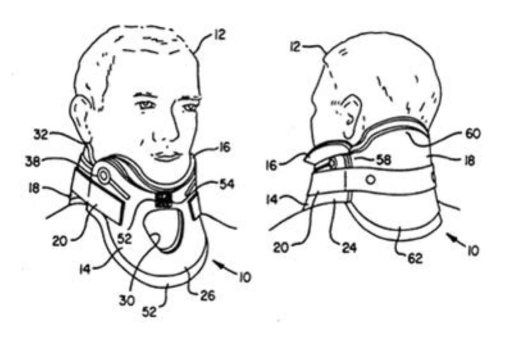
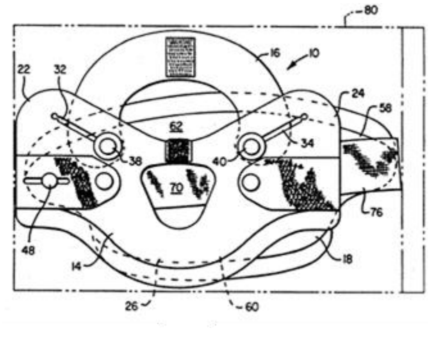
	
Front and Back view of the collar application	Cervical Collar Packed Flat

Figure 15 – Cervical Collar Applied to a Patient and Packed Flat. Adapted from *Stevenson & Brost (1992)*

2.4.6 – Patent. WO 95/22304 A1 – 24/08/1995

The patent number WO 95/22304 A1 from 1995 is related to an adjustable cervical collar. (Figure 16)

The process of adjustment usually seen on other devices consists of adjusting the chin support in height. In this patent, this type of height adjustment is an alternative embodiment. The principal version is the one in which the adjustment is made through a movable sternum and shoulder portion meaning that the collar should be fitted first against the chin and only then adjusted against the sternum and shoulders. The inventors used for this adjustment and to lock its position, a cooperative system of ratchet teeth and pawls having also presented a set of reverse ratchet teeth and pawls. Another important characteristic to be noticed in this adjustment system is the parallel movement possible to achieve while adjusting, preventing bad applications.

The shape of this collar is similar to the conventional ones presented on the collars' categories (typical support regions) and is produced as a one-piece encircling band. As for the material, a stiff plastic sheet ("high density polyethylene, polyvinyl chloride or other such stiff, sturdy plastic material") was used for the encircling band structure, and for patients' skin contact soft plastic pads were used. To create adhesion between these components, it is suggested adhesive or snap fasteners.

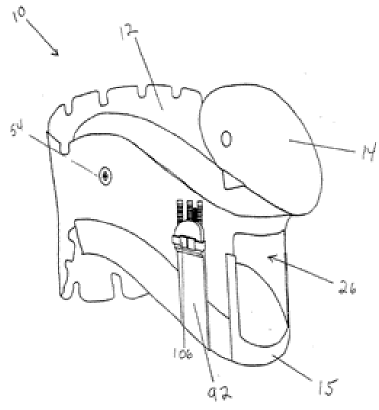
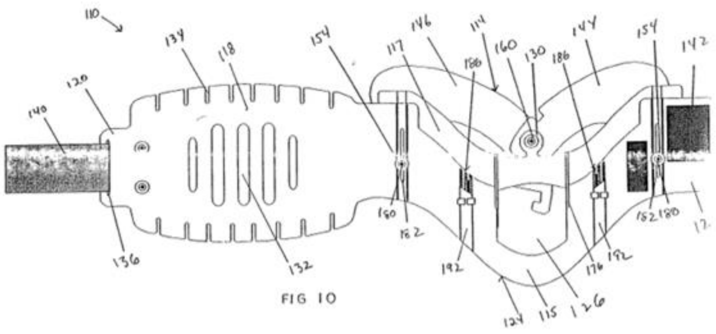
	
Front-Side View for better looking of the adjustment mechanism	Cervical collar in its flat condition

Figure 16 – Cervical Collar Closed and in its Flat Condition. Adapted from *Martin (1995)*

2.4.7 – Patent. US 5,688,229 A – 18/11/1997

The cervical collar displayed had the purpose of changing the common concept of having a variety of cervical collar sizes in the emergency scenario, because of the time that is taken when looking for the right size and also due to the amount of space that those groups usually take inside an emergency vehicle. This change of concept was suggested with a universal size collar possible to fit every patient by adjusting it in circumference and a height adjustment that, in this particular case, is performed on the chin level being capable of accommodating several neck lengths. (Figure 17)

In terms of material, a flexible plastic shell is used for the outer structure, closed-cell foaming for the contact material with the patient, metal or plastic for rivets, and hook and loop material for fastening. The specific materials used were not mentioned.

In this patent, the height adjustment of the chin portion is made with two parts connected to the chin. Those two parts present a smooth inner edge and a saw-tooth pattern which allow engaging or disengaging on the slot where both are inserted. (Figure 17)

This model presents a typical cervical collar shape and is built as a one-piece elongated encircling band.

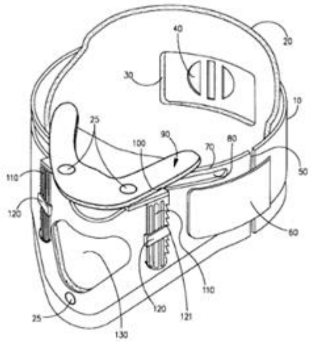
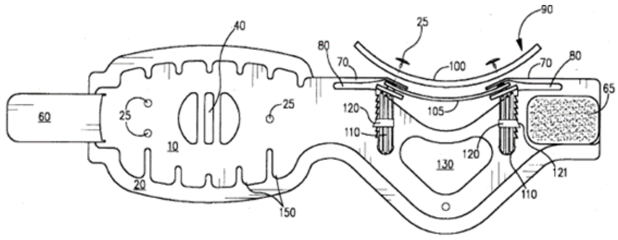
	
Front-Side View for better looking of the adjustment mechanism	Cervical collar in its flat condition

Figure 17 – Cervical Collar Closed and in its Flat Condition. Adapted from *Bauer (1997)*

2.4.8 – Patent. US 6,423,020 B1 – 23/07/2002

Like Bauer (1997), Koledin (2002) presents an adjustable cervical collar with a height adjustment system on the chin region. The inventor claims that the collar can be "sized on or off the patient and be properly applied to the neck under emergency or non-emergency conditions" also claiming the existence of infinitely adjustable positions between the shortest and longest range of the collar's neck sizes. Also, on the back of the collar is present a separate extension for the occipital region which can be elevated or lowered in three positions, being locked, and connected to the principal band, respectively with a pin and two rivets inserted in slots. The assembly of the occipital extension through rivets on the sliding slots allows the movement for adjustment of this portion and prevents its escape. (Figure 18)

The collar is generally stored in its flat condition thanks to the chin support that can be detached from the height adjustment mechanism, allowing it to be put in a flat condition too. To support the chin of the patient, that connection must be re-established and rotated 180 degrees to a horizontal position.

The adjustment mechanism, similar to the one used on Bauer (1997), is telescopic, toothed on the outer region of the inside part and on the inner region of the outside part, locking the position through the interaction between those teeth. The lock or release of the position is made through an arm button that compresses or not those two toothed parts. On the other hand, while Bauer (1997) used two telescopic adjustments on each side of the chin support, in this case, only one is used in the middle. - In comparison, this patent has a better chance of stability and immobilisation as on the other there might be a misalignment on the mutual adjustment.

The collar is a one-piece build and its structure is made of a flexible material like polyethylene (used also in other parts), hook and loop material on both ends to secure the collar in its operative position, and for the outer element of the height adjustment a stronger plastic material (nylon) was used. (Figure 18)

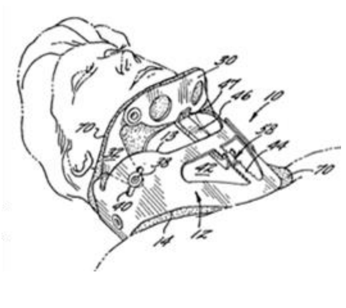
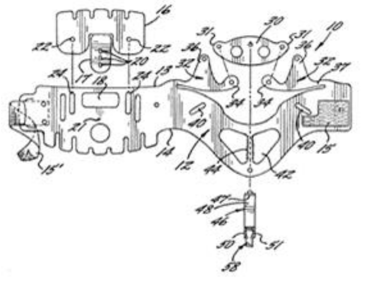
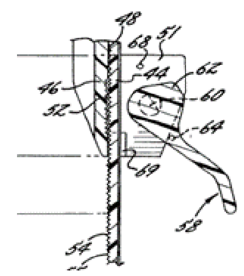
		
Cervical Collar Applied	Exploded view of the collar	Detailed view of the adjustment mechanism

Figure 18 – Detailed View of the Collar Features. Adapted from *Koledin (2002)*

2.4.9 – Patent. US 2003/0055367 A1 – 20/03/2003

This patent relates to a universal fit cervical collar with several adjustments. (Figure 19)

The collar is constituted of six parts, two main side pieces and four straps for each point of support (chin, chest, occipital and back). The side pieces are the ones where the straps are connected. Every strap can, on each side, be adjusted angularly and in terms of length which makes the collar applicable to every person. As the supports are straps, the range of visibility of the patient's neck is much higher than in common cervical collars, on the other hand, the structure seems rather fragile and might take too long to be completely applied to a patient.

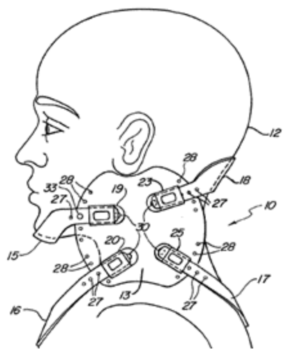
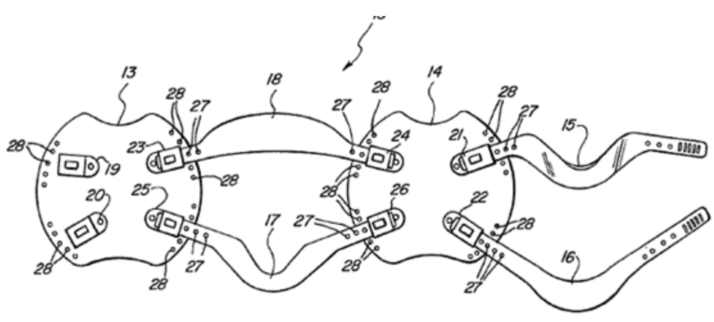
	
Cervical collar applied	Cervical collar extended view

Figure 19 – Extended and Applied View of the Collar. Adapted from *Dominguez (2003)*

2.4.10 – Patent. US 6,663,581 B1 – 16/12/2003

The patent relates to an adjustable cervical collar on the chin region, similar to the ones presented on Koledin (2002) and Bauer (1997) patents.

This collar is produced as a one-piece device and the biggest difference from the patents mentioned is the height adjustable locking mechanism. The locking mechanism consists of sliding a clip between protrusions located on the face of the encircling band, which prevent relative movement between the chin support and the main structure. This is a dual locking mechanism (two clips should be moved symmetrically), which means that both clips must be slid between the protrusions to immobilise the patient safely and totally. Also, on the face of the encircling band and next to the protrusions are presented the predefined positions where the clip can be slid to. This characteristic reduces the number of positions possible to be locked, having only what can be considered intermediate positions (short, regular, or tall), affecting the amount of correct sized applications. To increase the friction between the chin support and the main structure a solution with interference between teeth patterns was used. (Figure 20)

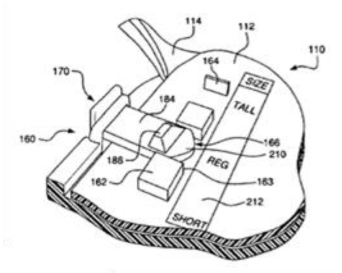
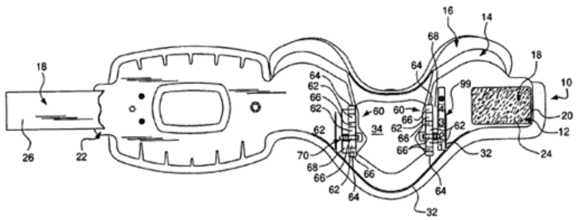
	
Detailed view of the height adjustment mechanism	View of the Collar Open

Figure 20 – View of the Collar and its Adjustment Mechanism. Adapted from *S. Calabrese (2003)*

2.4.11 – Patent. WO 2007/015912 A2 – 08/02/2007

The patent number WO 2007/015912 A2 from 2007 is related to a mechanism for height adjustment of the chin support. It provides a rack and pinion mechanism allowing for symmetrical adjustment with a single motion. Besides the geared mechanism, the invention also provides independent means for adjusting the chin support angularly. (Figure 21)

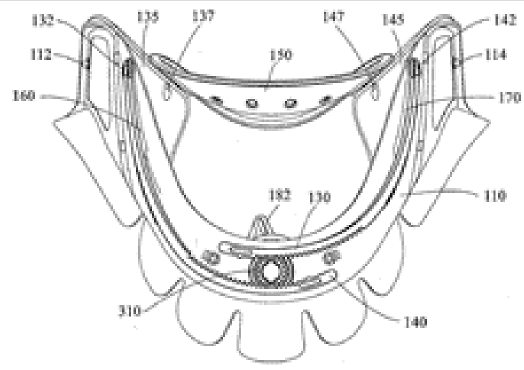


Figure 21 – Detailed View of the Adjustment Mechanism. Adapted from *Calco et al. (2007)*

2.4.12 – Patent. WO 2008/057095 A1 – 15/05/2008

Patron, M., introduces a cervical collar consisting of a group of support pieces with a unique fastening mean. The cervical collar is composed of spinal and neck support with two fastening straps connecting them in such a way that crossed tension forces are created, tightening them against the patient. It also presents a provision (bridge connection) for controlling the location where the straps cross, preventing excessive pressure on the neck. It is also a feature of this device the existence of a mechanism (in certain embodiments) recurring to tabs and protrusion or locking teeth, which allow height adjustment on the chin support. (Figure 22)

An advantage of this device is the number and independence of all the adjustments because they allow not just to secure and immobilise patients which can align their head in the neutral position but also the ones who present complaints and pain when aligning the spine and whose neck position cannot be moved. Also, the cross tension created by the straps is considered by the author to create a substantially tighter and more firm fitting from the collar resulting in better immobilisation.

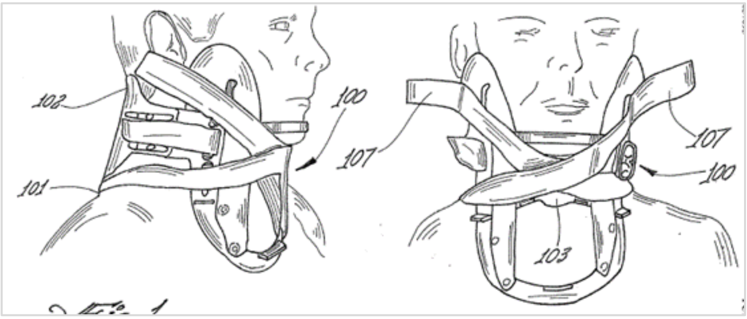


Figure 22 – Detailed View of the Collar Application Technique. Adapted from *Patron (2008)*

2.4.13 – Patent. BR MU8800209 U2 – 06/10/2009

This patent claims to present a cervical collar that is possible to produce at low cost and a simple building process. About this method, the author refers to this device as disposable. Concerning its shape, it is built in one piece and has a typical cervical collar shape. It is made in a flat shape and when applied, the support points need to be bent like Origami. The materials used were ethylene-vinyl acetate (EVA) as a soft material for touching with the patient, Velcro, and cardboard to give strength to the structure. Its production can be a handmade process. (Figure 23)

The author believed that the improvements described could result in an economically viable product, both in production as in material acquisition, free of biological risks for patients and paramedics, and ecological due to the reduced amount of petroleum derivative materials used.

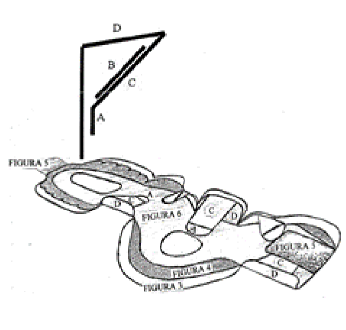
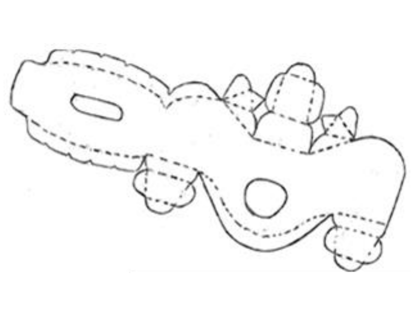
		
Direction of the bends needed	Contours of the bending regions	Cervical Collar ready for application

Figure 23 – Detailed View of the Collar Features. Adapted from *De Souza (2009)*

2.4.14 – Patent. KR 20110038274 A – 14/04/2011

This Korean patent describes a cervical spine guard with two monitoring sensors, a heartbeat monitoring sensor, and a respiratory monitoring sensor based on the doppler effect and which data can be consulted on an external device. As for the structure of the collar, the author refers to it as a “hard cover” “tightly” covering the neck. (Figure 24)

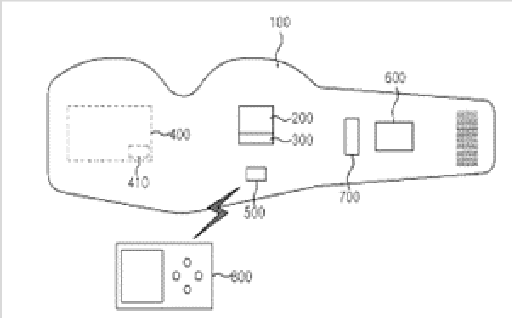
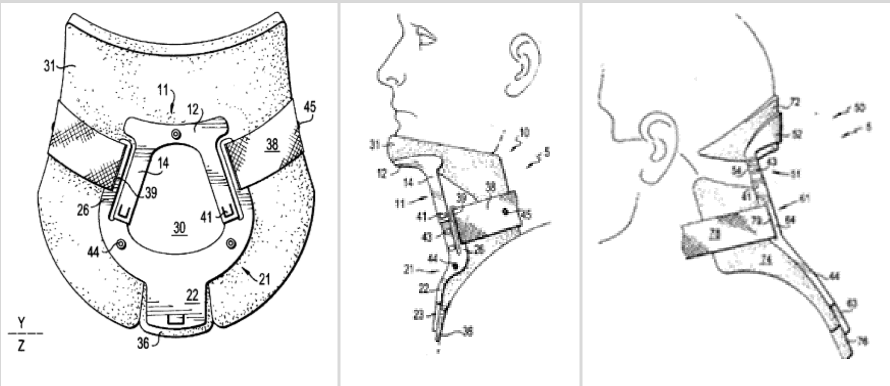


Figure 24 – Cervical Spine Guard Schematics. Adapted from patent number *Lee et al. (2011)*

2.4.15 – Patent. US 2012/0165712 A1 – 28/06/2012

A cervical collar which the principal characteristic is its type of construction built mostly of semi-rigid foam instead of rigid plastic, allowing the collar to better conform to the patient according to the portion thickness. That thickness also allows the cervical collar to be more flexible. For reinforcement, a small plastic component is present in the structure. (Figure 25)

This is a collar built in two pieces, presenting a circumferential adjustment through hook and loop (Velcro) and a height adjustment on both portions, depending on the embodiment referred to in the patent. (Figure 25)



Front view of the collar	Front portion applied	Back Portion applied

Figure 25 – Views of the Front and Back Portions. Adapted from *S. Calabrese (2012)*

2.4.16 – Patent. US 8,262,596 B2 – 11/09/2012

This is the first patent of a family and describes the concept that is intended with the development of a structure and mechanism. The main purpose of this invention is a cervical collar that allows non-invasive airway management.

It is an objective of this invention the creation of a cervical collar that ensures simultaneous neck protection, restricting any movement from the head relative to the body and preventing suffocation by keeping an open airway in the least invasive way possible. The drawings show a structure attached to the patient's head and restricting its movement while a support structure attached to the mandible (Jaw) allows its movement ensuring non-invasive airway management. The movement that the structure exerts on the patient's mandible is known as Jaw Thrust Manoeuvre, a non-invasive technique for airway management. (Figure 26)

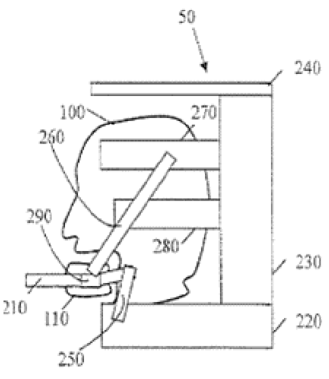
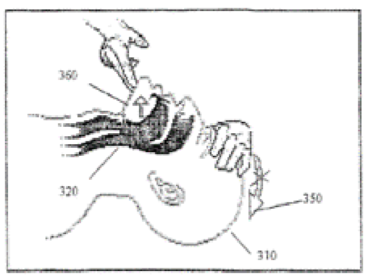
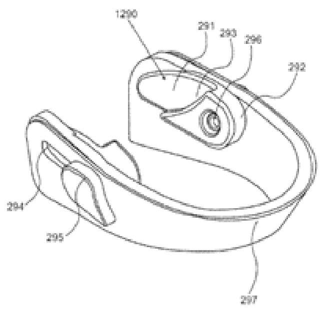
		
Immobilisation Structure	Jaw Thrust Manoeuvre	Mandible Adjustment Piece

Figure 26 – Different Features of the Cervical Collar. Adapted from *Gefen et al. (2012)*

2.4.17 – Patent. US 2013/0310722 A1 – 21/11/2013

The patent comprises a cervical collar that can accommodate anatomical changes such as swelling increase and decrease, and that allows chin height adjustment. (Figure 27)

Concerning its construction, it is made of two parts, anterior and posterior, and the structure is a combination of flexible and compliant edges with ventilation slots for reducing humidity spots and giving a better opening view. For circumferential adjustment, hook and loop material was used. (Figure 27)

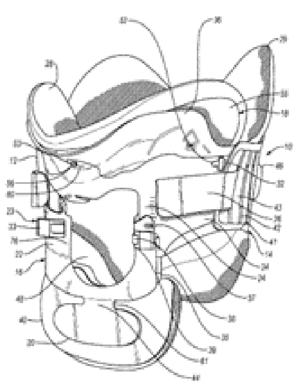
	
Full view of the Collar	Back Portion

Figure 27 – Parts of the Present Embodiment. Adapted from *Thorsteinsdottir & Ingimundarson (2013)*

2.4.18 – Patent. US 2014/0012172 A1 – 09/01/2014

Cervical collar with a practical vertical adjustment and a practical anterior and posterior connection system. The anterior and posterior portions are connected through a round spring element and the circumferential adjustment is made by pulling two straps that pass the side connector elements (which engage on the round spring elements). The vertical adjustment is made by pressing a spring button on the front of the collar (spring button that fixes the position of the upper part of the anterior portion), changing to the desired angular position, and then releasing the button to fix it. (Figure 28)

The patent is the representation of the cervical collar known as Eclipse Cervical Collar from VQORTHOCARE.

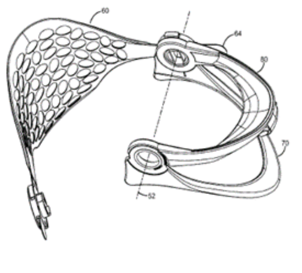
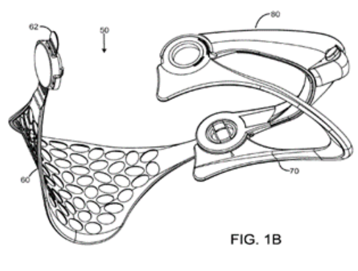
		
Top-Side View of the collar	Bottom-Side View of the collar	Real model

Figure 28 – Different Views of the Cervical Collar. Adapted from *W. A. Calco (2014)* and Eclipse (*n.d.)*

2.4.19 – Patent. EP 2783662 A1 – 01/10/2014

This patent is related to the cervical collar known on the market as NECKLITE. It is a lightweight and foldable cervical collar which makes it compact for storage and to carry, for example, by rescue teams. This is the simpler, lighter, and practical collar found on the search.

The collar is built as a one-piece and the estimated weight is around 100g. The material used is aluminium foil on the inside (or its alloys) and expandable material on the outside of the collar. The overall thickness of the device is between 4 and 8mm and can be stored flat, folded, or rolled.

The structure presents the typical support points (chin, chest, occipital and back) and to better fit different shaped patients the chin support has a variety of fins. As for circumferential adjustment it is made through hook and loop material. (Figures 29 and 30)

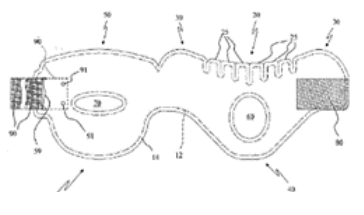
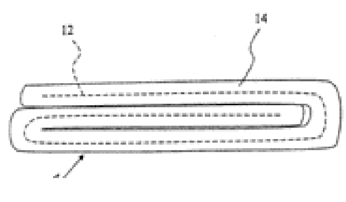
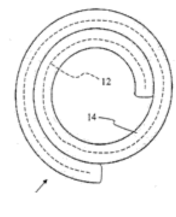
		
Cervical collar in flat condition	Packed in Folded condition	Packed in Rolled condition

Figure 29 – Cervical Collar in its Possible Conditions. Adapted from *Limontini (2014)*

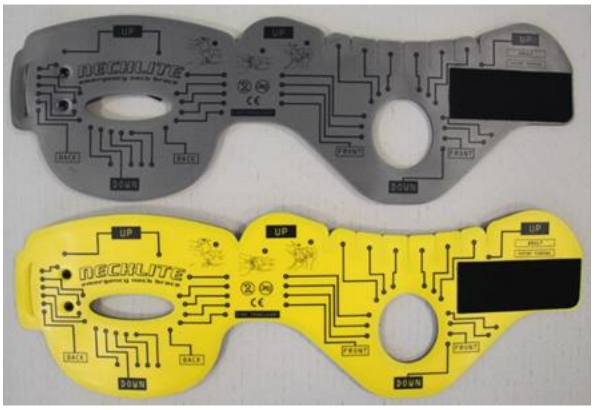
	
Front and Back View of the collar in flat condition	Packed in Rolled Condition

Figure 30 – Real Model of the Embodiment Presented. Adapted from *NECKLITE.COM (n.d.)*

2.4.20 – Patent. WO 2015/025319 A1 – 26/02/2015

The invention is referent to the cervical collar available on the market and known as LUBO. This patent is the last version (more recent) of a patent family initiated by the one published by Gefen *et al*. (2012) (present in this document on the subchapter 2.4.16). So, it is related to a cervical collar that allows non-invasive airway management.

As mentioned by Gefen *et al*. (2012) the purpose is to provide a complete immobilisation of the head about the body keeping an open airway through Jaw Thrust Manoeuvre by pushing the mandible forward. The mechanism for Jaw Thrust Manoeuvre is integrated on the collar and is angularly and longitudinally adjustable. It has two shaped elements that fit the back of the mandible and can be pushed or not to the front executing the Manoeuvre.

The collar is built as a one-piece and as it doesn't have chin support, presenting a better opening on the front of the neck allowing a clear view of the patient's neck. (Figure 31)

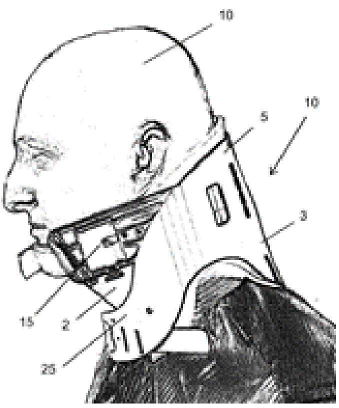
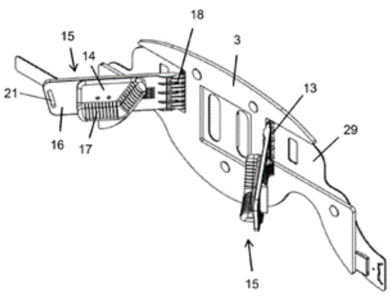
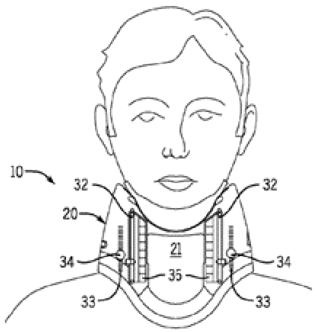
		
Side View of the Collar	Detailed view of the Jaw Thrust Manoeuvre Mechanism	Application of the Cervical Collar Adapted from https://www.inovytec.com/lubo/

Figure 31 – Different Features of this Model. Adapted from *Kantor (2015)*

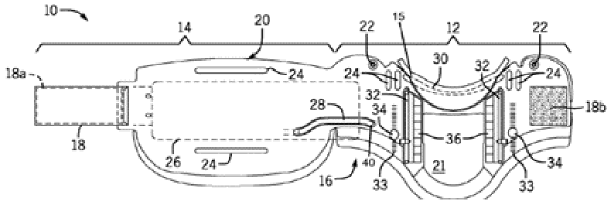
2.4.21 – Patent. US 2015/0190266 A1 – 09/07/2015

The project present on this patent relates to an adjustable and inflatable cervical collar. (Figure 32)

As for the adjustable characteristic, the method presented for locking the position is similar to the one presented by S. Calabrese (2003). There is a sliding chin support onto the main structure of the collar where there are slots (instead of protrusions as on the other patent) that receive securing clips locking the relative movement between the main structure and the chin support. The main difference between these two patents is the presence of an inflatable pocket that will give extra support and stability to the posterior part of the patient. The pocket extends up to 270 degrees around the neck leaving around 90 degrees on the frontal region to allow tracheostomy and other emergency procedures needed. It can be filled with a gas or liquid such as air, gel, foam, water, or other substance in an approximate quantity of 500 ml. This gas or liquid should be inserted through an inlet for a syringe on the collar and can be removed or reduced from the same inlet.



Front View of the Collar Applied



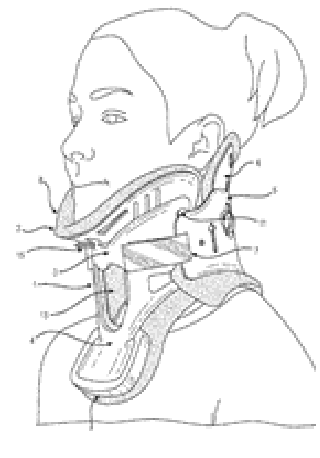
Cervical Collar Open View

Figure 32 – Views of the Cervical Collar. Adapted from *Hollern (2015)*

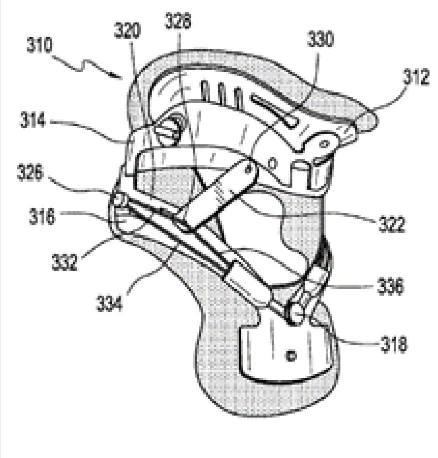
2.4.22 – Patent. US 2016/0287424 A1 – 06/10/2016

The patent developed by Webster *et al*. (2016) presents an adjustment mechanism that can be applied on different cervical collar models as long as they present a chin support platform adjustable in height and proceeding with the proper changes to integrate the system. In this particular case, the design was implemented on the Miami J collar (designation of one of the most used collars on the market).

The mechanism for adjustment consists of a cable engaged on the different front parts of the collar, usually the shoulder support (which is a region of the main structure) and the chin support that is usually connected with pins to the main structure allowing adjustment movements of this part, by turning a central wheel where the cable is rolled or unrolled, causing the cable to be shortened or lengthened and so increasing or decreasing the chin support height. (Figure 33)



Miami J collar applied

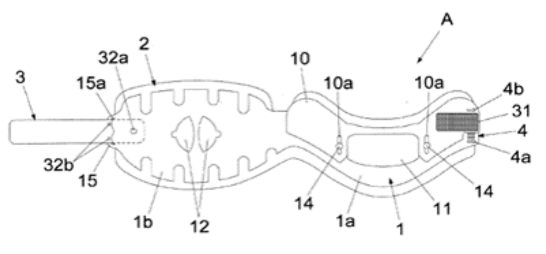


Cable adjustment Mechanism

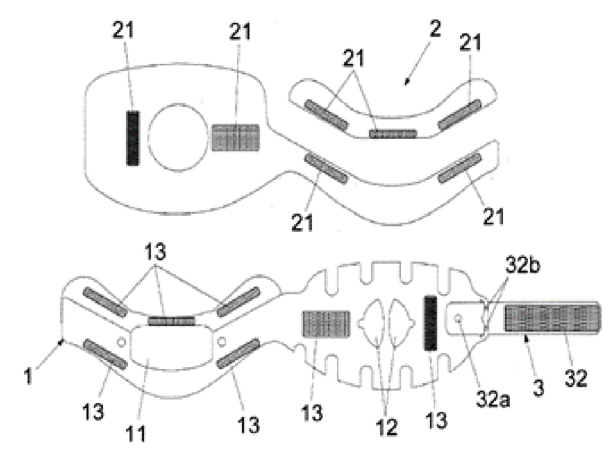
Figure 33 – Features of the Present Model. Adapted from *Webster et al. (2016)*

2.4.23 – Patent. US 2018/0028344 A1 – 01/02/2018

Kim (2018) presents a cervical collar in which certain parts are supposed to be removed, recycled, and replaced. Instead of products like the ones on patents BRMU8800209U2, US4987891A, and US5060637A in which the whole cervical collar is disposable and just for one time use, in this case, only one part of the collar is recycled (for example the one in contact with the patient's chin and mandible) being possible to reuse the main part of the structure. The need for replacing parts from the collar came from the fact that the patients are exposed to a "very unsanitary environment because it is merely washed with water rather than discarded" being reused only due to the cost of each device which turns unthinkable to replace them on every application. The collar is composed of an inner and outer shell, and both are connected with Velcro. The part replaced is the inner shell because this is the portion that is in contact with the patient's neck and mandible. Concerning the shape, the collar is a one-piece device and presents the typical shape and support regions. (Figure 34)



Cervical collar assembled



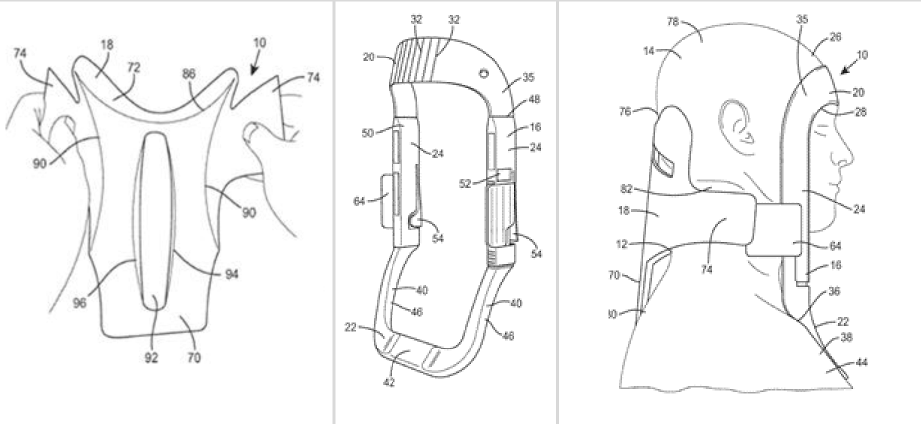
Exploded View of the Cervical Collar

Figure 34 – Different Views of the Cervical Collar. Adapted from *Kim (2018)*

2.4.24 – Patent. US 10,327,941 B2 – 25/06/2019

This invention by Torlei *et al*. (2019) relates to a collar whose principal characteristics are its different areas of support (usually exists chin support which doesn't happen here) and shape. According to the inventor, its features are considered to solve some problems verified on prior art.

The collar is a two-pieces composition, an anterior and a posterior portion. The anterior portion allows vertical/height adjustment through a telescopic construction and sits on the patient's forehead and chest. In relation to the posterior portion, it can be stored flat and was designed in such a way that when the activation arms (the part that encircles the side of the patient's neck and connects to the anterior portion) are pulled, it automatically gets the shape of the back and occipital region, fitting every patient. The circumferential adjustment is made through a hook and loop fastening mean (Velcro) placed on the activation arms. (Figure 35)



Mouldable Back Portion	Front Portion	Cervical Collar Fully Assembled

Figure 35 – Different Views of the Cervical Collar. Adapted from *Torlei et al. (2019)*

2.4.25 – Patent. CN 209808684 U – 20/12/2019

The Chinese patent mentioned refers to an intelligent inflatable neck support whose main characteristic is the application of sensors for monitoring different aspects of the user. The neck support is inflatable and has an integrated air pump electronically controlled. The sensors used are the heartbeat monitoring sensor, blood pressure monitoring sensor, respiratory monitoring sensor, blood oxygen saturation monitoring sensor, internal pressure sensor and carotid blood flow sensor. (Figure 36)

The main purpose of this invention is to relieve spondylosis pain and to reduce fatigue.

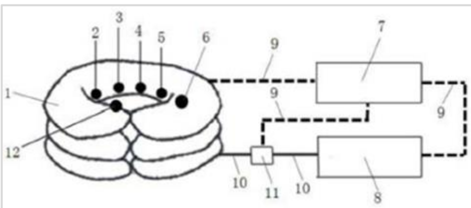


Figure 36 – Schematics of the Inflatable Neck Support. Adapted from *Xiao et al. (2019)*

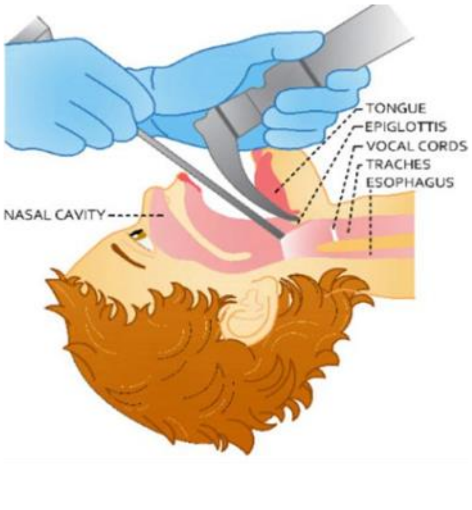
2.5 – Bad Effects of Cervical Collar Application to Emergency Patients

Airway Management, Endotracheal Intubation and/or Direct Laryngoscopy - Since the cervical collar's main purpose is to immobilise a patient and it is an equipment that contacts the skin directly, there are some structural points from the standard cervical collars that, besides not allowing the patient to move, may make some medical procedures difficult.

For standard collars, it is common to have a mandible/chin support that affects the effectiveness of Direct Laryngoscopy and/or Endotracheal intubation by reducing the mouth opening of the patient. (Ladny *et al*., 2018)

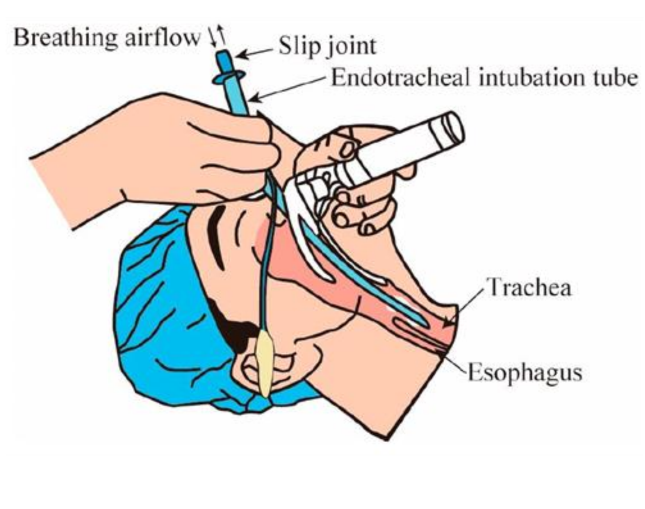
In the case of Endotracheal intubation (Figure 37), it is the medical procedure of introducing a tube through the mouth or nose until the trachea to keep the patient's airway clear, giving him breathing support. In emergencies, the most common is the placement of the tube through the mouth for which reason the mouth opening reduction consists of an obstacle. (Borke & Zieve, 2020)

Direct Laryngoscopy (Figure 37) is like endotracheal intubation, but its purpose is to get a view of the larynx. It is a common procedure when a surgery is performed in that region, resuscitation, or general anaesthesia. Sometimes laryngoscopy is performed before the endotracheal intubation to allow a clear view of the larynx and trachea to check if there shouldn't be any problems with the insertion of a tube or any obstruction on the airway. (Peterson *et al*., 2021)



Endotracheal Intubation

Adapted from Islam *et al*. (2020)



Direct Laryngoscopy

Adapted from Watanabe *et al*. (2017)

Figure 37 – Endotracheal Intubation and Direct Laryngoscopy.

Both procedures need mouth opening and even a properly applied cervical collar restricts around 25% of that opening. (Ladny *et al.*, 2018) (Carrison *et al.*, 2015) An inter-incisor distance higher than 20mm is a requirement as it is the typical dimension of the laryngoscope used in the intubation process. (Goutcher & Lochhead, 2005)

The effectiveness of the endotracheal intubation will also depend on the experience of the procedure executor. (Damiani, 2017)

Restricted Ventilation - According to Totten & Sugarman (1999), the immobilisation of a patient with a cervical collar and a hard spinal board causes a decrease in thoracic expansion and so, a restriction of around 15% of respiratory capability. In a more recent paper, the same restriction was mentioned but not quantified. (Gante, 2017)

Associated Pain and discomfort -There is evidence that cervical collars exacerbate pain, cause discomfort and in some cases a claustrophobic effect. One of the support points that standard cervical collars contact is in the region of the mastoid process. This region has a small thickness of tissue which can cause pain and tissue damage when excessive or prolonged pressure is applied to it. (Yakubtsevich *et al*., 2018) (Carrison *et al*., 2015)

Pressure Sores - Another downside of the standard cervical collars is that the intense and continuous contact of hard portions with the skin, may lead to pressure sores which increase the possibility of secondary infections. (Damiani, 2017) (Sparke *et al*., 2013) (Carrison *et al*., 2015)

Bad sizing selection/ Bad application - For standard cervical collars, being them "universal fitting" or not, the stabilisation of the patient gets compromised when it is badly applied. It is known that inadequate application, poor choice of sizing, or collars applied by untrained personnel are common. (Damiani, 2017) (Yakubtsevich *et al*., 2018) (Benger & Blackham, 2009)

Even when collars are properly chosen, one of the most common problems is the over-tightening of the collar which, besides compromising the evaluation of life parameters, can change the consciousness of the patient, and even worsen its condition. (Mobbs *et al*., 2002) (Benger & Blackham, 2009)

Increase of Intracranial Pressure (ICP) - Another issue related to the standard cervical collars is the obstruction of venous outflow that it causes on the neck. (Damiani, 2017) The mechanism for the obstruction remains unclear but there are suspicions for the collar to have external pressure on the jugular veins (tourniquet effect) that increases the ICP. (Stone *et al*., 2010) The increase of ICP can lead to cerebral oedema, increase the volume of bruises, neurologic deterioration, and pain. (Damiani, D., 2017) (Mobbs *et al*., 2002)

When the collar is applied in patients suffering from TBI, the increase of ICP can place them in a life-threatening situation.

Worsening of Patient Condition in Severe Cases – In a question of judgement whether cervical collars should or not be applied in certain conditions, according to Carrison *et al*. (2015), the application of Cervical Collars in high spine injuries are not recommended as in these cases the high spinal cord gets stretched worsening the patient condition.

Time of Application (Non-Technical) – Time is one of the most important factors when in an emergency scenario so, as fast paramedics can immobilise and transport the patient, the better. (Gante, 2017) Cervical collars usually delay the transfer of the patient to the hospital as they take time to be applied. So, the faster the cervical collar application is, the greater its effectiveness.

False Sense of Security (Non-Technical) – Once the cervical collars are usually applied in combination with other immobilisation devices, the theoretical full immobilisation gives the paramedics a false sense of security which sometimes makes them take some faster and vigorous movements that may endanger the patient. (Carrison *et al*., 2015)

2.6 – Discussion

Considering everything exposed in the previous subchapters 2.1 to 2.5, it is noticeable that there is a margin for improvement on the art. The cervical collar doesn't need to be just another equipment, it can also conciliate other features that are non-related to the immobilisation technique. That's the reason why it is important to understand not only the cervical column and immobilisation requirements, but also the process for patient approach, evaluation, and transport. By identifying needs on those "external" processes besides immobilisation, when compatible, possible solutions can be found and implemented on the cervical collar.

Following this line of thinking, as for improvements of external processes, the implementation of a respiratory rate monitoring system would allow for the paramedics to get instant information about the patient's condition, saving some time when re-evaluating the patient (as there is only needed to check the external device with the information) and even calling the attention of the emergency teams (with a sound alert on the external device) in the case of sudden changes. This can be achieved with a resource to contact or non-contact-based methods posteriorly connected to an electronic system on the cervical collar.

Another solution proposed with this work is the implementation of a pressure sensor to measure the pressure exerted on the head when immobilising the patient to reduce the probability of causing pressure sores, pain, and discomfort. This pressure sensor would also be connected to the electronic system mentioned for the respiratory rate monitoring system.

Concerning the problems reviewed in the articles, one that can be theoretically solved is the increase in ICP. Despite not having a defined causal mechanism, the compression of the jugular veins on the neck (tourniquet effect) is the most probable mechanism. So, a different shape of the cervical collar might solve the problem.

This work also aims to design a fully adjustable cervical collar for adult patients without metal parts (besides the electronic components necessary). For those electronic components, a solution is to locate them in regions of the collar which doesn't affect the patients' exams like X-Rays. (Subchapter 3.4)

3. NeProS Development Process

After planning the different improvements that theoretically solve some of the known problems of standard cervical collars and defining extra features for improvement, the next steps are to imagine and create. The concept is to develop a structure for protecting the cervical region, from where the abbreviation NeProS (Neck Protection Structure) has an origin.

The cervical collar will be designed following an iterative process.

The prototype will be designed with the software from Dassault Systèmes, SOLIDWORKS®. This software allows the creation of 2D, 3D Computer Aided Design (CAD) models and defines their equivalent properties to the real models to simulate their performance under certain conditions through finite element studies, for example.

As for the production, there is a 3D printer from PRUSA® available on ISEC's Laboratory of Applied Biomechanics. This is an advantage as the available equipment and production method matches the most economical production process, as explained in Chapter 4.1. Accompanied by the printer, a software named PRUSASLICER® is supplied. This software establishes the connection between the CAD modelling and the printing of any part. To open CAD files on this software, they must be under STL (Standard Triangle Language) format. STL format describes the surface of an object as a triangular mesh and is one of the most common formats within the CAD, 3D prototyping, Scanning and 3D printing world.

3.1 – Changing the Shape of the Cervical Collar

To change the shape of the cervical collar, it is essential to understand what kind of support it must give to immobilise the patient. According to the movements this device must restrict, we can define the following support points: Back of the head [Fig. 38 – 3] (to restrict extension), mandible [Fig. 38 - 1] (restrict lateral flexion, flexion, and rotation) or chin [Fig. 38 - 2] (restrict flexion), shoulders [Fig. 38 - 4], and chest [Fig. 38 - 5] and back (to support the collar). Figure 38 also represents the movement restrictions (red arrows) that the structure offers to the patient. Numbers 4 and 5 don't present any arrows as those are points where the structure will settle.

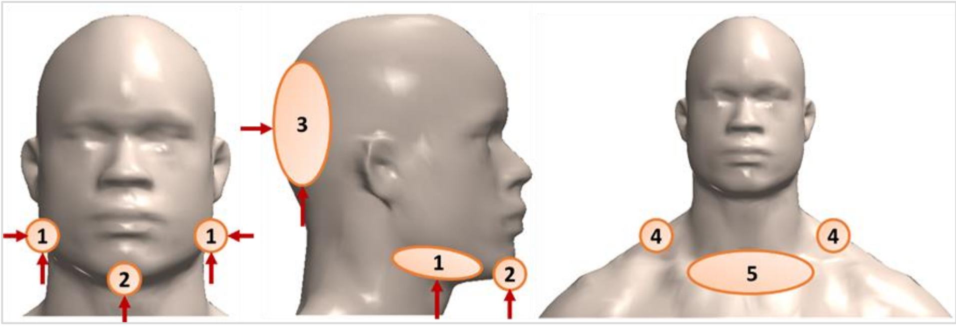


Figure 38 – Collar Support and Settle Regions. Adapted from *Bieber (2016)*
1 – Mandible Region; 2 – Chin; 3 – Back of the Head; 4 – Shoulders; 5 – Chest.

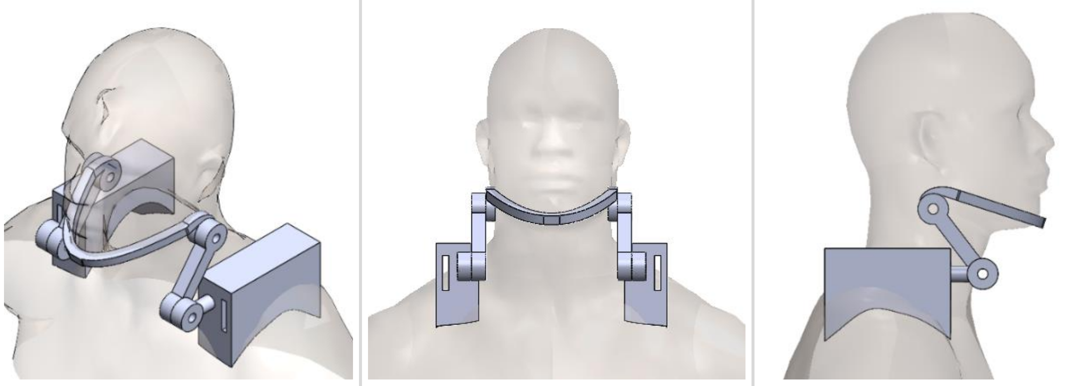
The dimensions for the cervical collar were based on *Knowing* (2017) as can be seen in Annex 6.

Also, for CAD model references, a Human body shape (Mannequin) (Bieber, 2016) with a height around 183 cm is used. Despite the body position doesn't be the same as when the collar is applied in an emergency, it can give a visual idea of how the cervical collar should fit the patient. The Mannequin is with arms open at a certain angle and the patients are supposed to have arms along the body.

3.1.1 – Model One

The main idea is to design a structure that would settle on the shoulders without interfering with the neck. The designing process was made in two main separate portions, the frontal portion, and the back portion.

The results of the structure designed with the requirements defined are presented in Figure 39. It is only a representative model of how this portion (frontal portion) could be applied. The mannequin is not the most favourable one as its position is with the arms lifted at a certain angle which is not the scenario of application (the correct is with arms along the body). In this position, the trapezium is contracted and increases the height of the shoulder as well as changing its angular shape.



Isometric View	Front View	Left View

Figure 39 – Different Perspectives of Model One

As it is supposed to fit every adult patient like in a universal model, it has rotational points that help the adjustment and application of the collar. Since this model is just to get a shape of how the cervical collar can be, there aren't any locking mechanisms that would allow the immobilisation of the patient.

A better understanding of this model and complete visualisation of the problems mentioned as well as the proposed improvements are exposed in **Appendix A.**

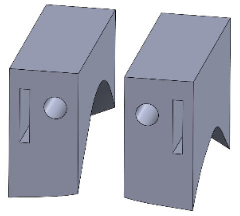
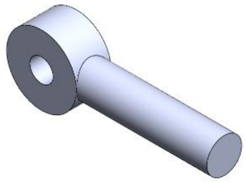
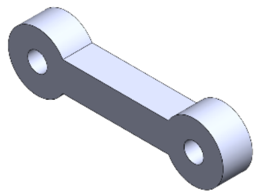
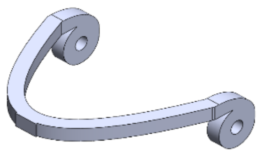
			
Shoulder Support	Rotational Element	Shoulder-Mandible Element	Mandible Support

Figure 40 – Different Parts that Constitute the Model One

From this possible structure, it is reviewed that there are some problems on the Shoulder Support concerning the shape of the region that is supposed to settle on the shoulders, as the angle is quite elevated and might injure the user and don’t have a proper fit (Figure 3 – Appendix A). It is also noticeable that the Shoulder-Mandible Element should have an adjustment system, like a telescopic one (for example), in order to better fit the different sized patients (Figure 4 – Appendix A). Another problem is on the Mandible Support, once there is needed a rotational element on both ends to prevent the torsion of the bendable band when the remaining structure gets stretched and rotated for better fitment. The Mandible Support needs to keep a flat top surface. (Figure 5 to 8 - Appendix A) The rotation of the group Rotational Element/Shoulder-Mandible Element/Mandible Support when adjusting the cervical collar is limited because the Shoulder-Mandible Element goes against the Shoulder Support, which blocks the movement and constitutes another problem.

3.1.2 – Model Two

On this model, the concept of design for the Shoulder Support changes. Since the problems from the first model already have a suggestion to be corrected/improved, the Shoulder Support follows a direction in which is also focused on the preparation for a Back Portion. In the first model, besides the square hole, nothing was made in order to conciliate a Back Portion, only to allow the frontal adjustments.

Keeping the new concept in mind, it was created a Shoulder Element with Telescopic Adjustment (Figure 41-1, 2). In addition, a Back Portion Element that will be a base for the future Back Portion design was also created (Figure 41-3).

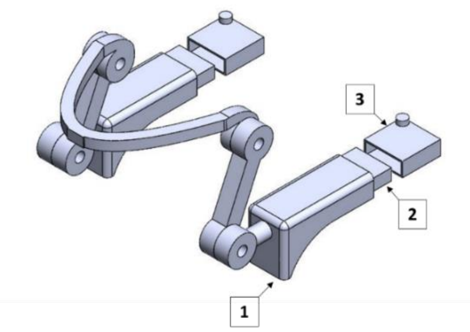


Figure 41 – Model Two.
1 – Shoulder Element; 2 – Telescopic Adjustment; 3 – Back Portion Element.

In this design, the Telescopic Adjustment slides in a guiding box inside the Shoulder Element (Figure 2 – Appendix B) which allows it to accommodate different sized patients. The objective is to insert the Telescopic Element into the Back Portion to lock it (the locking mechanism is not represented) and then adjust the Shoulder Element against the shoulder of the patient.

There is always room for improvement but the main objective now is to design an entire structure. For this reason, there will not be any other changes to this model.

For a better understanding of this model, check **Appendix B**.

3.1.3 – Model Three

The third model is the first to present a complete structure. Now that there are more pieces in each model, a colour system will be used to better identify pairs of parts and the pieces that have been changed compared to the previous model (meaning that the standard grey parts are the same as the previous model, not having suffered any changes). As the structure is not yet defined/complete, there is still no existence of locking mechanisms. The positioning of the patient about the structure is the same as on the First Model.

The parts that constitute this model are: 1. Mandible Support; 2. Chin Strap; 3. Chin Attachment; 4. Shoulder-Mandible Element; 5. Back Portion Element; 6. Main Back Portion. The previous numbers match the ones in Figure 42.

In figure 42 it is possible to see how the different parts are combined when applied to a patient and the assembled collar with exploded view between groups of parts. The virtual application is not a perfect fit for the Mannequin as it was designed just concerning the shape and approximate dimensions for an adult.

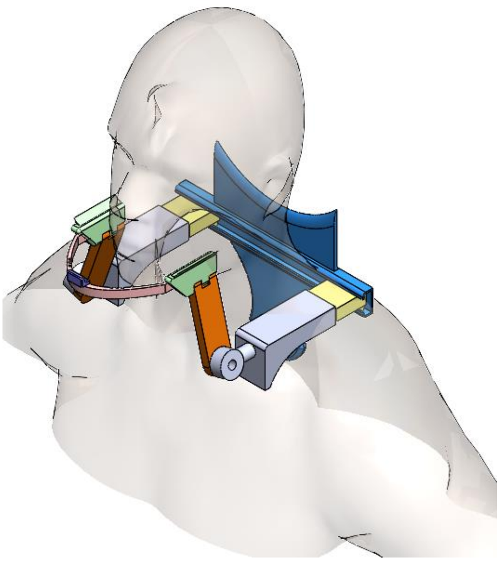
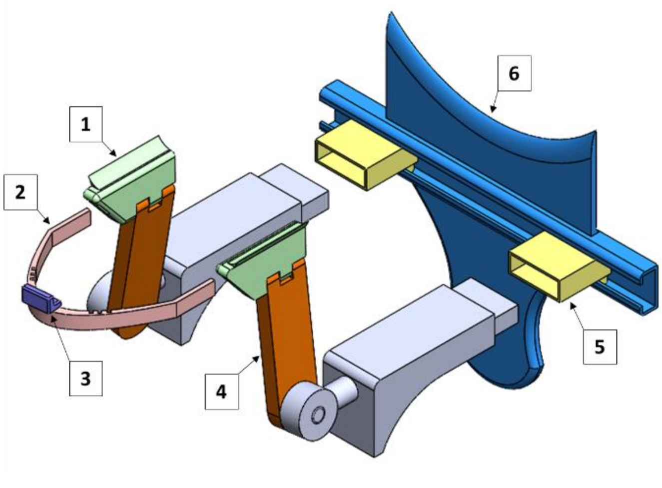
	
Model Three Virtual Application	Different Parts of Model Three

Figure 42 – Model Three.
1 – Mandible Support; 2 – Chin Strap; 3 – Chin Attachment; 4 – Shoulder-Mandible Element; 5 – Back Portion Element; 6 – Main Back Portion.

The main problems found on this structure are the bad sizing alignment between the Frontal and Back Portion (that can be solved with a telescopic adjustment on the Shoulder-Mandible Element that would lower the position from the Mandible and allow to be approximately on the same level as the occipital support (Figure 14 - Appendix C). The Mandible Support and the Shoulder-Mandible Element demand for the first one to be always on a parallel position to the ground in order to support the patients' mandible once it doesn't allow any angle of rotation on that region without translating. People with a different angular shape of the mandible will not be suitable (Figures 6 and 7 - Appendix C). The Rotational Element in this case is useless because it will change the position and angle of the Mandible Support which will not offer suitable support on the right supporting points (Figure 8 - Appendix C). The shape of the Chin Attachment can be improved as it might be too small and hurtful. Another problem is that the non-adjustable Main Back Portion will not perfectly fit every patient.

For a better understanding of this structure and its problems check **Appendix C**.

3.1.4 – Model Four

Since on the previous model an entire structure was created, in this model will be created possible solutions for locking mechanisms. Those were created on the connection of the Front and Back Portion (Figure 43 - 1), on the Shoulder-Mandible Element through a telescopic adjustment (Figure 43 - 2), and to fix the position of the Back Portion Elements (Figure 43 - 3).

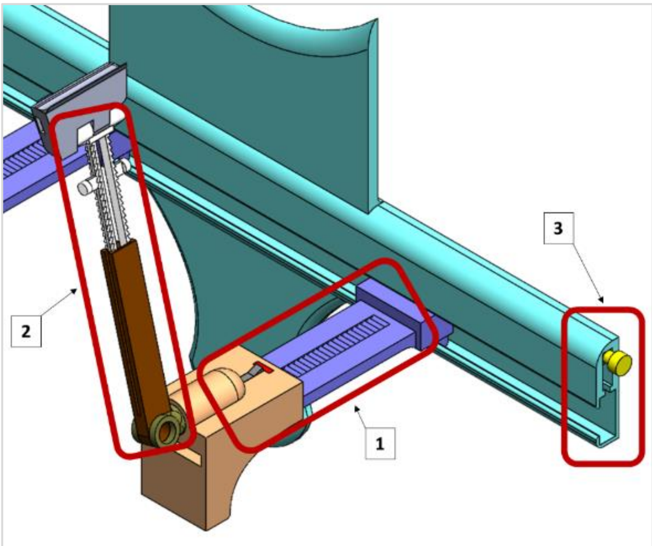


Figure 43 – Fourth Model Locking Mechanisms
1 – Shoulder Support and back Portion Connection; 2 – Shoulder-Mandible Telescopic Adjustment; 3 – Back Portion Locking Mechanism

Every mechanism and changes that have been made to this model are detailed in **Appendix D**.

3.1.5 – Model Five

This model is marked by the different Back Portion and its mechanics when compared to the previous models.

This change allowed to:

- lower the complexity and number of parts;
- add another immobilisation method that prevents the structure and the patient to move in relation to each other;
- prepare the structure for future electronic improvements like measuring the pressure on the back of the head when closing the cervical collar.
- elevate the head at a certain height that the cervical spine benefits from, as mentioned by De Lorenzo *et al*. (1996), and Schriger *et al*. (1991).

In this model, there was also changed the button locking mechanism on the connection of the Front and Back Portion. These mechanisms will have continued improvement by the time that new models are presented on the document as the main purpose is to design and implement fast locking mechanisms. There have also been changes on the Mandible Support, which now can support different degrees of mouth opening, or mandible shape, and was also incorporated a new Chin Strap (presented in two versions). (Figure 44)

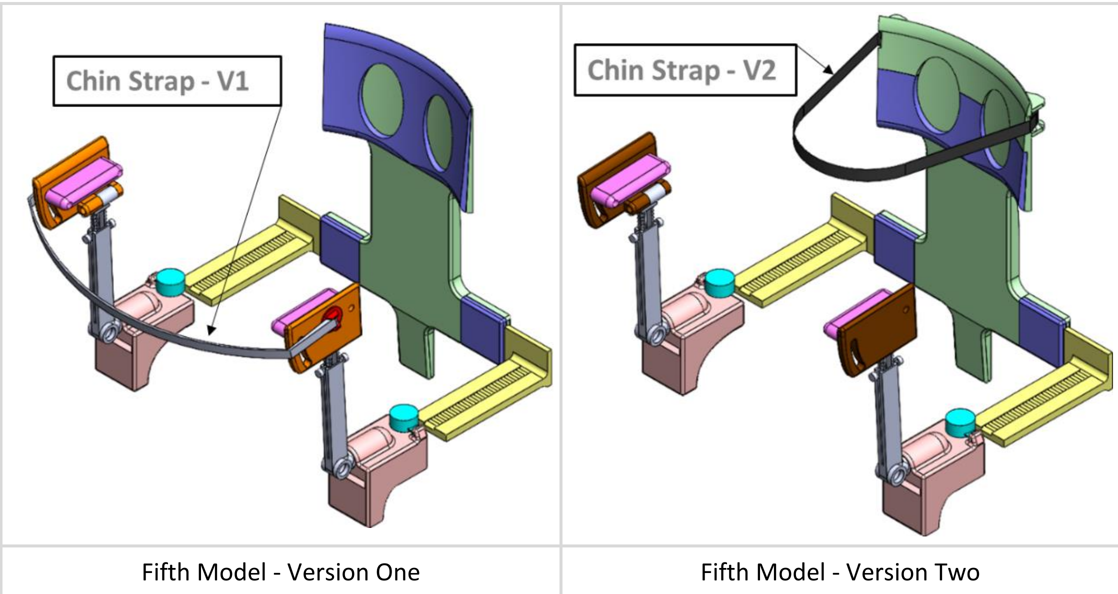


Figure 44 – Isometric View of Version One and Two of the Fifth Model

This model also starts the development of the equipment for measuring the pressure on the back of the head. In this case, the Main Back Portion has two holes ready to assemble two balloons inflated with air and connected to a pressure sensor to know when the ideal pressure is being applied during the fastening of the structure.

The Balloons' Development, its fundamentals and other related topics will be discussed in Chapter 3.2.

The concept of the Main Back Portion on the back of the head is completely defined, but there might be changes in the shape and size of the balloons as well as some minor changes on the Main Back Portion.

Every change and characteristics of this model are detailed in **Appendix E**.

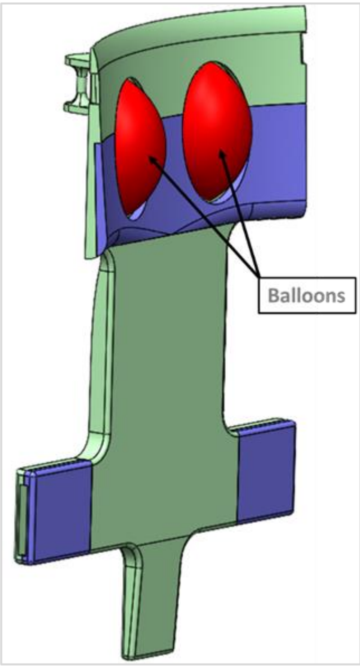


Figure 45 – Main Back Portion of the Second Version with the Balloons

3.1.6 – Model Six

The sixth model has only a change in the shape of the Shoulder Support. This change allows for the piece to contact a larger area of the patient's body and ensures a better and more comfortable fitting.

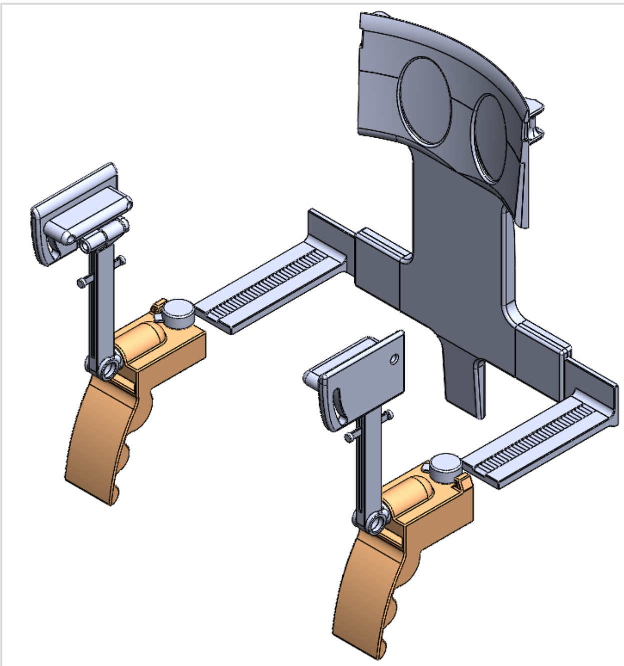


Figure 46 – Model Six

All the characteristics of this model are detailed in **Appendix F**.

The Model Six marks a change in the way the development will be. Until now the purpose was to develop a virtual structure to immobilise a patient but at this point will be developed and implemented locking mechanisms as well as prototype printing and testing.

3.1.7 – Model Seven

In this model, simple mechanisms are applied. Besides the button and tooth mechanisms of the Shoulder Elements, were also applied bolt locking mechanisms on the Rotational Element (that connects the Shoulder Support and the Shoulder-Mandible Support), on the telescopic system of the Shoulder-Mandible Element and Mandible Support connection.

Figure 47 shows the assembly of this model in which the dark blue coloured parts represent all the parts that need to be moved for locking or unlocking the positions of the adjustments (mainly bolts). The parts that had no changes remain with the standard grey colour.

Check **Appendix G** for a detailed description and view of every mechanism.

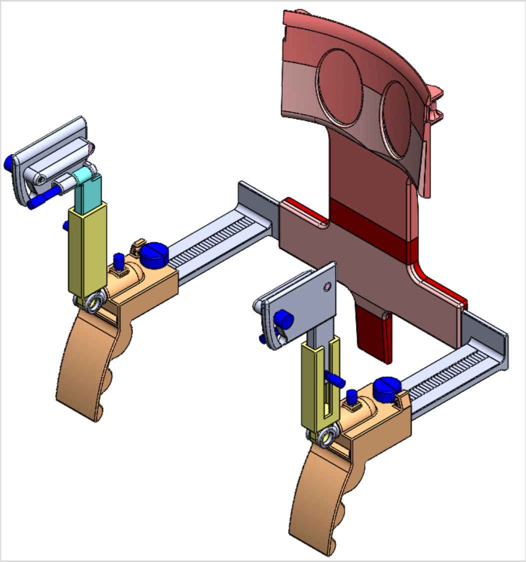


Figure 47 – Model Seven

3.1.8 – Final Model

This model is the final version of the prototype without the technological devices. It is fully designed without metal parts besides electronic components. The fast-locking mechanisms were achieved using elastic bands (brown colour on the assembly of Figure 48) that will create a spring effect on every mechanism (as shown in Appendix H).

In this model all the colours from the CAD file match the colours of the printed prototype, meaning that the grey colour code for non-edited parts no longer exists. On the other hand, there are some intermediate parts presented in Appendix H that, in some cases, have different colours than those from the printed Model, or because they are testing parts, or to have a better view of the mechanism.

By comparison with the previous model, a change on the top of the Main Back Portion is also noticeable due to the modifications performed in the design of the Balloons (Chapter 3.2). This new shape of the Main Back Portion allows it to fit them.

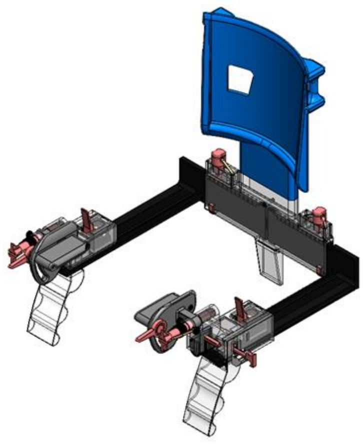
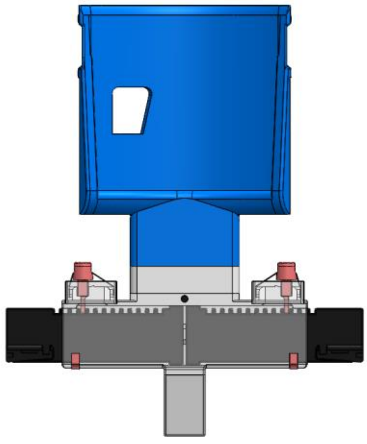
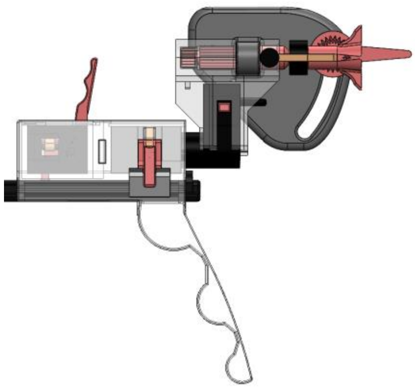
		
Isometric View of the Final Model	Front View of the Final Model	Left View of the Left Shoulder Support

Figure 48 – Final Model (CAD)

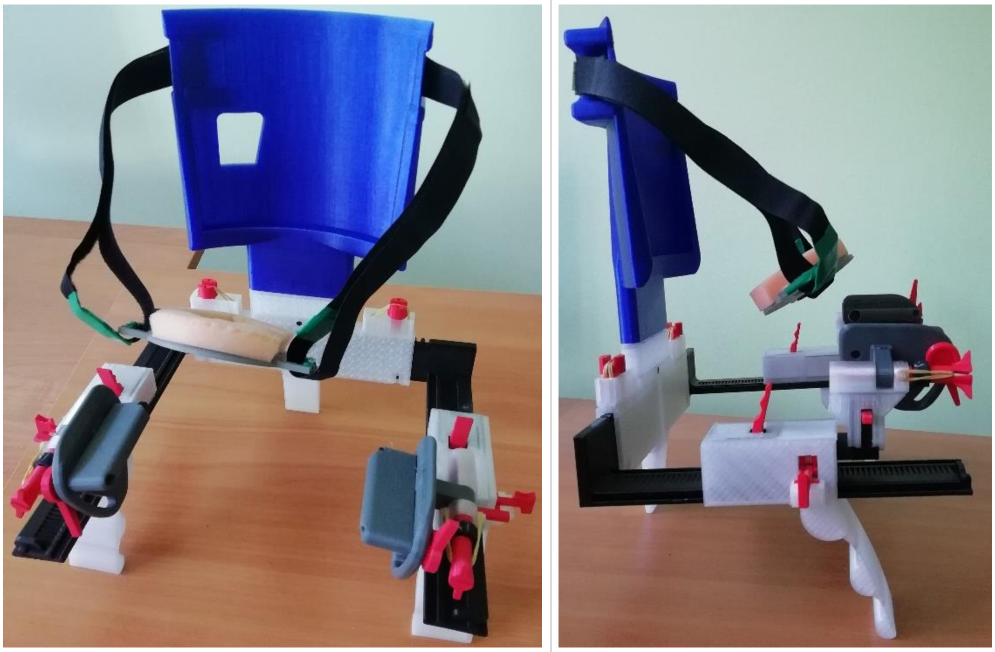


Figure 49 – Final Model (Real Model)

The evolution of the models resulted in a prototype that has as features six locking/adjustment mechanisms. Those are implemented in regions where they were considered needed to accomplish a universal fit. The common characteristic of the adjustments, and considered an innovative factor, is the utilisation of Elastic Bands and its spring effect to change from locked to the unlocked position (or vice-versa) in every mechanism.

Starting from the Back Portion of the Cervical Collar, the position of the Balloons, which cover a vertical extension of around 129 mm, is an average distance between the top of the head and the shoulders. The centre line of the Balloons is intended to match the centre line of the head+neck which match the occipital region.

In the back of the Back Portion are implemented two pins where the Chin Straps are connected. The Chin Strap and Chin Attachment are part of the adjustment system to assess the pressure exerted on the patient's head. Its adjustment is made by pulling the Chin Straps on each side of the structure in a direction far from the patient and that forces the Chin Attachment against its chin. Finally, it is secured via hook and loop material such as Velcro. (Figure 50)

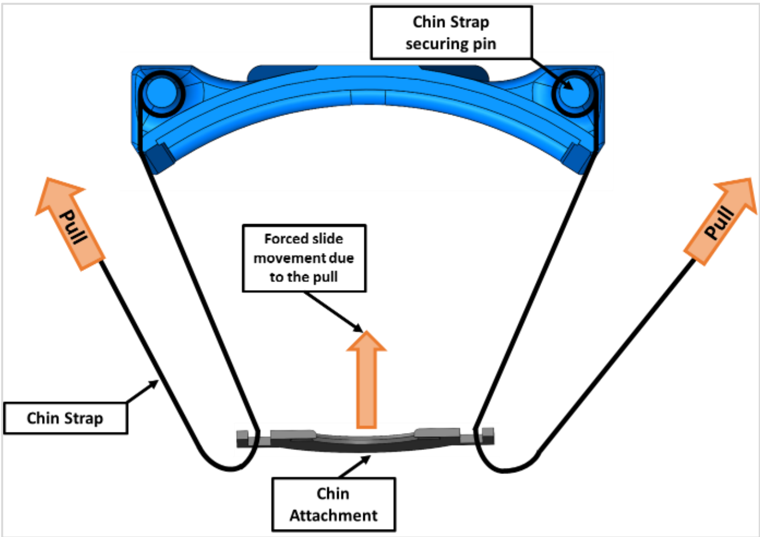


Figure 50 – Cut Top View of the Back Portion and the Chin Attachment

Also on the Back Portion, but hosted on its lower region, are two Sliding Elements. These allow the width of the structure to match the different real shoulder widths. It can conciliate a minimum width of around 262 mm when closed (considering the end part of the Sliding Element on each side) and achieve a maximum opening of around 375.4 mm (having the same reference on each side), having intermediate distances that can be locked in between. (Figure 51)

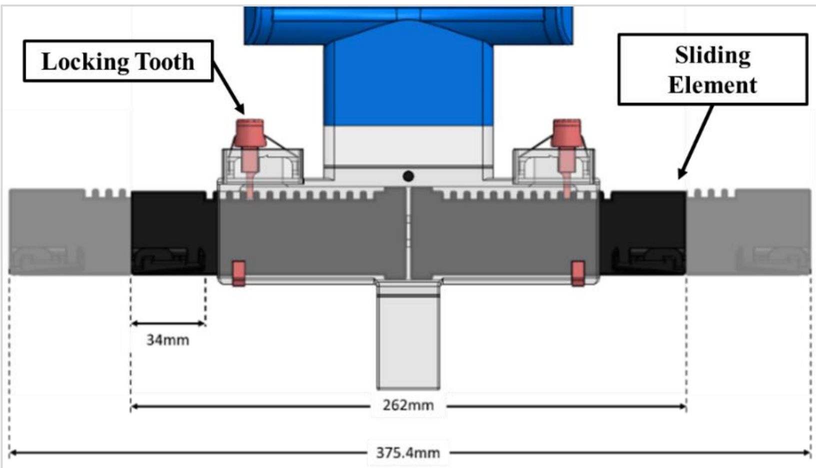
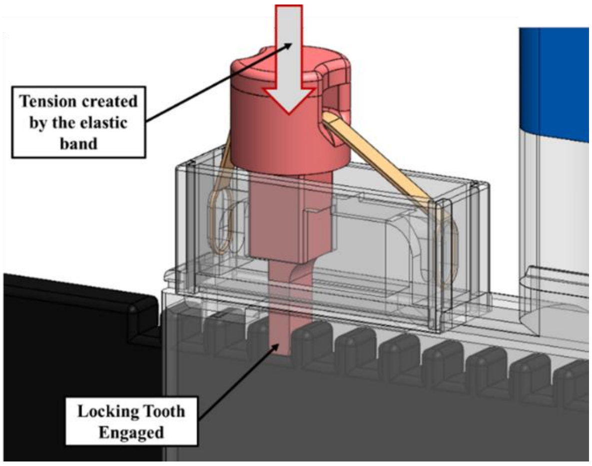


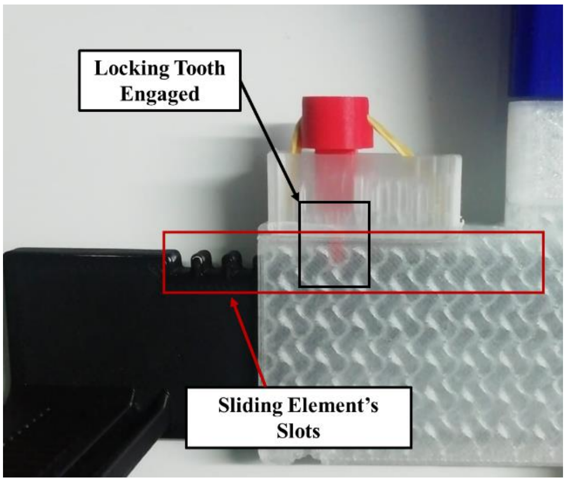
Figure 51 – Closed and Extended Dimensions of the Assembly on the Sliding Elements' Adjustment

As for locking the mentioned positions, the Sliding Elements present several slots on its top region where a Locking Tooth engages. The Locking Tooth has its movement restricted by its housing inserted on the Back Portion, having only two possible positions switchable in a movement parallel to the ground and guided by the housing. One of the positions is the engaged one and matches the lock of the slide movement, while the other allows for the structure to be adjusted. To unlock the mechanism, the Locking Tooth must be pulled and moved to the higher position where it is secured by a small indentation and the elastic bands' tension.

The Elastic Bands incorporated in the mechanism allows the Locking Tooth to be secure and static on the housing, and when aimed to the locking position, those help to get an instant lock due to the tension that they apply on it. That same tension, due to the lower anchor point of the Elastic Bands, keeps tension on the Locking Tooth while in a locked position which allows to secure it, preventing it from getting out. (Figure 52)



CAD Model



Real Model

Figure 52 – Locking Tooth Engaged Locking the Sliding Element's Movement, CAD vs Real

Done with the back adjustments, the connection of the Back and Front Portion is made between the Sliding Element (part from the Back Portion) and Shoulder Support (part from the Frontal Portion). The relative movement between each other allows the structure to be adjusted and fixated against the body on the chest region. This adjustment ensures the fitting of patients with different Back and Chest distances/dimensions. (Figure 53)

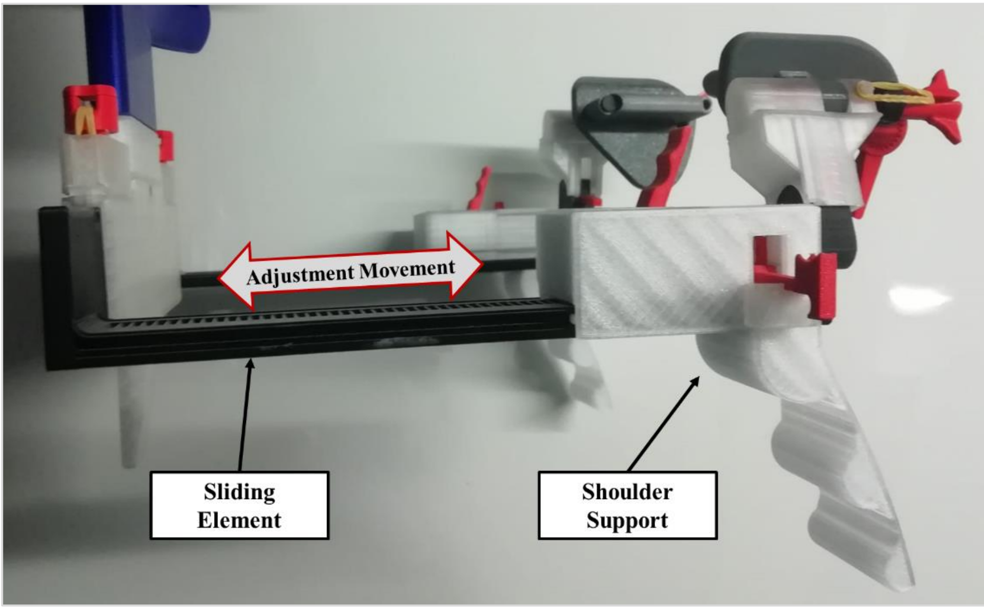
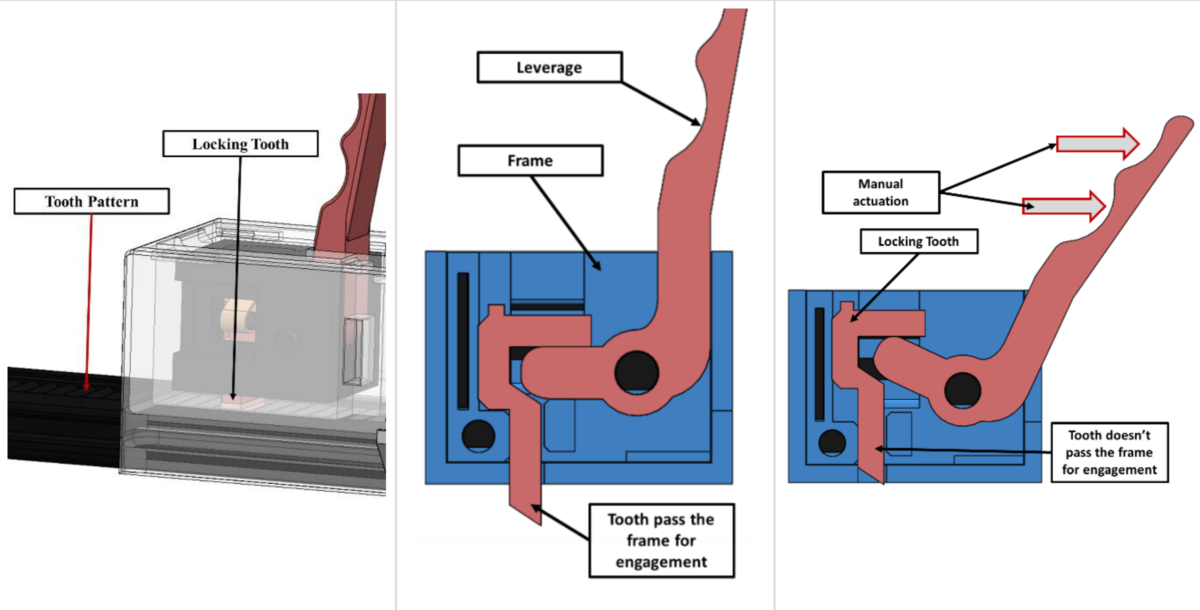


Figure 53 – Back and Front Portion Connection through the Sliding Element and the Shoulder Support

For locking the different relative positions, the Sliding Elements present a tooth pattern feature where a Locking Tooth (hosted on the Shoulder Support) engages and locks the position preventing the loose movement (direction to move the Shoulder Support away from the Back Portion). This engagement can be considered automatic as the Locking Tooth is under tension from the Elastic Band that pushes it for its locked position, keeping it there. To unlock its position and loosen the structure, a lever must be pulled and manually secured while the Shoulder Support's movement is performed. The tighten movement (to bring the Shoulder Support and the Back Portion together) can be performed by just pulling the Shoulder Support as the locking is instant due to the Elastic Bands' tension. (Figure 54)



Overall look of the mechanism	Cut view of the Mechanism (Locked Position)	Cut View of the Mechanism (Unlocked Position)

Figure 54 – Detailed View of the Shoulder Support's Locking Mechanism

The Shoulder Support has incorporated the Shoulder-Mandible Element (that as the name proclaims, makes the connection between the Shoulder Support and the Mandible Element). From a front view of the structure, it is possible to understand both adjustments related to this element. (Figure 55)

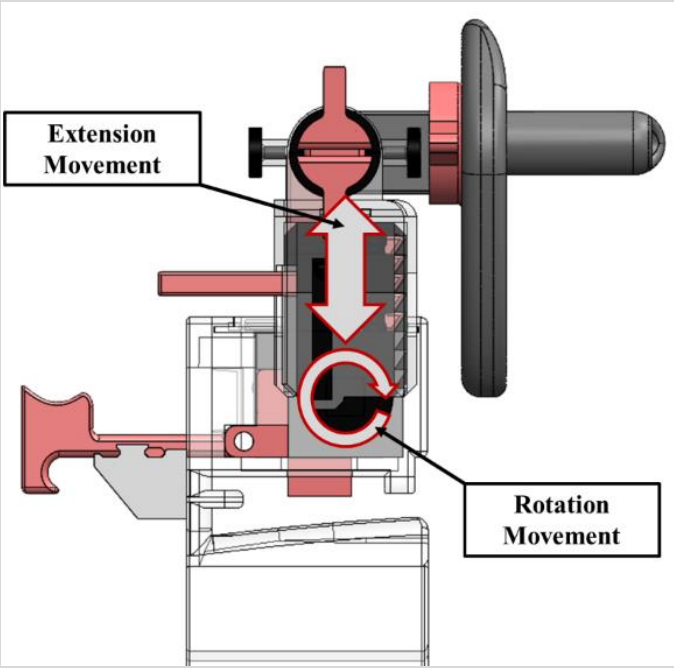
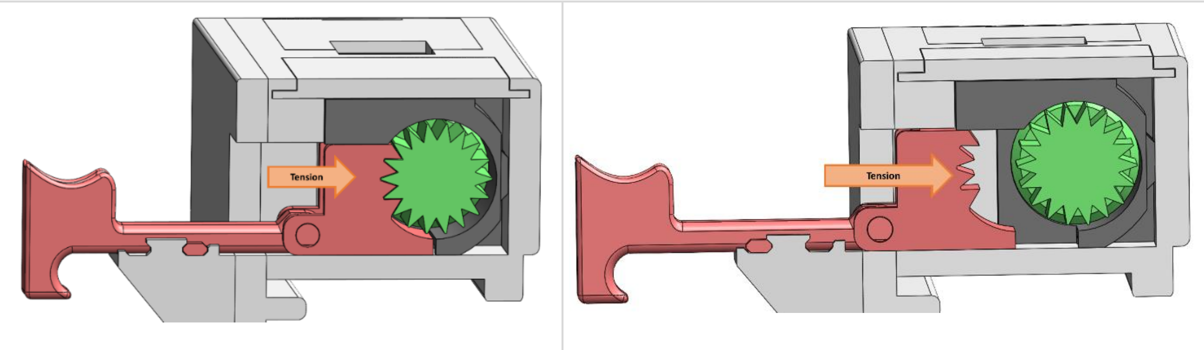


Figure 55 – Extension and Rotation Movement from the Left Shoulder-Mandible Element

The rotation adjustment allows it to aim the Mandible Element to the Mandible, and the Telescopic Adjustment allows it to take the element closer to it. As on the remaining adjustments, the locking mechanisms have Elastic Bands to keep tension on them, that tension puts them in the lock position. Also, both adjustments are based on tooth patterns and Locking teeth. To unlock the position, while on the rotation adjustment there is a lever that needs to be pulled to allow the movement, on the Telescopic Adjustment by just pulling the outer part, the extension movement is realised. On the other hand, after pulling the lever to unlock the rotation movement, there is an external support that allows for the position to be opened, being just a slight touch needed to disengage from that support and get the locked position. This instant reaction from the lever is due to the Elastic bands' tension. (Figure 56)



Locked Position	Unlocked Position

Figure 56 – Rotation Movement Locking Mechanism on the Shoulder Support

As for the Telescopic Adjustment, to return to the lower positions, a lever must be pulled to unlock the movement. (Figure 57 and 58)

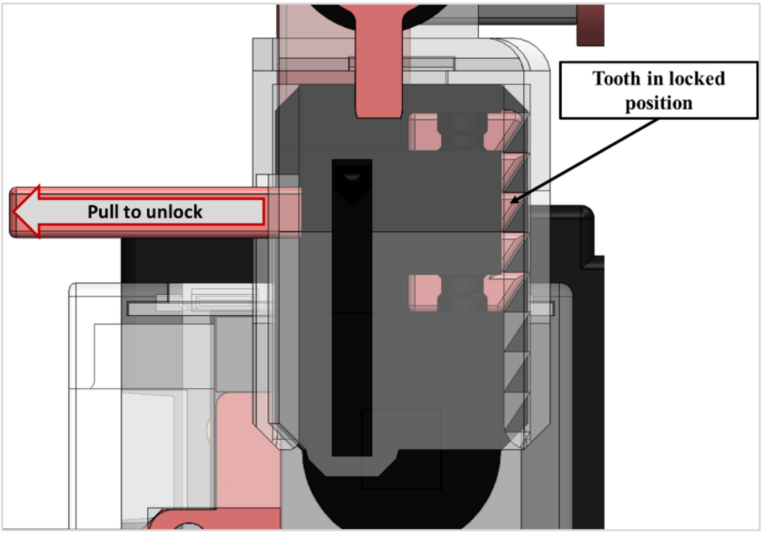
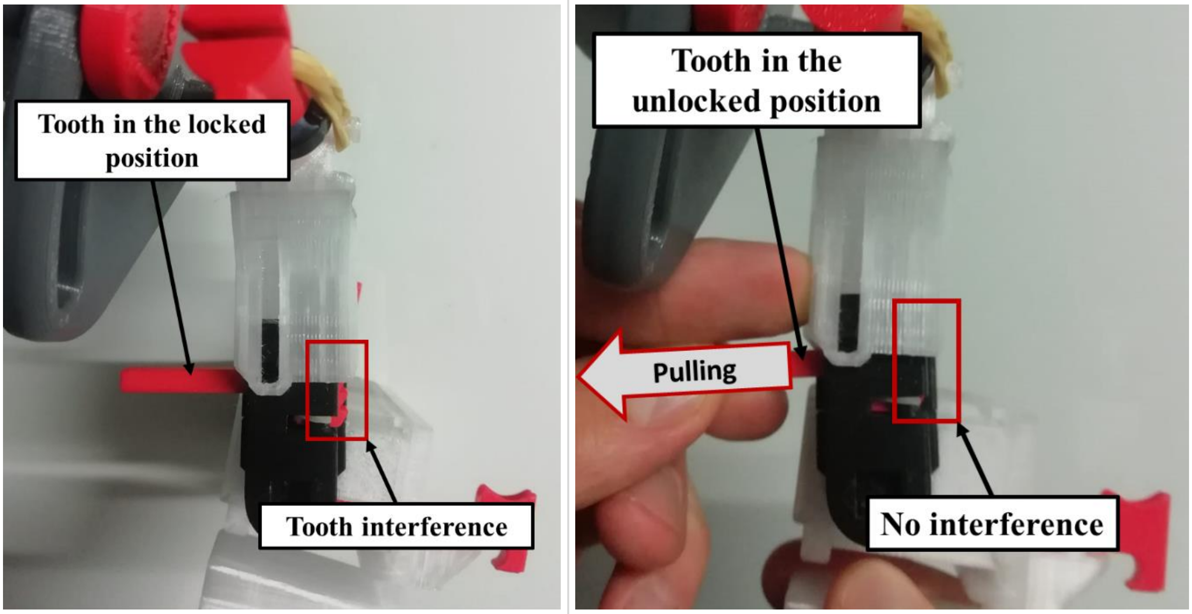


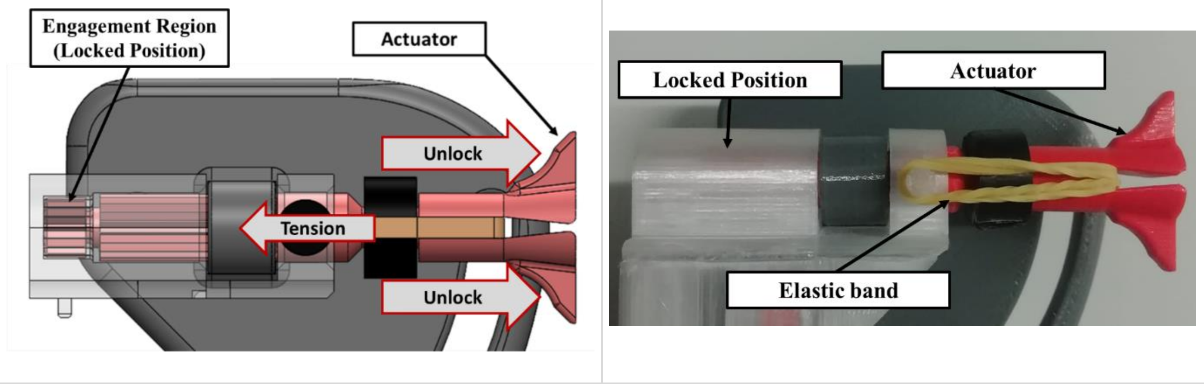
Figure 57 – Front View of the Shoulder-Mandible Element



Movement Locked	Movement Unlocked

Figure 58 – Tooth Interference in the Locked and the Unlocked Position in the Real Model

Following the different adjustments, the next is applied on the Mandible Support. The Mandible Support should be adjusted to match both the position and angularity of the mandible. To adjust its position, a similar tooth pattern previously used for the rotation movement was implemented. The natural position of this adjustment is locked and to unlock it, a manual Actuator must be pulled. Once the Actuator is released, the movement gets instantly locked due to the tension of the Elastic Bands. (Figure 59)



CAD Model	Real Model

Figure 59 - Mandible Support Position Adjustment

As for the angular adjustment it is based on the friction created between parts with the help of a Bolt. When the bolt is tightened, the angular position is secured. (Figure 60)

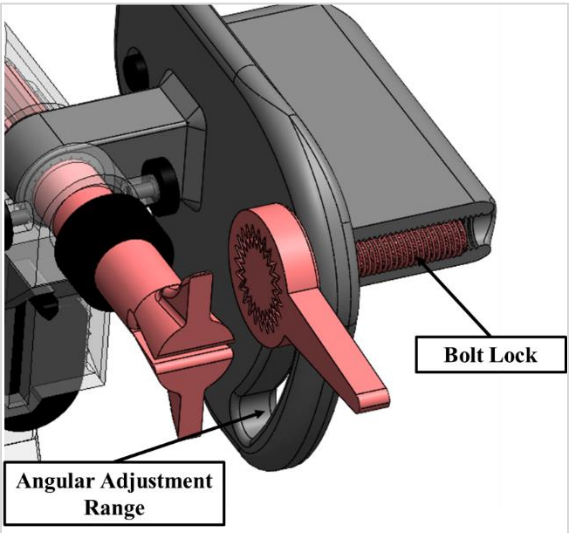


Figure 60 – Angular Adjustment on the Mandible Support

Figure 61 shows the collar applied to a healthy volunteer.

Figure 61 – Different Views of this Model Printed and Applied to a Healthy Volunteer

For a better understanding of the final prototype, its mechanisms, and the intermediate parts designed to achieve the final model, check **Appendix H – Final Prototype**.

3.2 – Balloons Development

The part being developed in this chapter and already mentioned in previous ones, is called Balloons.

The balloons are one important element of the fastening pressure monitoring system mentioned in previous chapters but with bigger importance to the Final Prototype (and Appendix H).

The fundamental of this method is that by having a closed chamber (like the balloon) with pressurised air, the pressure at every point on the walls will be the same (P1=P2=P3=P4=P5; P - Pressure). The same pressure will be verified on all the circuits where the air is. (Figure 62)

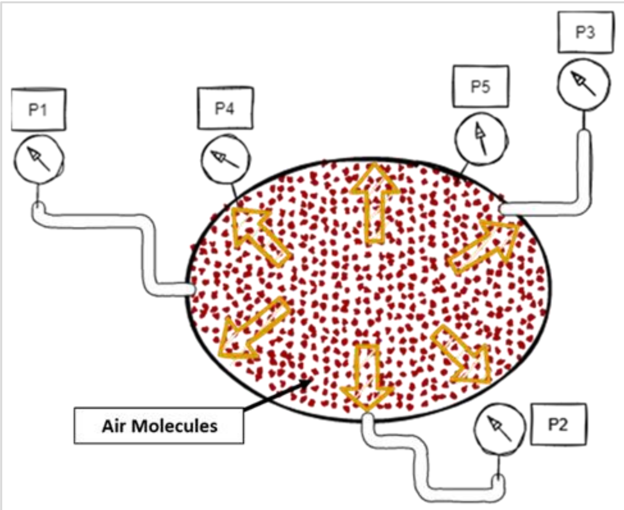


Figure 62 – Example of a Pressurised Closed System

In this case, the Balloons will be inflated with air and connected with hoses to a pressure sensor (to monitor the pressure changes), and a check valve system. The pressure is then measured by the pressure sensor and the data will be sent to an external device to be processed. When the pressure achieves a defined value, considered inoffensive for the patient and enough to immobilise it, it will give an alert on the external device for the paramedic to know when to stop the fastening forces.

The development of the balloons matches the development timeline of the cervical collar remaining parts, which means that both can impose changes on each other. The first thought came with the shape of the balloons, which after the 3D model, resulted in the Housing on the Back Portion of model five (Chapter 3.1.5). In this model, the idea consisted of two separate balloons assembled at the same distance of a centre line to help position the patients' head on the centre. (Figure 63)

(a)

(b)

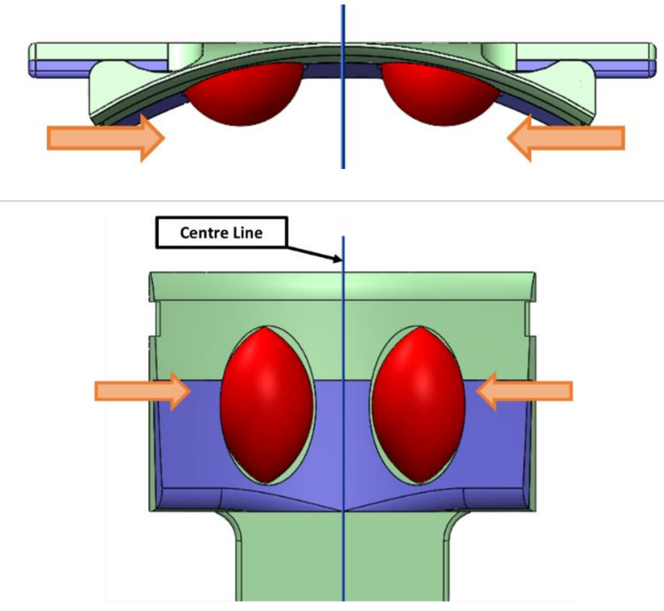


Figure 63 - Top (a) and Front View (b) of the Main Back Portion with the Balloons

The shape of the balloons was now defined. So, the production method as well as the materials needed to be chosen. As for the production method, the first thoughts were to use metal moulds and heat. For the material was thought to use some fragments of flexible Polyvinyl Chloride (PVC) that is a thermoplastic (need heat to be conformed) from a beach ball (Figure 64). The advantage of a beach ball is that it already presents a check valve that can be re-used for filling the balloons with air.

Figure 64 – Flexible PVC that Would've Been Used

After some discussion this idea was excluded due to the following reasons:

- The cost of producing the mould;
- The fact that the metal mould production is for a large scale and not for prototyping;
- The paperwork involved, since for using the Institute's CNC machine would be necessary requirements and formularies;
- The need for a high-temperature source and its related precautions;
- The material is not as elastic as intended.

Another possible solution was the use of elastomers like latex and silicone to create a united element as both present excellent elastic properties. To check the behaviour of the material, two different thickness latex gloves were tested under pressure. (Figure 65)

After the test, it was noticed that both were a good basis for the balloons, but the thick gloves (on the right) would result in a better part as they would be more resistant to wear and have a longer life. Also, concerning it is a medical device and is washed and sanitised with corrosive products, these are an advantage as they are resistant to most cleaning products.

Thin Gloves	Thick Gloves

Figure 65 – Behaviour of Thin and Thick Gloves

Meanwhile, a different and most suitable solution was thought. As the 3D printer is such versatile equipment and some materials present considerable elasticity (being suitable for the intended purpose), these shapes could be printed. The material chosen was *Recreus* filament *Filaflex 82A*, a Thermoplastic Polyether-Polyurethane Elastomer. The principal questions were if the printed components would be airtight, strong enough to keep the pressure (despite being a low pressure – less than 100 kPa, the maximum pressure value supported by the acquired pressure sensor) and yet comfortable for settling the patients' head.

The first printed versions didn't have any concern about the size and were more like attempts to understand the behaviour of the material during and after printing. The first print showed that a lot of changes in the shape would be needed (CAD model) and also on the parameters chosen on the printer's software. (Figure 66)

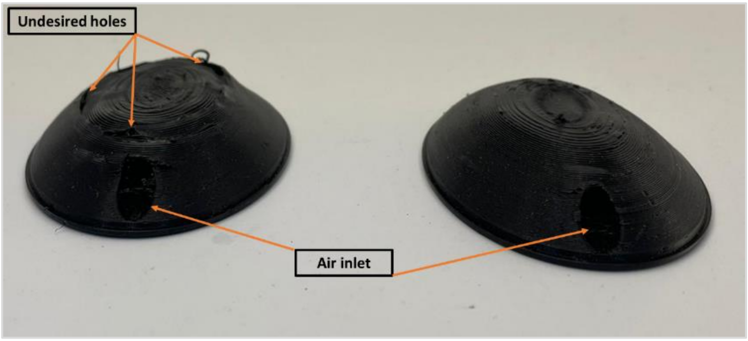
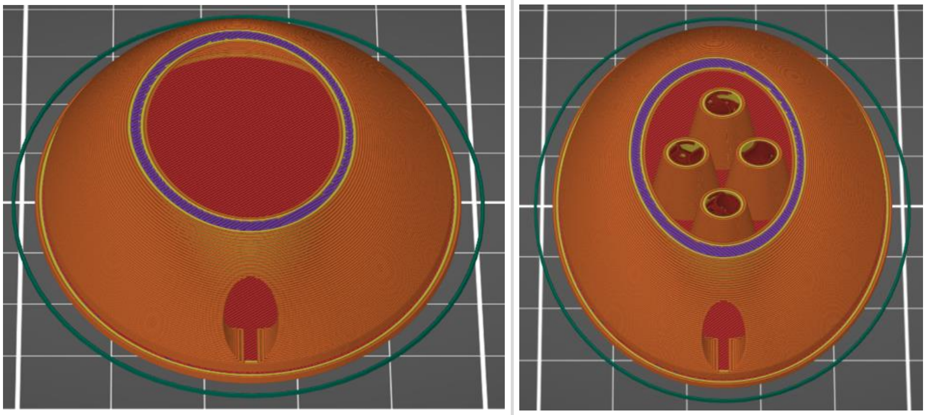


Figure 66 – First Printed Versions of the Balloons

As it is possible to see in Figure 66, the left part presents undesired holes while the other presents a perfect finish on the top. This is due to the different inside profiles on each one. While on the Left balloon the inside was empty, the second test (part on the right) presented 4 conic shaped elements on an ellipse distribution to increase the support on the walls near the top. (Figure 67) This inside supports allowed for the walls to be printed almost without warping, achieving a nice finish on the top. On the other hand, these elements, besides creating a connection between the bottom and the top layers which didn't allow for the balloon to stretch in that direction when inflated, also increase the rigidity when compressed, which eliminates the comfort and pillow effect intended. The characteristic that was validated on this first test was the fact that the use of this material allows airtight objects.



Left Balloon – Empty inside	Right Balloon – Supported Inside

Figure 67 – Balloons Empty Inside (0% Infill) and with Internal Supports

The changes on the CAD model that can be made (for this object) are related to the side walls angle, one of the major concerns in terms of printing with flexible material, as the walls even at 45 degrees with the printer bed have some tendency to warp. This phenomenon usually causes the printer to shock with the already printed part, causing printing errors, or even printing cancellation. Besides that, the warp happens when the support created by the layers isn't strong enough. This might happen because the flexible properties are more difficult to control and to predict good base support.

Concerning the printer's software settings, besides the material requirement changes like the **bed temperature** to 0ºC and **nozzle temperature** to 215º-250ºC, the **number of perimeters** (number of contours before the infill on each layer - by increasing the number of perimeters is increased the strength of the part printed), **number of top layers** (the top and bottom layers are printed with 100% infill, bridging all the infill pattern and creating solid layers – higher the number of layers, sooner it will start to create the solid layers and the thicker it will be), **layer height** (thickness of each layer – presents an inverse relation between the time of the printing and it's detail), **infill density** (as the name mention it represents the percentage of material infill – higher the density, higher the compression resistance or stiffness), **infill pattern** (help to create greater inside support when in combination with the infill density and is important for this case where the inside will be filled with air), **fill and bridging angle** (angle direction in which each layer gets deposited – helps to create greater supports when in combination with other parameters), **speed** (printing speeds – smaller speeds can help achieve better results), extrusion multiplier (corrects proportionally the flow of material to be deposited), and **cooling** (the fan speed, and when it operates or not - helps to cool certain layers to achieve specific effects), may help to achieve better results on the printed parts, as well as obtain special effects.

As for different shapes, it was also tried with an entire balloon with two circular ends to keep the intention of centring the patients' head. In the first option, it was designed as a curved object with the curvature of the top of the Main Back Portion where the balloons will be inserted. The problem with this design is the printing due to the hanging regions on the ends. The possibility of creating supports is also excluded due to the reduced support that this flexible material would offer. (Figure 68)

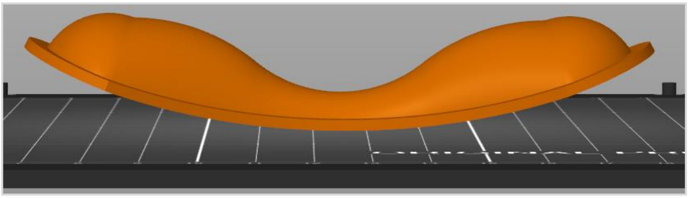


Figure 68 – Balloons with Both Ends Hanging

Keeping the shape of an entire part with the two circular ends, some trials are made flat instead of a curved and hanging shape. In addition to that, the element was filled with material (printed with a density of 5%), and the inlet hole was positioned on the bottom preparing it to assemble on the Top of the Main Back Portion and to receive a hose through its back. (Figure 69)

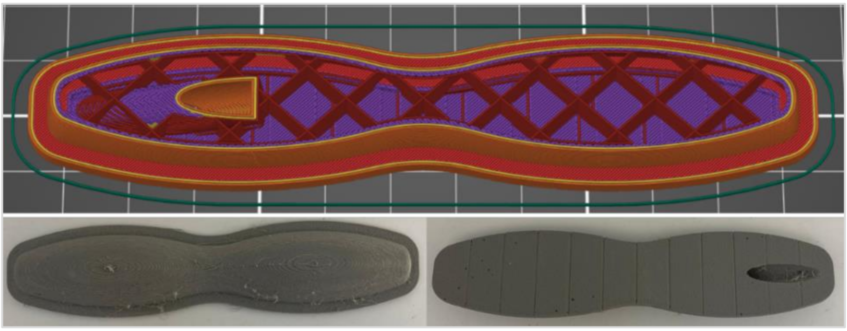


Figure 69 – Printed Part with 5% of Density

The print with a certain infill density presented good results on the walls (in this case they don't have such low angles which can also help with the printing). On the other hand, in this case, the software builds perimeters around the inlet hole which causes that region to be rigid when compressed (not wanted). As for inflating with air, the rectilinear infill pattern doesn't present any barrier to the air passage because the layer deposition is interspersed, as is possible to see in Figure 70, leaving an air passage between consecutive layers in the same direction due to a 90 degrees delayed layer in between (interspersed). Additionally, besides that gap created by the interspersed layers, due to the material flexibility and depending on the bridging distance between intersection points (where the different direction layers intersect and where the support is stronger – higher density increases the number of intersection points), during the printing the layers may fall or warp and fuse with the anterior layer in the same direction. These connections are not as strong as the remaining and the air may break some of them allowing the air to distribute all the way on the balloon. The fact that the infill constituted an advantage, validated the development of the balloons with this parameter instead of empty ones.

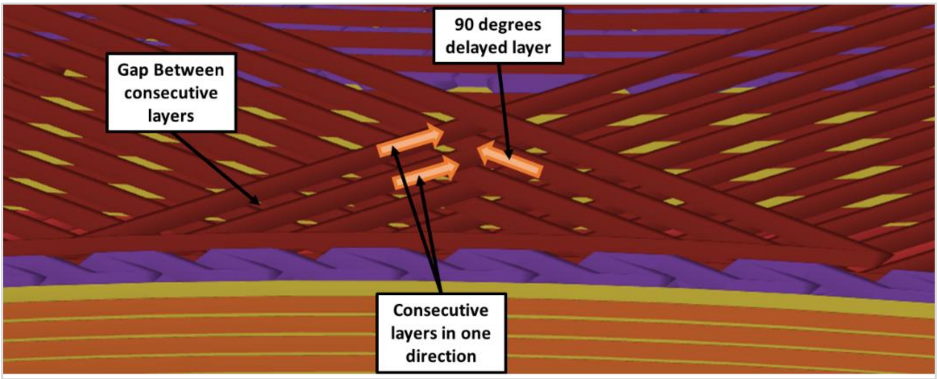


Figure 70 – Layers Deposition According to Rectilinear Infill

Besides that, other important information obtained with the tests is the direction in which the balloon is intended to inflate. When there is a combination of a thin flat bottom composition of layers, and a round shape that accumulates thickness on the walls and top layers, the direction of the inflate may not take the direction intended, forcing the bottom layers instead of the top ones. This means that the bottom of the balloons needs reinforcement in thickness to prevent the air from influencing it. Figure 71 shows a half-sphere with a skirt of 1 mm in which the air direction forces the flat bottom layers instead of the walls on the side and top, regions that accumulated wall thickness and strength due to the shape.

Top View inflated	Bottom view non inflated	Bottom view inflated

Figure 71 – Behaviour of Half Sphere-Shaped Balloon Inflated with Pressurised Air

With this knowledge, a decision of using two materials to build the balloons was taken. The combination of a rigid bottom part and a flexible material on the top would theoretically make the air inflate the balloons and not stretch the bottom part. Between some options available the most suitable ones were PETG and PLA. The first one was the material selected as it presents better durability, lower stiffness - that allows some deformation keeping strength and has greater chemical and water resistance.

The first combined part to be printed was printed with a rectangular rigid base with 1.5 mm (thickness) and with a similar shape to the one presented in Figure 69. The adhesion between both materials showed to be very good before testing. To increase the area of contact between both materials was added a fillet on the outside contour of the balloons. (Figure 72)

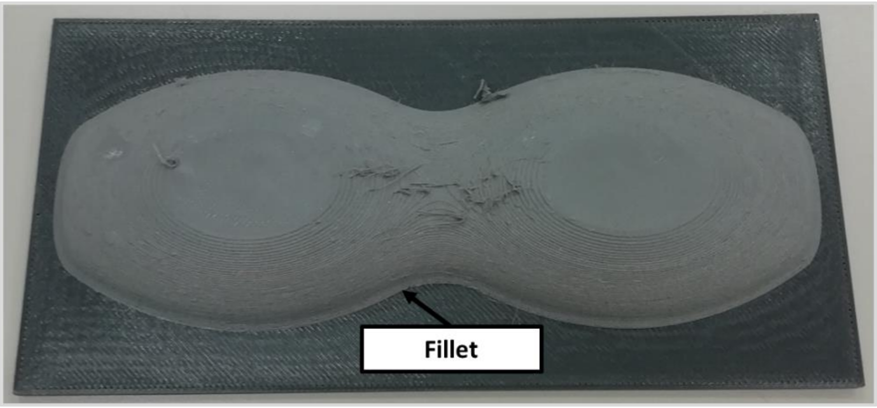


Figure 72 – Balloons with Rigid Base

The inside of the balloon was printed with a density of 5% and to test it, a hole was opened on the bottom to insert a hose. The test of this part presented some warp on the rigid base as it is possible to see in Figure 73.

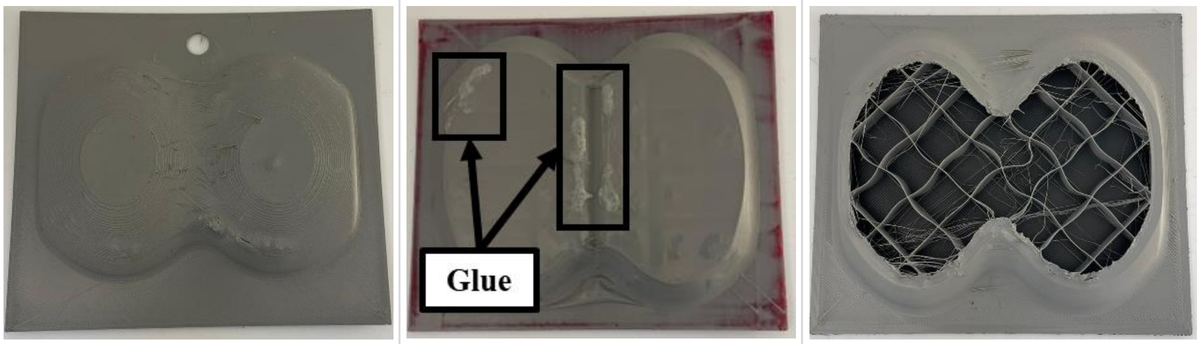
	
Empty	Inflated

Figure 73 – Test of the Balloons with Rigid Base

As the results of this combination were reasonable, the Main Back Portion was re-designed to make possible the accommodation of a square rigid base like the one presented. So, the Top Part of the Main Back Portion was changed to the one presented in Chapter 3.1.8 and explained in Appendix H – Figure 5.

After the print in Figure 73, several models were tested, with different shapes, and different rigid thicknesses (knowing that the total thickness should not exceed 2 mm to keep a tolerance of 0.2 mm for the sliding guides – these assumed tolerances are related to the characteristics of the printer and the material used, mainly considering the expected material contractions and expansions that a part suffers after being printed due to temperature changes). In these different shape tests, the overall size was already approximate to reality. Concerning the printing, the density was around 2-5% depending on the test, low speeds (average of 40-45 mm/s on all the parameters to increase quality), increase on the extrusion multiplier parameter to 1.3 when printing the flexible material as the amount of it that was being deposited wasn't enough, and printing temperature to 250 ^{o}C because optically evaluating the material deposition, it seemed to present a more uniform deposition and fusion. Of course, these parameters will depend on printer to printer, and this was the most adequate for this one. As for the printer's software material change, the layer height is defined for when the user wants to stop the printing for the material to be manually changed. It's important to remember that the parameters that are desired for the flexible material need to be changed directly on the printer display after changing materials, otherwise the parameters remain the same as for the rigid material which is the first material to be printed for easier removal from the printer bed.

Figure 74 shows different shaped print tests that presented relevant evolution but, in some cases, there were regions where glue was needed to keep the balloons airtight.

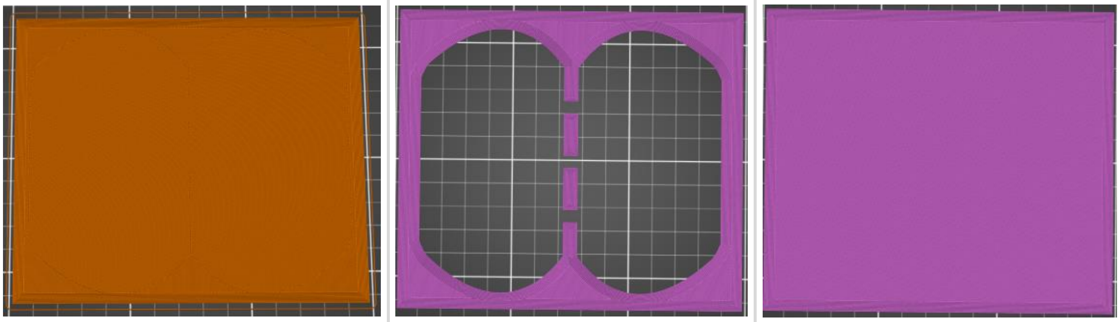


(a) (b) (c)

Figure 74 – Different Experiments of Balloons with Rigid Base

The printing from Figure 74 - a resulted in a considerably good print. It showed to be airtight, and the material adhesion was pretty good. In Figure 74 - b the deposition around the balloon's shape is poor being this a result of extremely high speeds when printing the rigid base (user error because increased the speed of the printing to 200%) creating higher and lower spots that in a layer height of 0.15 mm, affected the quality of the print which directly affected the flexible material deposition. The nozzle tangentially touches the part on the high spots created by the high speeds resulting in no deposition (red regions on the picture). This created a deficient adhesion between both materials. On the other hand, also on the top of this shape were verified a considerably high number of holes that were covered with glue and allowed an airtight piece (even with the low amount of material around the shape because the correct number of perimeters and the good thickness of the balloons' walls created a good adhesion with the base). Figure 74 – c presents a failed print of a similar shape to the one presented in Figure 74 - b but with some changes on the top. Those changes increased the weight of the material on the walls and created some warp that caused the nozzle to shock with them. After some restarts, the error continued to happen, and the printing was interrupted. On the same figure, it is possible to see the density infill, and some already broken connections that allow air to flow, as explained before. On the other hand, the regions around the balloons presented good quality. On every print, the thickness of the rigid base is 1.5 mm and the remaining square area was filled with flexible material to the height of around 2 mm.

Another shape that was tested is a completely flat one, on the rigid base printing and also on the flexible material printing. This shape was printed with a different combination of layers orders and layers heights. It was printed with the combinations Rigid-Flexible and Flexible-Rigid-Flexible, and the different layers profile is shown in Figure 75 with the respective heights example.



0 – 1.2 [mm]	1.3 – 1.6 [mm]	1.7 – 2.00 [mm]

Figure 75 – Heights Where the Profile Changes

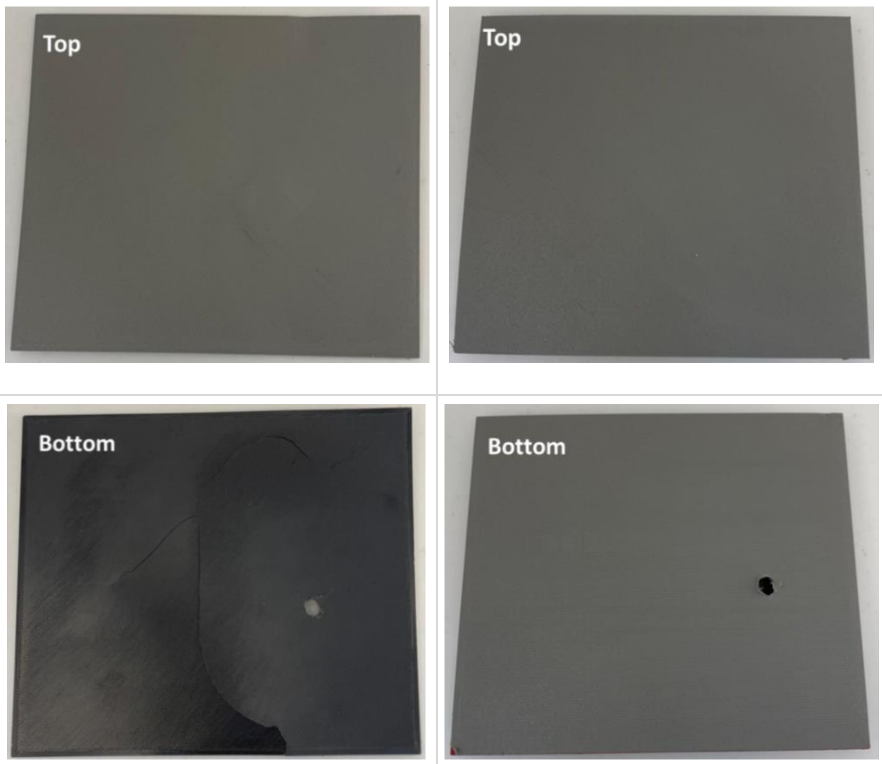
There were four trials:

1. Rigid material until 1.2 mm and the remaining printing with flexible one;
2. Rigid material until 1.6 mm and the remaining printing with flexible one;
3. Rigid Material until 1.4 mm and the remaining printing with flexible one;
4. Flexible material until 0.5 mm, rigid material until 1.6 mm and flexible material again till the end.

The combination number 4 had as purpose the creation of a flexible layer to give an extra strength as, during the test of trial 1, the rigid part broke under pressure (excessive pressure applied when inflating). (Figure 76)

Trial 4 besides presenting a good resistance when inflating, turns the assembly process harder as due to its higher friction doesn’t allow it to slide the part to the right position on the Main Back Portion, due to their tight fit. It also increases the printing time as 2 changes of filament are needed. (Figure 76)

Trials 2 and 3 were performed to check if there would be any improvement in material adhesion, which was verified on trial 2. By increasing the number of perimeters, was also verified a better adhesion mainly on the contour of the balloons on the inside squares of the profile. This combination is the one that is being now applied in combination with the structure of the final model.



Trial 1	Trial 4

Figure 76 – Top and Bottom View of Trial 1 and 4

Another particularity of the printing was the increase in the fan speed. This increase allowed the layers to dry faster and so, to prevent a good connection when the first layer after the materials change is being printed. This effect of low adhesion is necessary as the middle shape in Figure 75 (the shape that defines the balloons contours), creates a space between the bottom [0 – 1.4 mm] and top layers [1.4 – 2 mm] and by drying them faster, prevents from creating a greater connection. This allows for those opposite layers to be separated when the balloons get inflated, without affecting the remaining layers' adhesion, as verified. To help the balloons get the shape intended when inflated, a frame was designed and printed in PETG making the contour of it. (Figure 77) Like the balloons, this frame is also printed flat. When assembling, both are glued to each other.

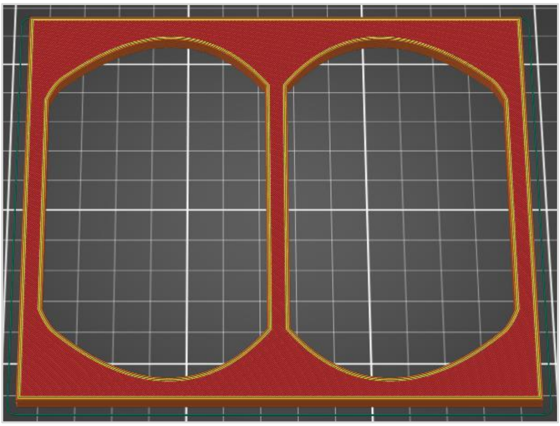


Figure 77 – Balloons' Contour Frame

Concerning the post-processing and assembly, as the Top of the Main Back Portion has a curved surface and the balloons and its frame present a flat one, these need to be moulded to that curved shape. When designed, in terms of dimensions both had in consideration the length of the curved line on the Main Back Portion between sliding guides, which allowed for the parts to get a tight fit. Then they are forced into position and heated with a heat gun and left with weights for about 12 hours to get accommodated to the shape. (Figure 78) As thermoplastics, both get the desired shape and then are glued. In Figure 78 it is also possible to see the balloons inflated.

	
Post-Processing	Balloons Inflated

Figure 78 – Post-Processing and Test of the Balloons

3.3 – Check Valve Development

Associated with the balloons and as they are meant to be filled with air, a hose line needs to be built. To reduce weight and yet allow the balloons to inflate whenever their pressure is not convenient for use, a system with a check valve was built. With this valve, the air pump doesn't need to be attached to the cervical collar and just be used whenever necessary.

There are check valves on the market that are relatively light and with low volume but since we had a 3D printer available a valve prototype was designed and produced. To produce the valve, PETG and Silicon were used. The silicon is moulded and then inserted inside the printing by stopping and restarting it at a certain point. Figure 79 shows a cut view of the valve as well as a representation of the circuit.

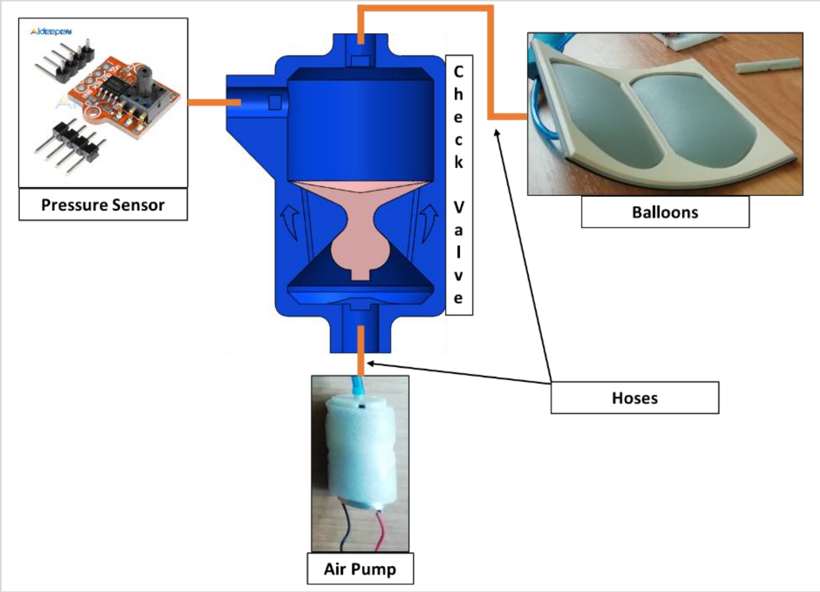


Figure 79 – Check Valve Cut View and Associated Circuit

Theoretically, the valve allows flow in one direction retaining the air on the opposite one and so, keeping pressure on the system. The air pump introduces air in the system that flows through 1 mm^2 holes, and by bending the ends of the circular silicon cover, fills the Balloons. The pressure is read by the pressure sensor and when the maximum value is achieved (or value desired), the air pump is turned off and the silicon cover covers the holes preventing the air from leaking. The spheric section on the bottom of the silicon part, with the thinner section of the check valve body in the middle of the cover, allows for the silicon part to be stuck in the right position.

For producing the silicon, a mould was 3D printed. Then, by using clamps for securing and compressing the mould, the silicon is injected. Several shapes were tested for this part, mainly varying the thickness of the circular cover. On the left of Figure 80 is presented a mould with the silicon part produced and on the right is a photo of the procedure.

As for printing the valve body, its position was the same as shown in Figure 79 (upstanding position/vertical) and was used printing supports on the bottom of the valve, but never inside as the body was designed having in consideration the no need for supports on the remaining regions.

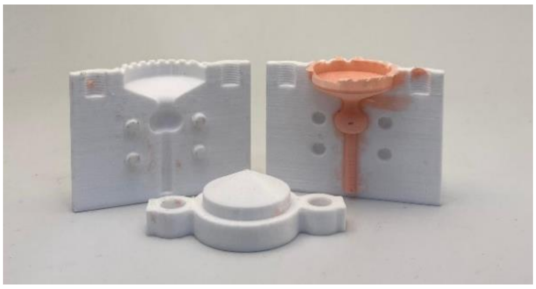
	
Mould	Procedure

Figure 80 – Mould and Procedure for Producing the Silicon Cover

After connecting all the hoses to the valve and the remaining parts, a simple test was made to check if the system was airtight. To assess that, the pressure sensor was connected to a testing PCB and the graphic curves for pressure were acquired and analysed. Figure 81 shows the graphic Pressure-Time without calibrated values of pressure [Pa] (the reason why the pressure values are negative), just to assess the airtightness of the system over time [seconds]. As it is possible to see, there are a lot of regions like the one signalled with the tag “Pressure drops”. This behaviour of the curve represents pressure drops and match leaks. The graphic curves of small oscillations match the interactions made on the balloons by applying forces on them, increasing and decreasing the pressure inside. The higher increases in pressure represent air inflates returning the pressure to its maximum values. The constant pressure verified is the result intended for this system and represents airtightness.

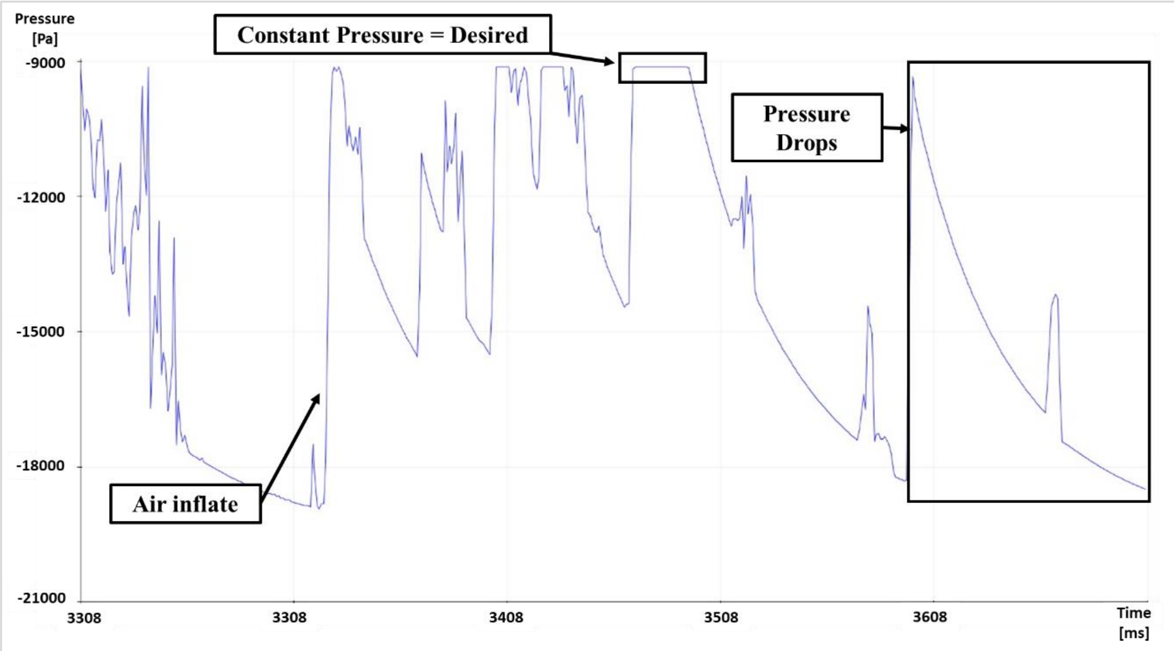


Figure 81 – Pressure Sensor Graphic Curves

After this test, it was determined that there was a leak on some component which, after visual inspection, was verified on a broken hose that was replaced. Repeating the process, the leak was still present so, to check the valve and balloons airtightness, some water diving experiments were performed. (Figure 82 - left) If the body presented bubbles when inflated, it would represent air leaks. During this test, the balloons showed to be airtight, on the other hand, the check valve presented numerous leaks. Trying to solve this problem, 10 layers of a waterproof gel coat were applied, but even after that, the leak remained despite being in a smaller amount (Figure 82 - Right).

	
Water test	Leak bubble

Figure 82 – Watertightness Test of the Valve

As the problem remained and because the printing quality of the valve was very low due to the printing parameters (high speeds mainly), the decision to re-print this part was taken. Concerning the design of the valve, the bottom part that needed support on the first version is now redesigned which resulted in a printing without supports. The results showed an airtight system during a small period tested (around 5 to 10 minutes). These results don't mean that the balloons are airtight in long testing periods.

3.4 – Electronic Systems

The electronic system was developed during the mobility at PSU, in Russia. At this institution, several decisions were taken concerning the different methods for measuring the proposed parameters, the pressure exerted on the head, and the respiratory monitoring system. There were also discussed other needs of this application such as the type of power supply, the device where the data should be sent, PCB's size and shape requirements, and the number of connectors, for example.

3.4.1 – Pressure Measuring System

The first steps in the direction of implementing a Pressure Measuring System for assessing the fastening efforts that are being applied to the patient's head were discussed two possible methods. The first, and most obvious, through the use of a Load Cell, and the second and implemented solution, through a Closed Pressurised System.

The Load Cells are commonly used elements to measure weights or efforts exerted on a certain point or region. These are devices usually made from metal materials, such as steel or aluminium (materials that are very strong but also present ability for deformation, despite minimal, due to the elastic properties), that constitute the body, and present strain gauges attached to them, that due to their composition are the measuring component. Figure 83 shows the purchased Load Cell ready for connection with the PCB.

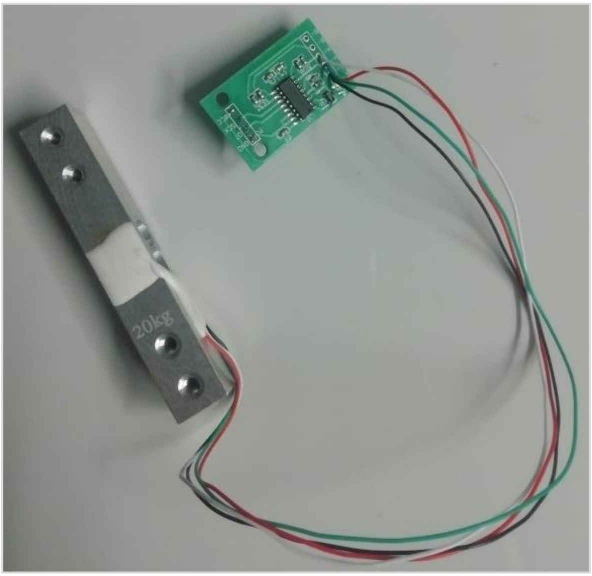


Figure 83 – Load Cell Ready for Connection with a PCB

The Strain Gauges (Figure 84) are sensors made of conductive material that measures electrical resistance variations according to the strain that it is being subjected. The strain is a deformation of a material and here is where the metal body enters in the equation. The Strain Gauge is glued to the Metal Body that by suffering any loads will deform consequently deforming the glued sensor which results in variations in the electrical resistance. These variations, with the Metal Body properties (shape, length, profile, etc) as well as the sensor ones (as its sensitivity, dimensions, resistance, etc), can be gathered and processed for assessing the load applied.

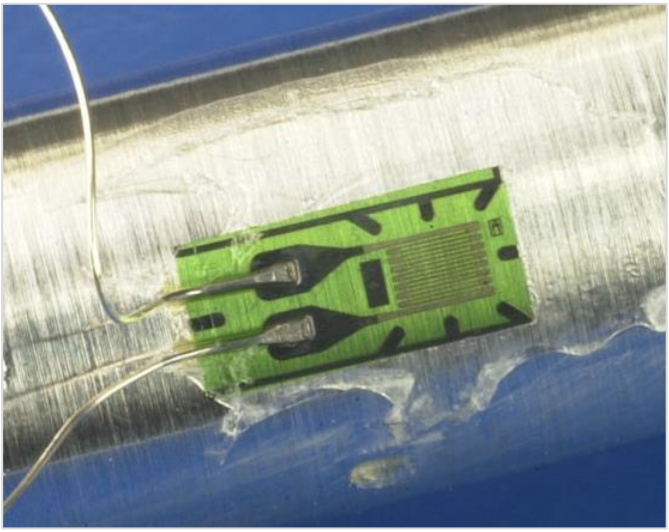


Figure 84 – Strain Gauge applied. Adapted from Strain *(n.d.)*

As the Load Cells are associated with hard components, it isn't the best solution for this application as the purpose is to assess the pressure on the back of the head which has as a requirement soft and comfortable padding. It could also be applied foam layers between the head and the different components used for applying the Load Cell, but the measurements would be immediately affected. Since there was an alternative solution, its pros and cons were assessed to determine which one is the best for the purpose.

The body used for the Closed Pressurised System is described in subchapter 3.2, under the name of Balloons. This solution, in contrast to the load cell, presents soft and comfortable padding for the head.

Subchapter 3.3, which complements the explained in subchapter 3.2, completes the Closed Pressurised System with the Check Valve, the Pressure Sensor, and the Air Pump.

Air/Water Pressure Sensors have a similar working principle to the one verified on the Load Cell as both have piezoresistive elements as measuring components. But, in this case, the Pressure Sensor presents a diaphragm (Figure 85) that is deformed when there is pressure applied on it. The diaphragm is connected with those piezoresistive elements that, by measuring the different resistance variations, allow to assess the pressure values applied through data processing in the microcontrollers or processor elements.

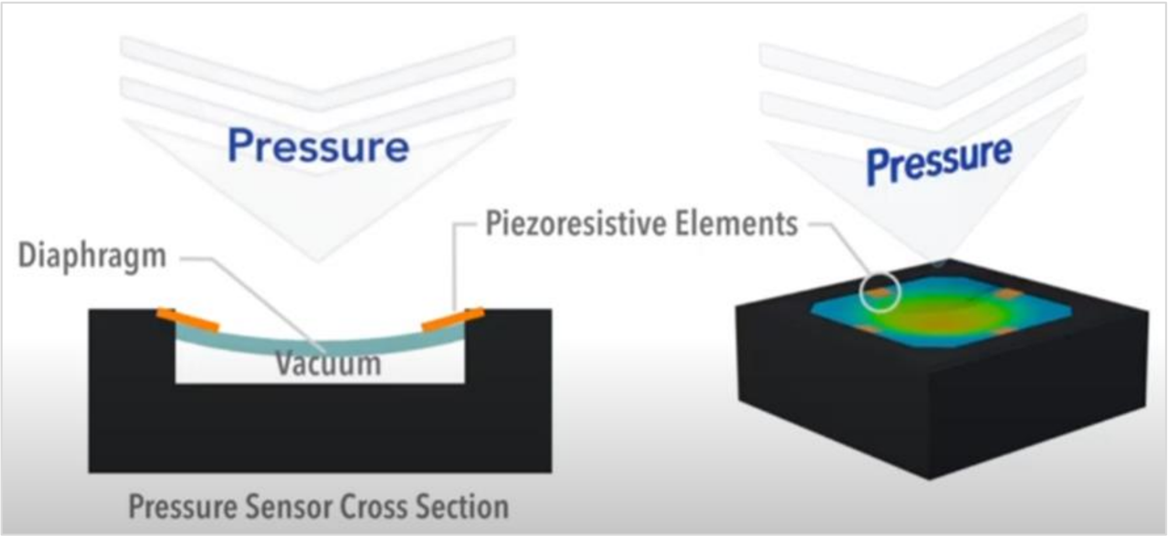


Figure 85 – Diaphragm deformed due to applied pressure. Adapted from *ALPS (2020)*

As this is a reliable method and the results achieved with the Balloons are very good, this is the solution for assessing the fastening pressure of the structure.

3.4.2 – The Respiratory Rate Monitoring System

For the Respiratory Rate Monitoring System, the search indicated contact and non-contact-based methods. Since the cervical orthosis is a device applied on the head region, the method intended to assess the respiratory rate should be on the head or top of the chest region because, independently of the choice, the sensors, or devices necessary to perform the monitoring, must be connected to the PCB either to get an energy supply from the same battery or to send the data acquired. Wireless solutions are possible but increase the price of the prototype a lot.

For the non-contact-based techniques, Al-Naji *et al.* (2017) summarised different possible methods for measuring the respiratory rate and displayed it on a figure. The figure was adapted to this document and labelled as Figure 86.

Influencing challenges		Doppler Effect based methods		Thermal Imaging based methods	Camera Imaging based methods	
		Electromagnetic Radar	LDV		Color	Motion
Noise artifacts immunity	Motion artifacts	*	*	**	***	**
	Ambient enviro.	*****	****	****	**	****
Subject movement immunity		*	*	**	***	**
ROIs		*	*	**	***	***
Multiple subject		*	*	*	**	**
Detecting range		***	***	*	*	*
Active/Passive		A	A	P	P	P
Biological effects		*****	**	*	*	*
Cost		***	****	****	*	*
Short*/Long***** term		*	**	****	*****	*****

Figure 86 – Non-Contact-Based Methods for Measuring Respiratory Rate. Adapted from *Al-Naji et al. (2017)*

Either due to the method's price (Doppler Effect and Thermal Imaging) or due to the conditions required to practice certain methods (Camera Imaging - where a camera and patient filming is required), these methods were discarded from the beginning. The Korean patent from Lee *et al*. (2011), mentioned a Doppler Effect method for measuring the heart and breathing activity of a patient but the equipment and how the method is applied wasn't specified.

Massaroni *et al*. (2019) published a review about contact-based methods for measuring respiratory rate. In that review, the author summarises the different methods and displays them on a figure. That figure was adapted to this document and labelled as Figure 87.

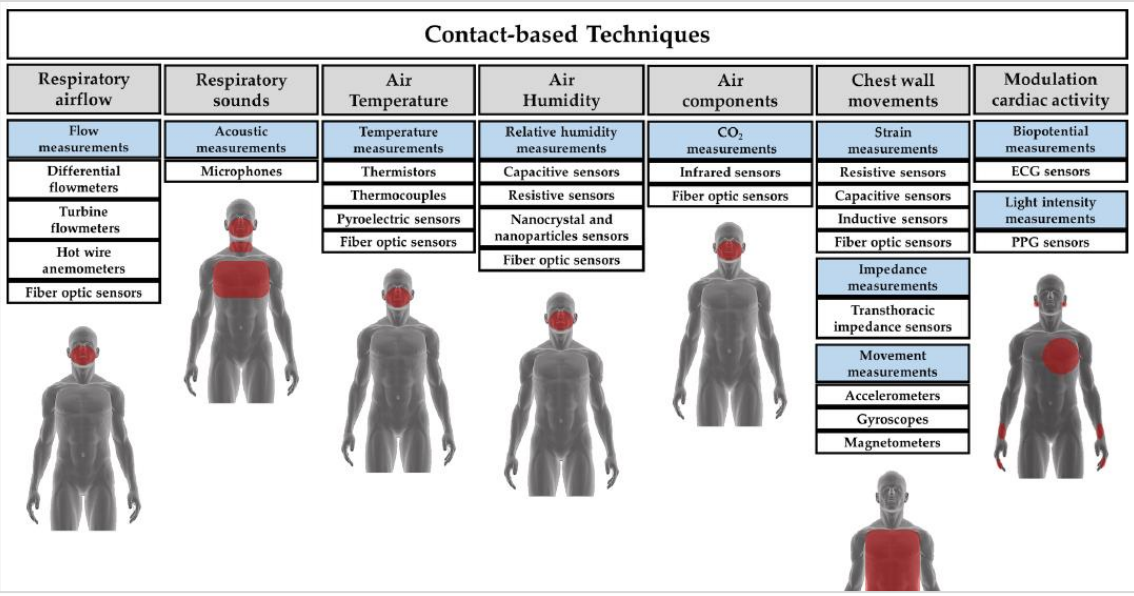


Figure 87 – Contact-Based Techniques for Measuring Respiratory Rate. Adapted from *Massaroni et al. (2019)*

Almost every method is compatible with the location required. On the other hand, the ones that interfere with the mouth region were excluded because in some of the protocols for approaching and treating the victim masks are used for oxygenation and any device on that region could affect that process. As a result, the method considered to be the most suitable, was the acoustic one, with microphones. According to the same author, there are some adhesive sensors that can stick to the skin and be used to measure these respiratory sounds. These stickers and respective wires would result in a simple and easy application in combination with the cervical collar.

Despite being a possible and cheap solution, the microphones present poor performance due to environmental factors and patient movement. According to Corbishley & Rodriguez-Villegas (2008), these effects can be reduced by an aluminium conical bell. These authors developed an acoustic-based method for breathing monitoring through a miniaturised, wearable, battery-operated device (microphone included). There, a study where the respiratory signal is monitored in the presence of noises and interference artefacts. Based on the results of the experience it is shown a developed algorithm that allows an average success rate of 91.3% (only five subjects were monitored).

The aluminium conical bell used to amplify the signal and prevent environmental artefacts was the conical bell from a stethoscope. Tests were performed and it was possible to get a curve for the respiration, but the signal cleaning algorithm was too complex and there was no available time (due to COVID limitations) to finish it. For stronger processing power as any algorithm for cleaning the signal and process it is technologically heavy, a server was programmed to receive the data and to process it (part missing) on a computer or device with high processing power re-sending the processed data to the smartphone connected via Bluetooth to the PCB.

3.4.3 – The Printed Circuit Board (PCB)

To connect all the different systems and send the data for an external device (the one that will assist the emergency staff), a PCB needed to be developed. According to the application intended for this device, the microcontroller selected (the most important part of the PCB) was the ESP 32 from the company ESPRESSIF. This microcontroller is adequate for mobile devices or wearable electronics, due to its low power consumption, also having Bluetooth and Wi-Fi functionalities which are ideal for sending data to external devices.

The firmware code of the device is developed with *ARDUINO* software.

Figure 88 shows the PCB sketch with the respective electronic components needed for the project.

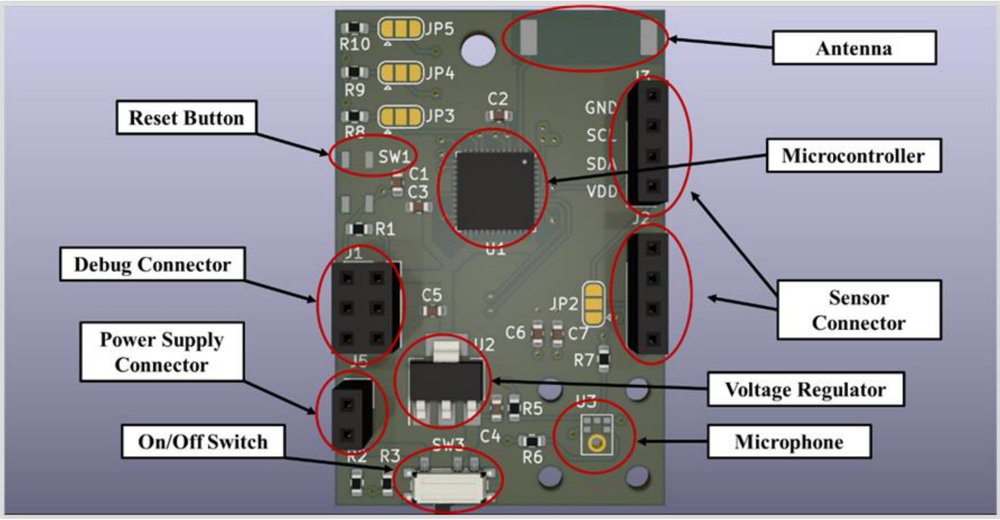


Figure 88 – NeProS's PCB – 3D Model

The different components signalled in figure 88 are now described with their respective function or characteristic:

- Reset Button – used to Reset the entire system of the PCB. This causes the device to clean the memory and reboot;
- Debug Connector – allows to connect to a computer or compatible external device to correct bugs or errors found on the firmware code during testing;
- Power Supply Connector – where the battery is connected to power the device;
- On/Off Switch – switch to turn On or Off the device when connected to a power supply;
- Microphone – component used for the Respiratory Rate Monitoring System;
- Voltage Regulator – essential to keep the voltages inside the range tolerated by the device;
- Sensor Connectors – to implement other sensors on the system (like the pressure sensor, because it is an external sensor);
- Microcontroller – essential to control the different circuit tasks (to process and as a memory, for example);
- Antenna – to provide a method for wireless communication.

Between the different power supply options available, and since the PCB works on a power of 3.3V (power requirements from the microcontroller) controlled by the voltage regulator, the solution applied to the system was a 9V rechargeable battery. The difference in voltage on the system is converted to heat by the regulator. This is the most compact among the rechargeable batteries, which for a portable device is an advantage. A solution with a power bank, that already has an integrated recharge system, was also considered but this option is too big and heavy for the application. When the battery doesn't provide enough power, it should be removed and recharged on a compatible charger. Developing a recharge circuit was excluded due to several risks associated, like fire or explosion.

Even more compact batteries can be used, but those are disposable. This increases the cost during the life of the equipment and represents unnecessary waste of resources.

3.4.4 – The Interface

As for displaying the different readings of the PCB, an interface for the user must be available. That interface was developed with the *MIT App Inventor*. This is a simple software for creating apps with the benefit that it is clear and easy for those who are new to the subject. Instead of developing a series of code lines, this software facilitates that task by giving already semi-coded boxes (puzzle pieces) with functions. The app creation functions like a puzzle and the predefined conditions on each piece have more than one piece of logic "answers" for forming the code sequence. Those sequences are simple to build in this software because the piece that comes after the first one, will present the shape for that contour space. Figure 89 shows a short sample of the code for this project app, and figure 90 shows an example from the available library of conditions explaining the easiness of forming sequences due to the compatibility of shapes.

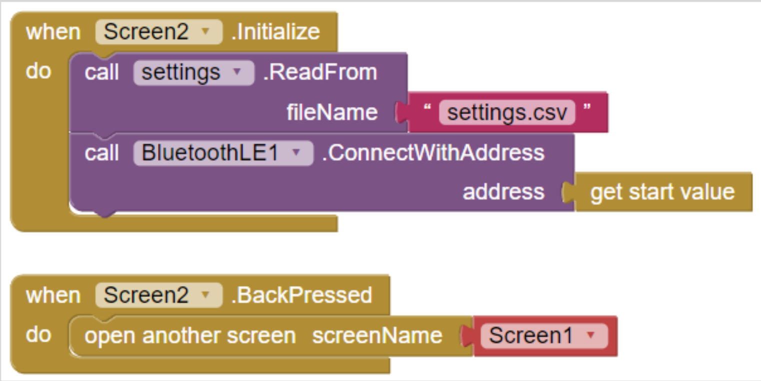


Figure 89 – NeProS's Code/Puzzle Sample

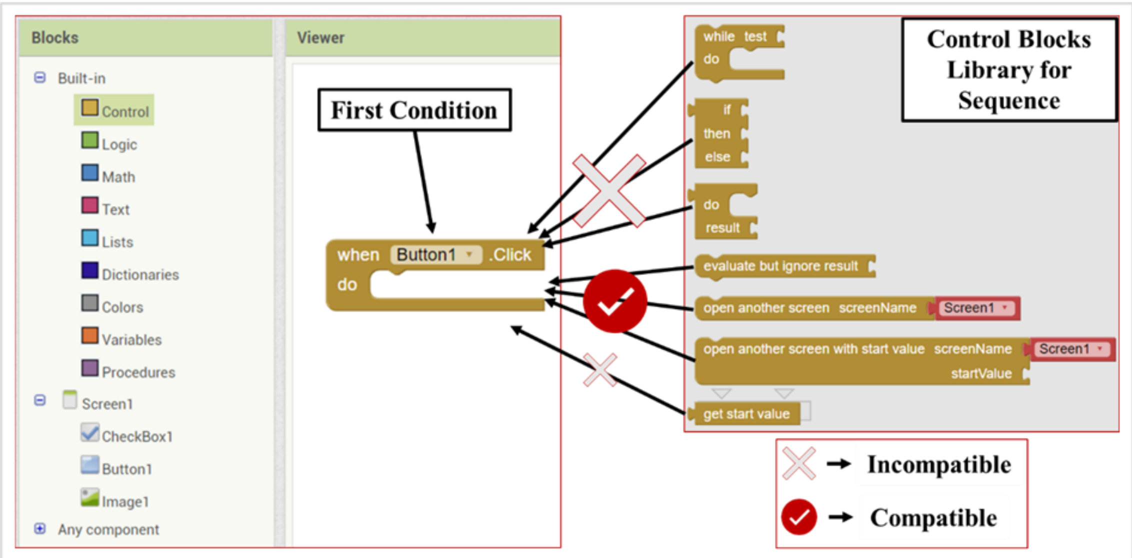


Figure 90 – Example of how Sequence Compositions are Made

Besides the code, the interface design itself is easy for newbies to the art as the software has a vast library of predefined conditions that just needs to be dragged to a phone image as in figure 91. These predefined conditions, in this case, must be completed in terms of their properties (colours, size, text, for example).

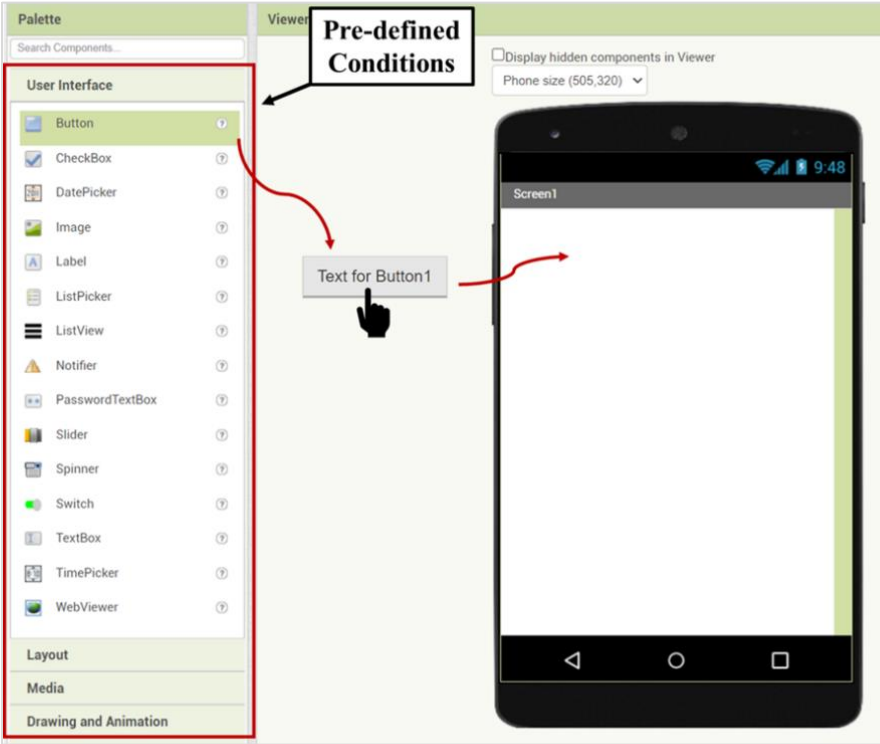


Figure 91 – Interface Design with *MIT App Inventor*

3.4.5 – Using the Interface

Starting the app on an android phone, the first screen shows a variety of information related to the connection with the device. As can be seen in figure 92, the app describes the several steps to establish the connection and presents two interactive buttons labelled "Scan" and "Connect" for that. The button "Scan" begins the search for Bluetooth devices in the area and after selecting the intended one for connecting, pressing the button "Connect" starts the values reading.

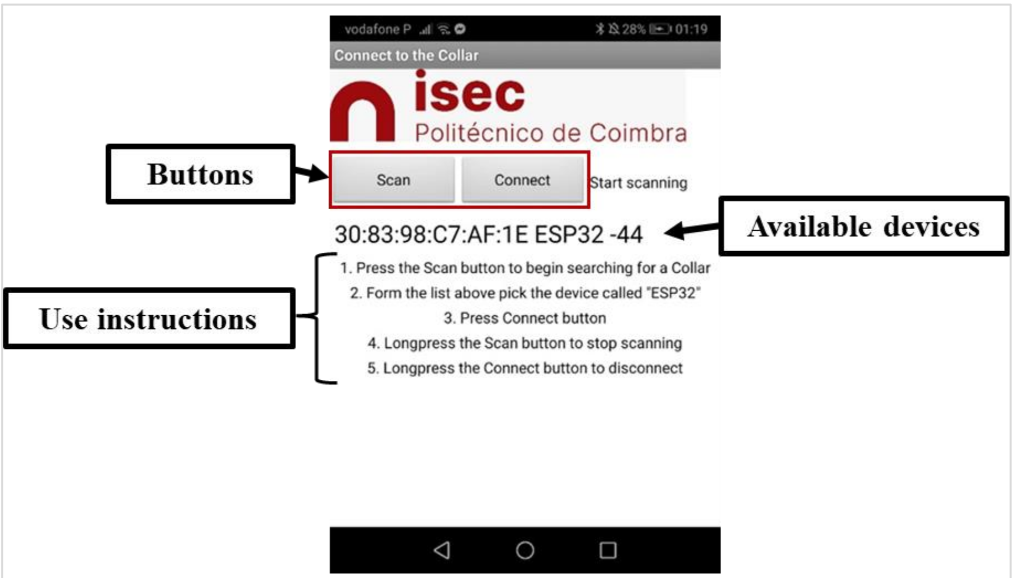


Figure 92 – NeProS' App Starting Screen (After Pressing the Scan Button)

Once on the second screen of the app (Figure 93), right after pressing the "Connect" button, it is possible to see an image with the front view of NeProS with the balloon's region in green colour. When a certain pressure value exceeds the value defined as dangerous for the patient, the green region becomes red and that's the sign of alert for the emergency staff. Below the NeProS' image, there is also a Pressure/Time chart for the monitoring of curve behaviour, like on the tests performed to check if the system is airtight, precisely to check if there is any leakage on the system when the collar is filled with air but without any effort on it. Yet on the second screen, there is a "Pressure Value" text box mentioning the pressure that is being applied at the moment for guidance. Below the mentioned features was placed a "Settings" button to access a third screen.

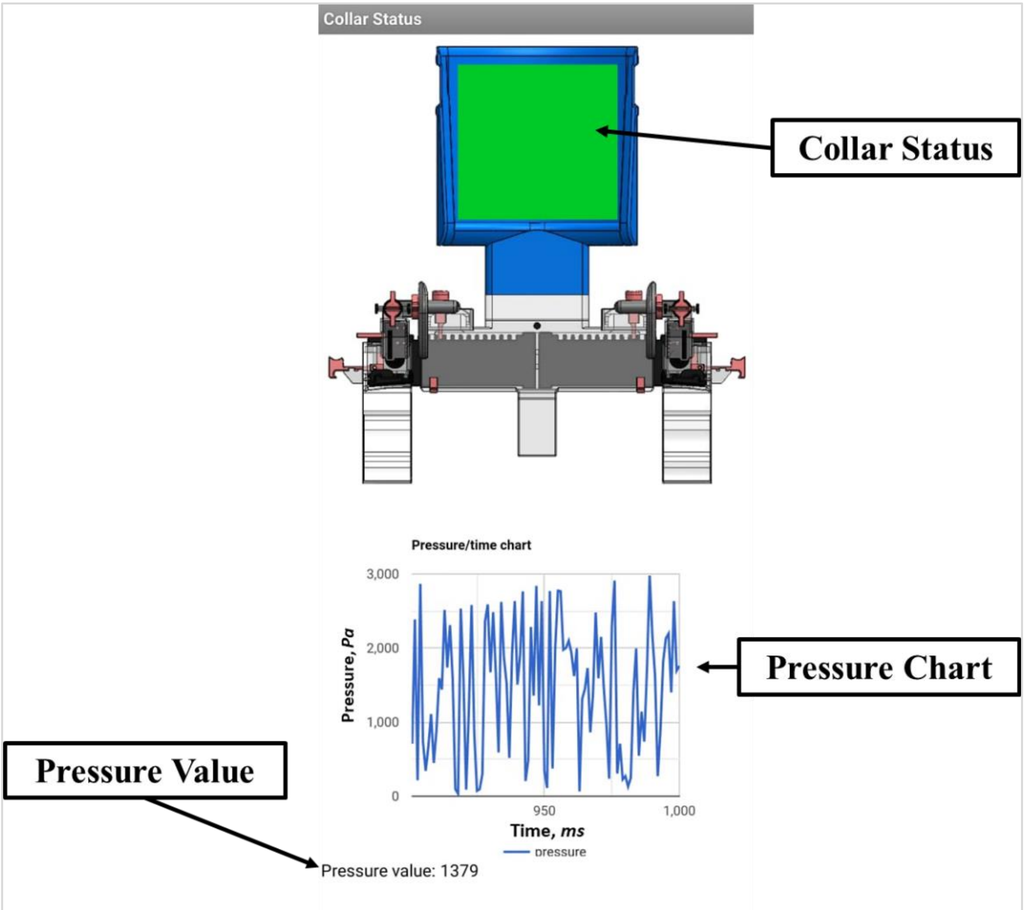


Figure 93 – App's Second Screen

In the settings menu are two options, one for setting threshold values, where the 30% increase over the head's weight should be defined for each patient, and one for updating the device firmware. The one "Set Threshold Values" opens another screen where a new pressure limit value is manually defined.

After immobilising the patient and due to its head weight, it causes an effort input on the pressure system increasing the pressure value. When the topic is related to prolonged applications (several days or weeks), like when a patient is confined to bed with low movements and usually in decubitus position, according to Daley & Bhat (2020) the pressure ulcers occur when the pressure exceeds capillary closing pressure (from 3.3 to 4.26 kPa). As in emergency immobilisation cases the time of exposure varies from a few minutes to a couple of hours, the same reference values cannot be used, and a medical study should be realised to assess the pressure line that separates healthy from harmful values. Other factors that may favour the creation of pressure ulcers are shearing forces or constant exposure to high moisture percentages.

The option suggested meanwhile is to apply pressure 30% above the value read when the head is settled above the balloons. This is only a testing strategy and doesn't have any medical reference.

The "Firmware Update" button will allow for the device to be updated. This process is usually performed when there is any change on the app code or to fix errors or bugs from the PCB own management code.

3.4.6 – Integration of the PCB in the Structure

The PCB was developed after the mechanical component of the project, so its integration is post-production of the prototype. Despite having a defined region for positioning the PCB, its dimensions were unknown which makes it reasonable for a post-production integration. Now that the dimensions are known, 45 mm of length, 30 mm of width, and around 15 mm of thickness with the sensor connectors and the pressure sensor connected (around 5 mm without any connector or adapter), the adapter for its integration will be designed and produced. (Figure 94)

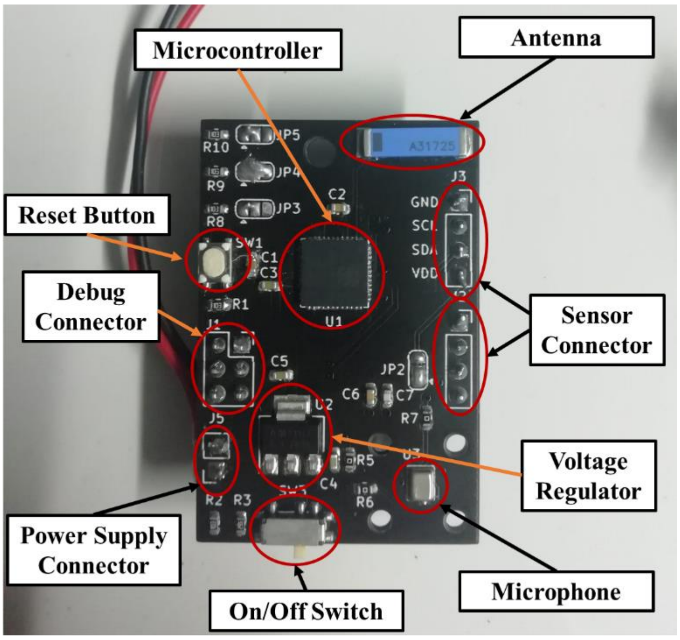


Figure 94 – NeProS' PCB

After the acquisition of the assembled PCB, the adapter was printed and meant to connect it to the back of the Back Portion of the Collar as displayed in Figure 95. This adapter is meant to be glued on the Back Portion and the PCB bolted on it.

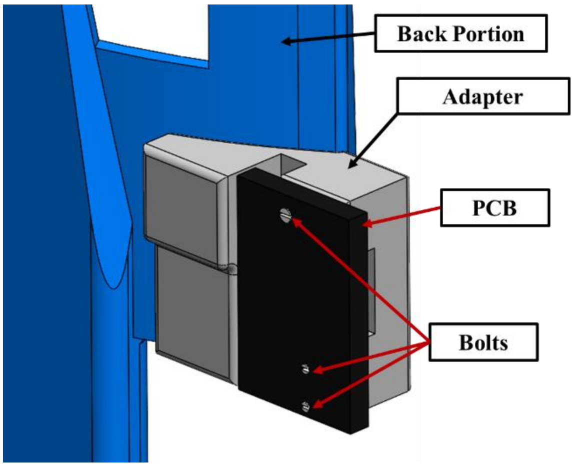
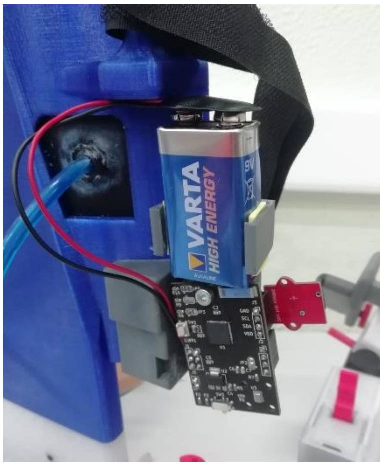
	
3D model of the Assembly	Real Model

Figure 95 – Integration of the PCB on NeProS

The final position of the PCB is located at around 71.54 mm from the centre line of the structure. According to Knowing (2017), the highest head circumference value is around 165 mm which means that the PCB location affects around 10.96 mm of the patient's radiologic imaging exams. Despite being affected with metal components in a considerable area, it is far from the centre line that is the most important region to evaluate in the case of vertebral column injury. (Figure 96)

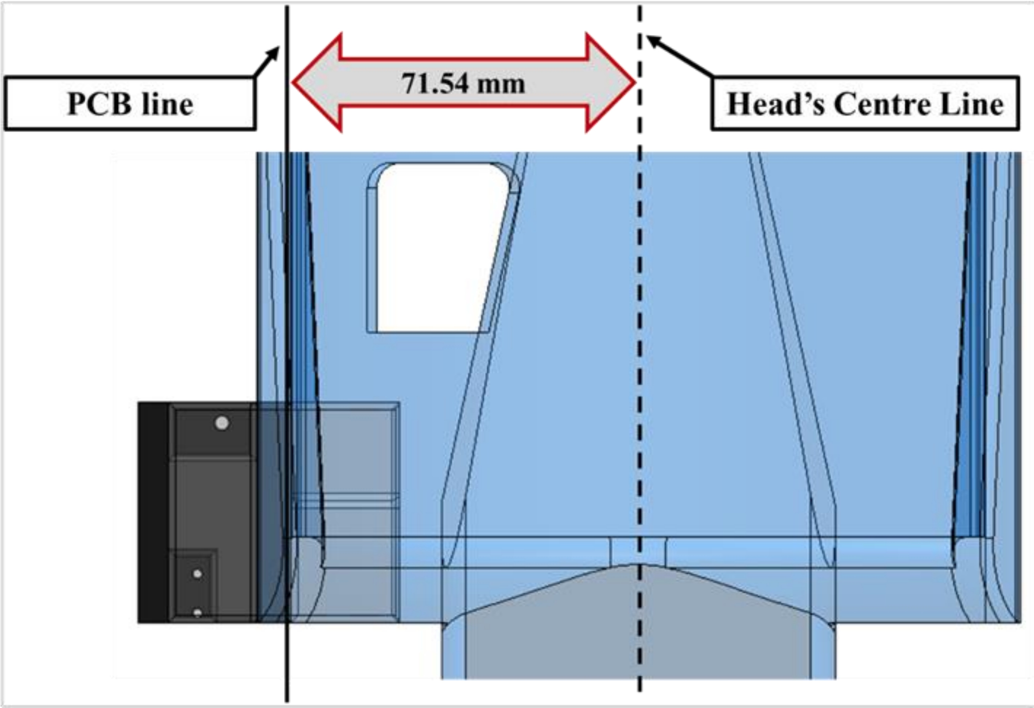


Figure 96 – Position of the PCB in Relation with the Patient's Head

Despite the battery being subjected to possible changes to meet medical requirements and compatibilities, a small support was also created on the top of the PCB position. This way, the prototype doesn't present any loose electronic components.

4. Materials, Estimated Cost, Time, and Type of Production

Nowadays, for prototyping, 3D Printing is the first option that comes to mind in every industry. This principle and its development in recent years, allowed us to apply this type of production to low and medium volume productions as it turned out to be profitable and a cheaper option within its pros and cons. The choice for this type of production is shown and justified in the present chapter where the overall process (not specific 3D printing processes) is compared to conventional ones concerning the capability of producing certain shapes, its volume and cost, lead time, and compatible materials inside the plastic groups of material.

4.1 – Type of Production

In the industry, to produce a part (or a group of parts) using plastic materials, the right manufacturing process should be studied and selected according to the necessities to turn its production into the most profitable possible and fulfil schedule requirements. On the other hand, the first approach that should be made is to understand the type of production that best fulfils the shape requirement, once more complex shapes may exclude certain processes that wouldn't offer the quality or even be possible to produce them. In summary, the factors that should condition the type of production selection are: (*Guide*, n.d)

- Shape – The higher complexity of a part, namely its interior features, limits the manufacturing process choice. Some of those that are excluded can be adapted for producing complex internal features but will affect the process concerning the economical field;
- Volume/Cost – The annual volume of parts planned for production is the question to be answered as there are processes that present high start-up costs that can be considered inexpensive on the annual per-part level, or processes that present low start-up costs but almost don't benefit when the volume of production increases;
- Lead Time – In this case, the question is: How fast does the company or the client need the parts? To meet schedules and production goals, the factories should have into consideration that some manufacturing processes take no longer than 24 hours to produce some parts, as well as there are some processes that just by preparing specific tools or moulds might take from weeks to several months;
- Material – The balance between cost, functionality and aesthetics should be achieved while these are inserted in the several available manufacturing processes.

Figure 97 displays the different manufacturing processes for plastics and its Volume-Cost per part relation. It is easily distinguishable that for lower volume productions 3D Printing represents the most economical solution.

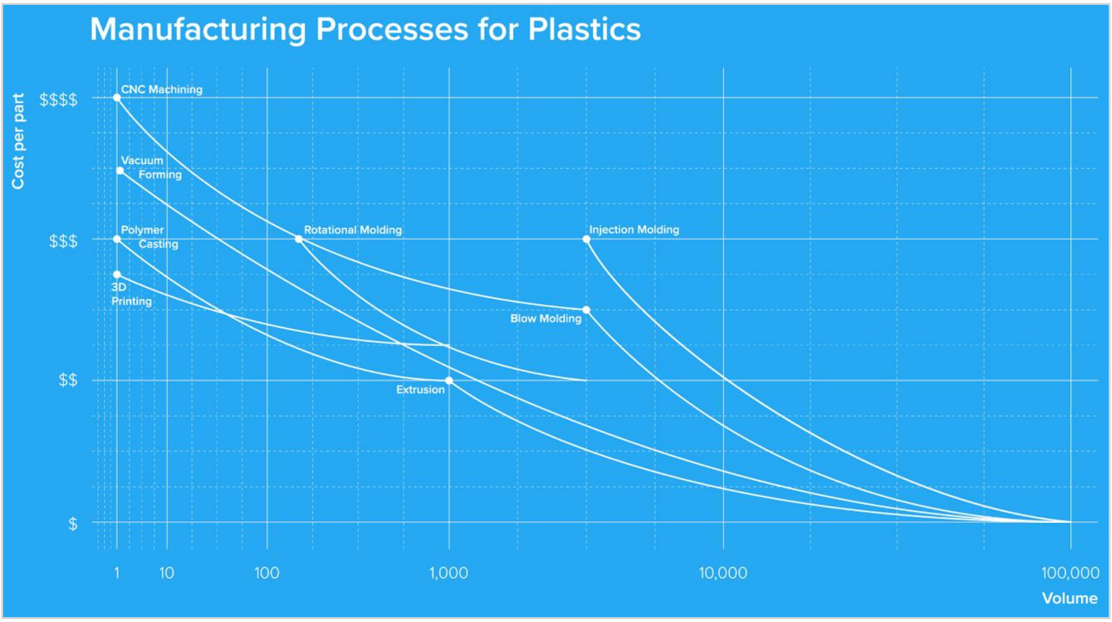


Figure 97 – Volume$_x$Cost per Part Graphic for Different Manufacturing Processes. Adapted from *Guide (n.d.)*

To better distinguish these processes, are now presented the materials' restriction of each method having in consideration that the two main groups of plastic commonly used are Thermoplastics and Thermosetting Plastics. Both need heat to conform them, and the major difference between both is that on the second one, the curing process and the bonds created are irreversible. Even in the presence of a heat source, the material will decompose instead of melt which makes it impossible to recycle and reuse. (*Guide*, n.d)

The ideal materials for the project are thermoplastics as these are widely offered on the market as filament or pellets which are easier to use in a non-industrial environment and are possible to recycle and reuse. This second factor is important as due to the iterative designing process, until achieving a final prototype, some material will be wasted, and some parts will present errors. Those resultant parts can be melted and re-used, resulting in an economic design cycle.

The different manufacturing processes and compatible materials are (*Guide*, n.d)*:*

- 3D Printing – Depends on the technology selected but Thermoplastics are commonly used;
- CNC Machining – Compatible with every Plastic. Might need specialised tools for softer plastics;
- Polymer Casting – Thermoset plastics are the most common materials used. Thermoplastics are also compatible;
- Rotational Moulding – Polyethylene (Thermoplastic) is the most used material. Other Thermoplastics are compatible;
- Vacuum Forming – Most Thermoplastics are compatible;
- Injection Moulding – Most Thermoplastics are compatible;
- Extrusion – Most Thermoplastics are compatible;
- Blow Moulding – Most Thermoplastics are compatible.

According to these material restrictions of each process, it's possible to exclude some of them as on the project thermoplastics will be used as material.

Figure 98 shows the remaining relations of volume, cost (quantitative), lead time (consists of waiting, setup, real operating, and post-processing time) of each type of production, degree of freedom concerning the shape complexity (high degrees are compatible with complex shapes).

Manufacturing Process	Volume (parts)	Setup Cost	Cost per Part	Lead Time	Degree of Freedom
3D Printing	~1-1000	€	€€€	< 24 hours	High
CNC Machining	~1-5000	€€	€€€€	< 24 hours	Medium
Polymer Casting	~1-1000	€	€€	< 24 hours to a few days	High
Rotational Moulding	~200-5000	€€€	€€	Days to a few weeks	Medium
Vacuum Forming	Any Volume	€-€€€€	€-€€€	<24 hours to weeks	Low[1]
Injection Moulding	5000+	€€€€€	€	2 to 4 months	Medium to High
Extrusion	1000+	€€€	€	Weeks	Low[2]
Blow Moulding	5000+	€€€€	€	Weeks	Low[3]

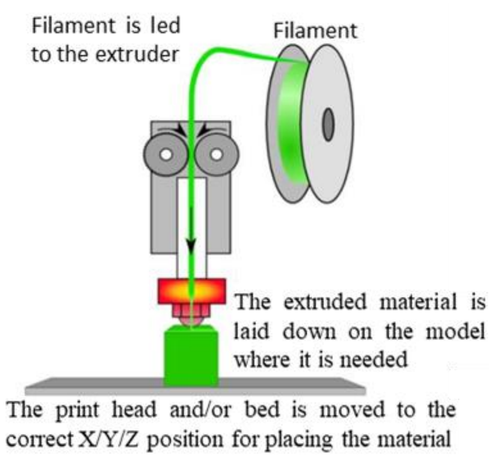
Figure 98 – Comparison Between Plastic Manufacturing Processes. Adapted from *Guide (n.d.)*

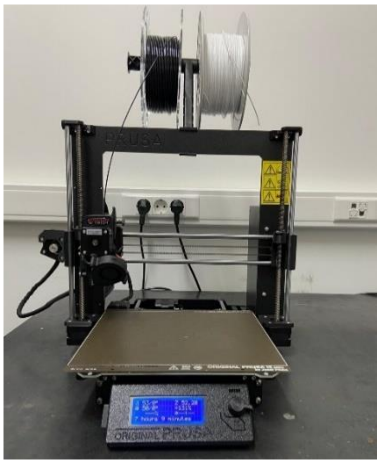
Note: 1 – Only thin-wall parts and no complex geometries. 2- Only long continuous shapes. 3- Only hollow, thin-walled shapes with no complex geometries.

Relating the data presented in Figure 97 and 98, 3D Printing is shown as the most adequate method as the compatibility with a low volume of production, its ability to extend to a medium volume of production, the low setup cost and the versatility concerning the complexity of the shapes are some of the most important factors when prototyping. The speed offered by the method is also a plus.

3D printing is an Additive Manufacturing process that has been widely developed in recent years being now compatible with any kind of materials like metal, ceramics, and thermoplastics as examples. Several technologies vary on how the layers are connected and deposited, but the technology that is used in this project is the fused filament fabrication (FFF) and the equipment used is a PRUSA i3 MK3S+ (*Original*, n.d.)

Fused Filament Fabrication is the most recent term for the process known as Fused Deposition Modelling (FDM). The printing principle is the same consisting of a Filament of material (solid) that is pulled through a feeding mechanism that step by step will introduce material towards the Extruder where the Nozzle is. The Nozzle is a small metal piece (usually brass) that ensures the diameter of the material that flows through. This dimension is ensured because the Nozzle is surrounded by a Heating Element and by achieving high temperatures (MAX ~ 250ºC) on the extruder, allows it to melt the material that is flowing, and so, to control the amount that is being deposited. As the material flows, the deposition is made on an XYZ coordinate system being deposited on the printer bed where the extruder passes through. In the case of the printer used, the extruder moves in the XZ direction and the printer bed in the Y direction. The deposition is made by layers that can be increased in height (Z=0.05; 0.10; 0.15 [mm] for example) and the different parameters changed when printing the project were already mentioned as examples in Chapter 3.2.





FFF 3D Printing Basic Components Adapted from kantaros & Dimitrios (2021)	PRUSA I3 MK3S+

Figure 99 – FFF 3D Printing Basic Components and PRUSA I3 MK3S+

4.2 – NeProS' Materials, Time, and Estimated Cost of Production

The materials used for producing some parts of NeProS have already been described in Chapter 3.2. From a variety of possible thermoplastics, the most used are Acrylonitrile Butadiene Styrene (ABS) and Polylactic Acid (PLA). Besides these materials there is also Polyethylene Terephthalate Glycol (PETG) that presents a balance between flexibility and strength, turning it greater for applications where less rigidity is intended, having higher resistance than ABS and PLA (which would break under flexion). The PLA being a cheap material and presenting similar considerable strength, is a good option for locking teeth. Also, since it is easy to print, it is a better material to get the desired dimensions and tolerances. As this model is just a prototype, the tests will define other material requirements in the case of failure.

Figure 100 shows the different groups of parts according to the colour or its designation on Appendix H – Final Prototype, and the material used for it. The materials were chosen according to their predicted necessity of being more or less flexible for testing purposes. As for production there is still needed topology optimization and finite element studies.

About the production time, it is presented individually in Figure 100, describing the time taken for printing supports, the part itself and an approximate time for post-processing. These times are calculated on the printer's software and the parameters considered were the standard ones (standard speed for each material, 0.15mm of layer height, 15% of density and a 0.4 mm nozzle). Changing the parameters like described in Chapter 3.2, each print would take longer.

Group of Parts	**Material Used**	**Printing Time** [h:min]			**Weight** [g]	
		Supports	**Parts**	**Post-Processing**	**Parts**	**Supports**
Grey Parts (Varied)	PETG	00:06	06:53	00:02	53	0.44
Black Parts (Varied)	PETG	00:10	06:30	00:06	42.25	0.56
Transparent Parts (Varied)	PETG	00:15	05:56	00:12	37.07	1.15
Lower Main Back Portion and Covers (Transparent)	PETG	00:22	06:44	00:12	76.77	1.95
Top Main Back Portion (Transparent)	PETG	01:27	14:06	00:01	113.35	9.89
Shoulder Supports and Covers (Transparent)	PETG	01:22	11:25	00:15	96.79	9.43
Balloons Frame (Any Colour)	PETG	00:00	01:28	00:00	16.33	0
Check Valve (Any Colour)	PETG	00:00	02:16	00:00	17.82	0
Sliding Element (Black)	PLA Tough	00:00	13:30	00:01	104.28	0
Black Parts_2 (Varied)	PLA Tough	00:01	01:02	00:01	4.76	0.4
Red Parts (Varied)	PLA	00:16	05:38	00:04	29.89	1.04
Balloons	PETG	00:00	02:03	00:00	43.65	0
	TPU	00:00	01:03	00:00	12.74	0
Chin Attachment	TPU	00:00	01:23	00:00	15.56	0

Figure 100 – Material Used, Printing Time and Estimated Weight for Producing the Collar

It is also presented in Figure 100 the used material weight on each group of parts. The total weight of the mechanical structure without electronics is around 664.26g and the material waste (supports) is 24.86g. The materials cost presented in the following lines has market values reference for a private user and not for an entity or industry.

Having the printing time, the amount of material used and the market prices for the private consumer energy (€/kWh) it is possible to estimate the price to produce the prototype's structure. The cost of PETG and PLA filaments is 17.90€ per 850g, (*Easy PETG*, n.d.) (*Easy PLA*, n.d.) the PLA Tough (for extra strength) has a price of 27.07€ per 750g (*PLA Tough*, n.d.), and the *Filaflex* filament has a price of 24.21€ per 500g (*Filaflex*, n.d.). The materials cost shown are the ones for the filaments of specific manufacturers that, in this case, match the ones used during printing. These costs may be lower or higher depending on the manufacturer, and on the volume of the request, for example, higher amounts on request usually match lower cost per roll/metre/weight of the material. As for the energy price, according to Preços, (2021), the energy cost in Portugal for a private consumer in 2021 started from 0.2089€/kWh.

Concerning the energy consumption from the printer, the official website mentions that when printing PLA the consumption is 80W and when printing ABS the consumption is 120W. For a cost estimation study, the power consumption considered will be 100W for every print regardless of the material. (*Prusa Knowledgebase*, 2021)

Figure 101 shows the prices resulting from the structure and the electronics as well as the total price for a private user. The expenses with labour, printing equipment and shipping fees are not included.

Price Estimation for one collar production [€]	
Material	16.93
Energy	1.67
Pressure Sensor	2.6
Technical Elastic Bands	0.40
Non-Technical Elastic Bands	0.25
Straps	0.20
Battery	3.5
Foams	0.40
PCB	40
Total	**65.95**

Figure 101 – Price Estimation for Collar Production [€]

5. Tests and Results

For assessing the immobilisation offered by NeProS to a patient, a simple application test was performed on 6 healthy volunteers (3 males and 3 females), with an average of 24 years old. It should be noted that the test involved only the simple application of the collar, without any risks concerning the health of the volunteers, since any transportation was made. No data were collected from volunteers other than their age and anthropometric dimensions of head and shoulder regions. After explaining the purpose of the work, the volunteers signed an informed consent, following the Helsinki Declaration. They have also authorised the use of their image for research and divulgation purposes.

The tests were performed with the volunteers in the dorsal decubitus position, as it is one of the most common positions on the protocols, with the arms along the body.

The assistant was positioned on the top of the head to create the manual head stabilisation as in Figures 8, 9 and 10, and the collar was then slid against the shoulders with every locking mechanism in the open position (exception for the Mandible Angle Adjustment and Mandible Support). (Figure 102)

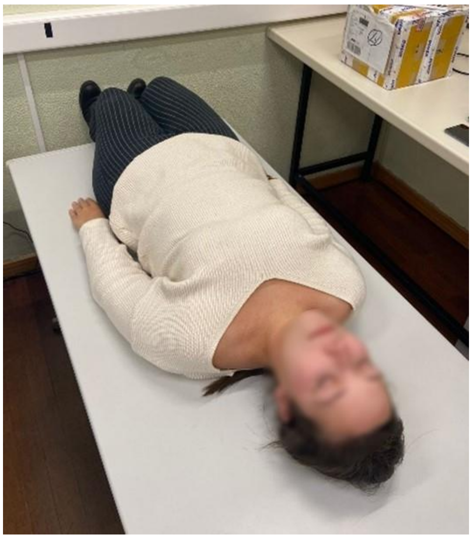
	
Volunteer on Dorsal Decubitus	Assistant approach and Manual Head Stabilisation

Figure 102 – Beginning of the Test

Then, the immobilisation of the patient was performed by locking the successive mechanisms and evaluating the volunteer’s opinion concerning the immobilisation offered. During this step, it was also questioned about the comfort and pain, as well as their locations. (Figure 103)

During all the procedures, the structure was carefully applied and not hardly fastened as one of the main purposes of the tests was to detect faults and needs on the prototype for a future iteration. During and after the test, a report (Appendix I) was filled by the volunteer.

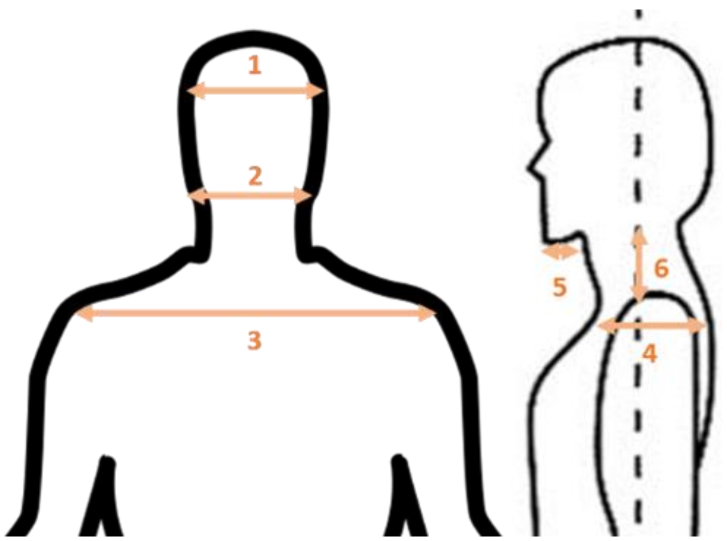
	
Adjustments fastening	Report Filling with Volunteer Feedback while immobilised

Figure 103 – Second and Third Stage of the Test

During all the procedures, the structure was carefully applied and not hardly fastened as one of the main purposes of the tests was to detect faults and needs on the prototype for a future iteration. During and after the test, a report (Appendix I) was filled by the volunteer.

After the registration on the report about the quality of movement restriction (Figure 103), measurements were taken. These measurements are important to understand the dimensions required during the design and dimensioning of the structure according to a certain population, as mentioned in Appendix H – Final Prototype. These measurements helped to understand the need for changing the dimensions as on Tests number 1 and 5, the structure showed to be too big and too small, respectively. In both cases, the part that didn’t have the adequate dimension was the Shoulder-Mandible Element or, as it also can be considered, the parts that didn’t have the adequate dimensions were the Shoulder-Mandible Element and the Mandible Support group. In the test number 5, the Mandible Support wasn’t even able to touch the mandible. On the other hand, the remaining 4 applications presented a considerably good size fitting and proper immobilisation.

As for measurements of the volunteers, the distances used as a reference for the test and for future improvement of the collar (despite being a small study population) are the ones presented in Figure 104 with the results attached.



Volunteer Measurements [mm]			
N	Min	Max	Average
1	140 ± 5	155 ± 5	146 ± 5
2	105 ± 5	130 ± 5	116 ± 5
3	370 ± 10	450 ± 10	405 ± 10
4	130 ± 10	180 ± 10	146 ± 10
5	55 ± 5	70 ± 5	61 ± 5
6	60 ± 5	95 ± 5	77 ± 5

Figure 104 – Volunteers Measurements for Future Reference

According to the report and excluding those two tests that didn't support the patient on the right support points, on a scale of 1 (very poor restriction) and 5 (very good restriction), the average of the results for the movement restriction, according to their opinion, are presented in Figure 105.

Parameter	Average (four tests)
Restriction of Flexion Movement	3.25
Restriction of Extension Movement	3.25
Restriction of Left and Right Rotation	3.75
Restriction of Lateral Flexion	4.75

Figure 105 – Movement Restriction Test Results

In the filled report, one of the main achievements of the tests was the verification of non-contact, or pressure, between the structure and the neck which theoretically prevents the tourniquet effect mentioned in Chapter 2.5. Every volunteer stated that the collar doesn't apply any pressure on the neck. To the affirmation "Felt Discomfort when being immobilised", the volunteers stated that there was no discomfort but considered some parts of the structure rigid for contact with the skin, namely on the Mandible Support Region. The remaining questions helped verify the comfort of the remaining support points. Also on the chest level, there was no complaint about the Shoulder Support against the patient chest, and to the affirmation "The Shoulder Support conditioned my breathing performance", the volunteers' answer was unanimous and found it to not restrict the breathing motion.

The suggestions text on the end of the report had as the main result the discomfort that the mandible support creates when in contact with the skin, as already stated. This can be solved with the application of foams on those painful regions.

From the application point of view, several changes are needed as there are characteristics of the design that conditioned its application. The major conditioning factor and that invalidated two of the performed tests were related to the device dimensions and the range of distances that are possible to achieve with the collar adjustments. The regions where these bad dimensions are more expressive are the Shoulder-Mandible Element and the Mandible Support group. This can be solved by changing the position of the group to a lower one in the Shoulder Support or by redesigning these adjustment mechanisms. Also, despite the distance between Sliding Elements (Figures 22 and 23 – Appendix H), on the shoulders, being suitable for the dimensions from where the project was based on, and suitable for the tests, reducing the distance between them when in a closed position would benefit its application and would reduce the weight of the structure.

Also on the Sliding Elements, and pointed to the view of the immobilisation performer, there should be a reference system recorded on each of those Sliding Elements that would assist the application in terms of symmetry. Otherwise, the application takes longer as the performer must count every square hole of the Sliding Elements' Locking Mechanism on each side of the Back Portion and match them.

Another region that was highlighted during the tests was the Angle Adjustment Element that, due to its shape and size, affected the comfort of the volunteers by applying a slight pressure below the mandible against the neck. This pressure could cause pressure ulcers or even increase on the ICP despite the small region that it affects. To solve this problem, a triangular region can be excluded from this shape, as in Figure 106. Even with this change, theoretically, the support offered by this element would remain.

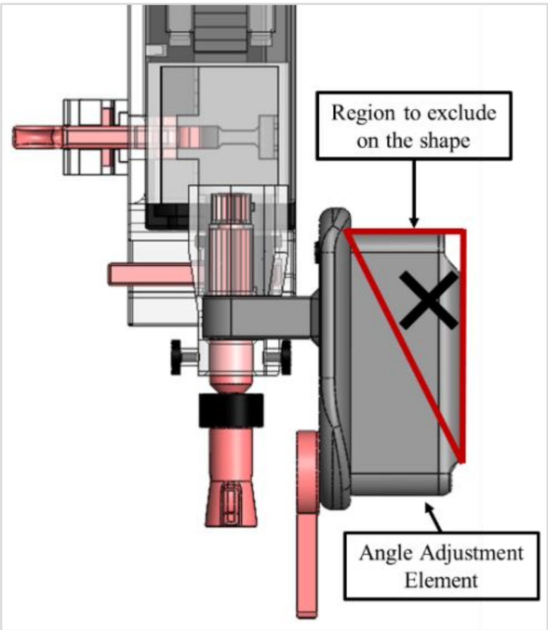


Figure 106 – Top View of the Assembly. Suggestion for Solving an Undesired Pressure Contact Point

Also, in that region but as a group, the overall size of the Mandible Support and the Chin Attachment may increase the difficulty of both applications when immobilising the patient.

In the Back Part of the collar, the Locking Tooth that locks the Sliding Elements' position showed to have bad access when the patient is in dorsal decubitus. Also, due to its circular shape on the top, where the paramedic usually grabs to pull the tooth, it gets stuck because that circular shape exceeds the thickness of the structure and is compressed by the floor and the structure that is being forced backwards by the patient's head. (Figure 107) This can be solved with a redesign of this part ensuring also greater access to it.

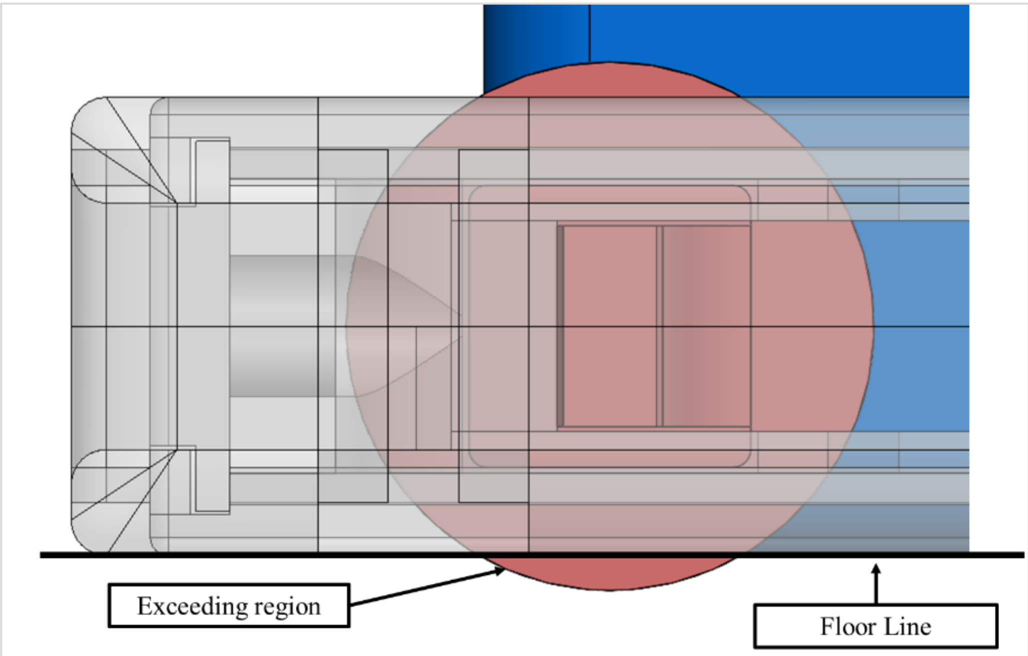


Figure 107 – Bottom View of the Back Part on the Mentioned Region

The tests were performed without the final version balloons, and for that reason, the comfort of those couldn't be assessed. As an alternative, some older version balloons were used to simulate the height achieved by the final version of them. (Chapter 3.3.3)

6. Conclusions and Future Work

6.1 – Mechanical Section

The structure obtained presents all the features and adjustments necessary for immobilisation, and all the developed mechanisms present high stability and strength. Theoretically, the areas that weren't touched or compressed by the structure have now a better flow of blood in the case of TBI injuries, and the Mandible Angle Adjustment allows improved airway management on injured patients that need assistance on and through that region.

In situations where the neck can't be moved for a neutral alignment, or in situations like the one suggested by Benger & Blackham (2009), where "alert, stable and co-operative trauma patients do not require mandatory immobilisation of the cervical spine" and that instead, a position of comfort for the patient may be more appropriate when the patient's neck is blocked in a slight lateral flexion position, the collar can also be applied and offer support due to its possible asymmetric adjustments. This would result in relative support of the patient without any injury or further damage.

The tests implemented with the system show feasibility of the developed solution as also the need for some improvements to be implemented in the near future.

Concerning the future work, the iterative process of designing and testing until achieving a perfect immobilisation for everyone on just one device should continue because the results obtained present a lot of improvement margin. The access and consultation of the Standard Guide for Characteristics for Cervical Spine Immobilisation Collar(s) (CSIC), American Standard Number ASTM F1559-94(2015), should be ensured as for this project it wasn't possible because the cost associated was high.

Measurements on a large population should be taken, considering that most of the faults detected on the collar were related to poor sizing. These measurements between specific points like the ones performed during the tests would also help to re-dimension the collar adjustments for a universal fit in a single model.

In a future better fit model, to evaluate specific features designed for the collar such as airway management, mouth opening adjustment, or occipital height achieved by the balloons, tests should be performed. For the occipital height and alignment of the cervical spine, it is recommended a similar test as the one performed by De Lorenzo *et al*. (1996), that through radiologic exams verified the alignment of the cervical spine with the help of occipital padding. This method is recommended due to the high reliability and accuracy. On the other hand, any other method can be used to assess it. As for the mouth opening restriction and airway management, a test like the one performed by Goutcher & Lochhead (2005), is adequate. They measured the maximal inter-incisor distance in healthy volunteers while immobilised with different cervical collars. It should also be considered the measurement with the mouth open in successive positions till the maximum one possible, considered comfortable, or by collar limitation. As it is a feature of this collar and the adjustment of the mandible support is possible to follow the mouth opening, the immobilisation offered in each position should also be assessed to validate the adjustment and to allow improvement by the understanding of its needs.

During the future iterative design process and to prepare the collar for market production, topology optimization and finite element studies must accompany the progress. This would result in less weight keeping the same strength of the structure, less time of production and consequently reduced costs either in material or in energy consumption.

6.2 – Electronic Section

The airtightness achieved with the balloons system, and the increase in height that they offer, are two accomplishments and demonstrate that it is possible to implement different technological solutions to make the life of a patient safer and more comfortable. As for future work of this feature, the app should present a tare or reset button for the process of assessing the pressure applied to be faster. This way, when the patient settles its head on the balloons, there isn't any need for going to settings and setting threshold values as those would be calculated immediately. Also, the calibration of the pressure sensor should be performed for achieving a fully workable system.

The process of implementing a microphone on NeProS was started during the ICM programme, in Russia. The microphone was purchased and the first prototype built like the one of Corbishley & Rodriguez-Villegas (2008). Due to COVID limitations, the Respiratory Rate Monitoring System was not possible to be fully implemented. This would result in an innovative process and value the cervical collar application due to its versatility.

The PCB in use is ready to conciliate this feature but is still necessary to finish the signal cleaning algorithm, finish the remaining data processing code, and conciliate with the interface.

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Appendix A

The parts that belong to the first model are identified as: *Shoulder Support* (Figure 1-1); *Rotational Element* (Figure 1-2); *Shoulder-Mandible Element* (Figure 1-3); and *Mandible Support* (Figure 1-4).

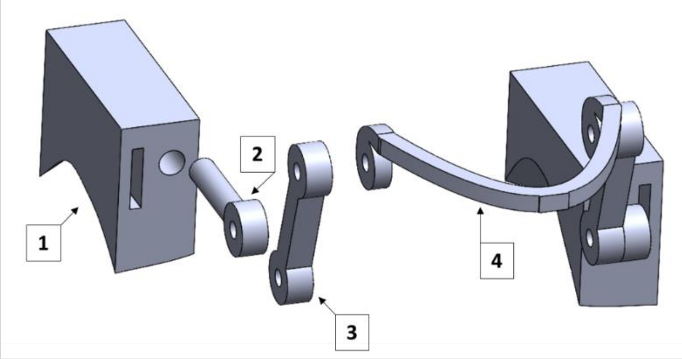


Figure 1 – Semi-Exploded View of the First Model Assembly

The *Shoulder Support* settles on the shoulders and gives a supported base for the rest of the structure. It has two shaped holes (a circular and a square one). The circular hole is to insert the *Rotational Element*, and the square one is a possibility to connect a future Back Portion. The *Rotational Element* is the connection between the *Shoulder Support* and the *Shoulder-Mandible Element* where, in both cases, there should have been a locking mechanism to immobilise the structure. The *Shoulder-Mandible Element* has rotational freedom around the hole's axis on both ends and helps transmit the chin forces to the shoulders (when in the presence of a locking mechanism) as well as allows to bring the *Mandible Support* against the patient. Concerning the *Mandible Support*, it is supposed to be bendable in the *y*-direction (Figure 2) in order to conform to the size and shape of every patient's chin. It can be achieved using a bendable material (not recommended as it wouldn't be strong enough to immobilise the patient) or with a different shape.

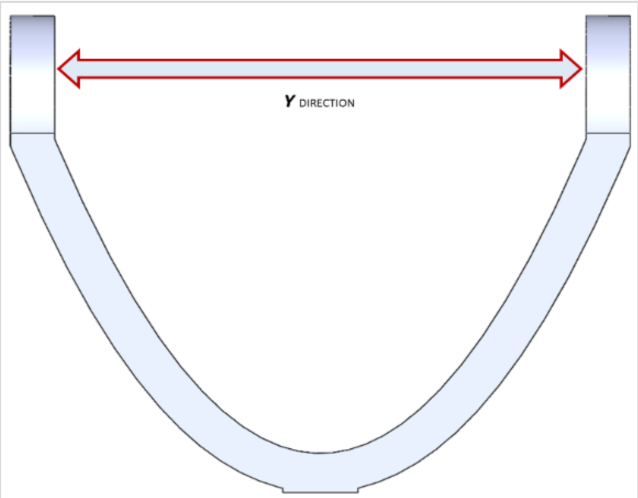


Figure 2 – Top View of the Mandible Support

Main Document References

Figure 3 shows a cut view of the *Shoulder Support*. As it is possible to see, the degree **α** should be smaller because of the natural shape of the shoulder. It has a slight inclination due to the muscles and tendons between the neck and the arms that, even when in a relaxed and neutral position, can be considered for the design of the collar. With the angle presented on the design, it also creates a vigorous edge that might cause discomfort or even injure the patient.

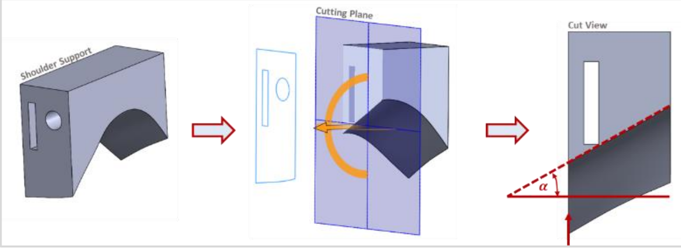


Figure 3 – Cut View of the Shoulder Support

Since this improved element (Figure 4) can increase its length, it allows better fitment. Besides its ability to extend, there is still missing a locking mechanism to fix the position.

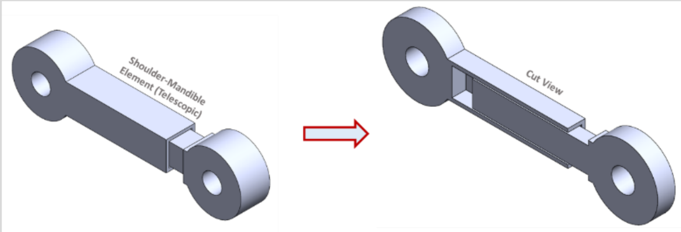


Figure 4 – Cut View of the improved Shoulder-Mandible Element

In Figure 5 is simulated a real adjustment of the collar to fit a patient that has a mandible width **d,** but has different neck and shoulder sizes so that is needed an increase of the distance between *Shoulder Supports*. To increase that distance, a force **F** is applied. The orange arrows in Figure 5 describe the natural movement of the structure and Figure 6 simulates the presented situation.

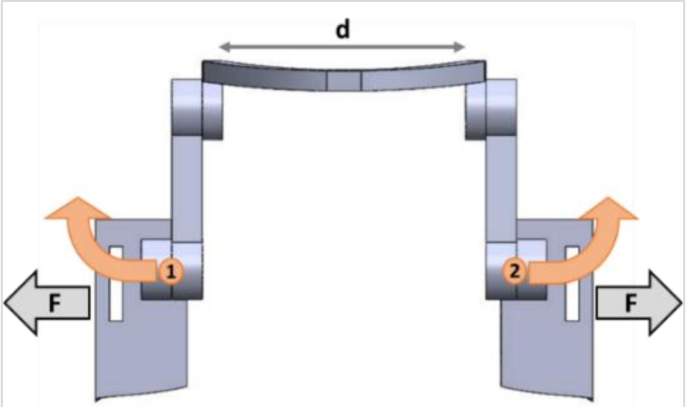


Figure 5 – Front View of the Front Portion Assembly

The pink arrows in Figures 6-a and 6-b represent the external forces **F** that are applied to the structure, in a simplified assembly for a better understanding of the point. On the other hand, the green arrows represent the restrictions of the movement that, in this case, represent the fixed distance **d** of the mandible. It is applied only to an edge because the restriction we want to simulate is just the translation, keeping the rotation in order to understand the behaviour of the *Mandible Support* when the structure gets stretched and rotated.

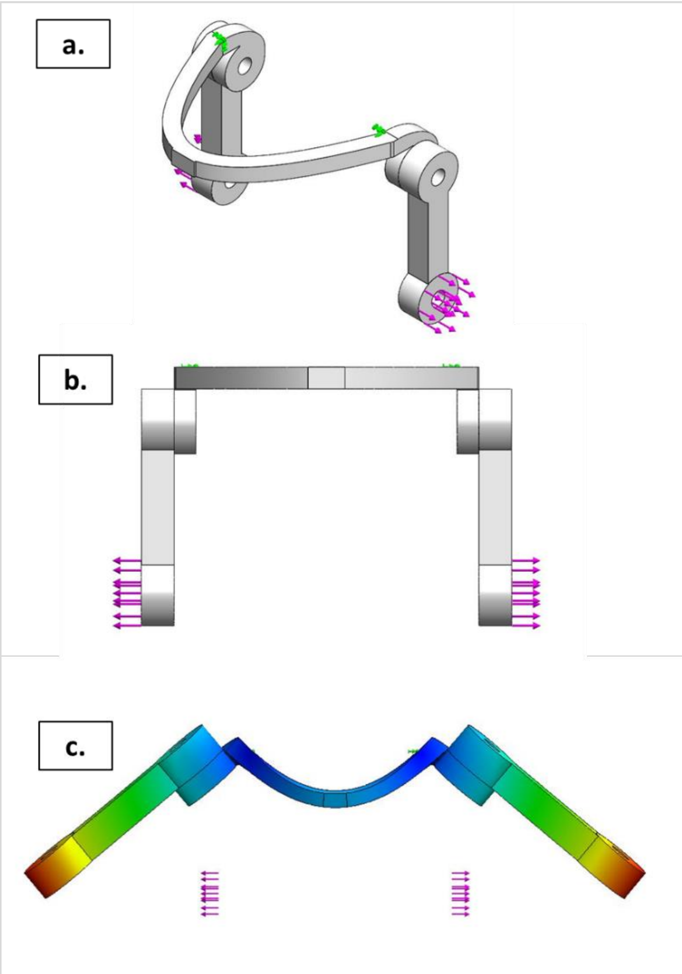


Figure 6 – Simulation to Check Mandible Support Behaviour. ***a*** *- Isometric View of the Simplified Assembly with Simulation Forces Represented;* ***b****- Front View of the Simplified Assembly with Simulation forces represented;* ***c****- Front View of the Simulation's Displacement Chart.*

This simulation is important to verify the predictions that there would be a problem with the *Mandible Support* as it wouldn't keep a flat top surface when the structure gets stretched for better fitment. In Figure 6-c it is possible to see the curvature of the *Mandible Support* on the mentioned region. So, it was important to improve this part design.

The results of that re-design are presented in Figure 7.

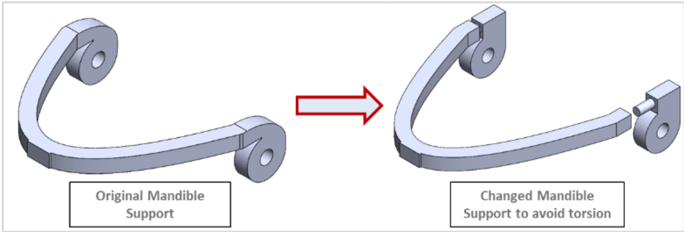


Figure 7 – Mandible Support Design Improvement

As mentioned, Figure 7 shows the evolution between two designs and the main changes are the virtual result of what was mentioned on the main document ("there is needed a *Rotational Element* on both ends in order to prevent the torsion of the bendable band when the remaining structure gets stretched and rotated for better fitment"). The labelled "Changed *Mandible Support* to avoid torsion" in Figure 7 is a semi-exploded view of the assembly and it is possible to see one of the *Rotational Elements* that were added to this part on the right of the image. They are inserted in a hole that was made on the c-shaped part allowing rotation without torsion.

Figure 8 shows the fully assembled structure in two positions

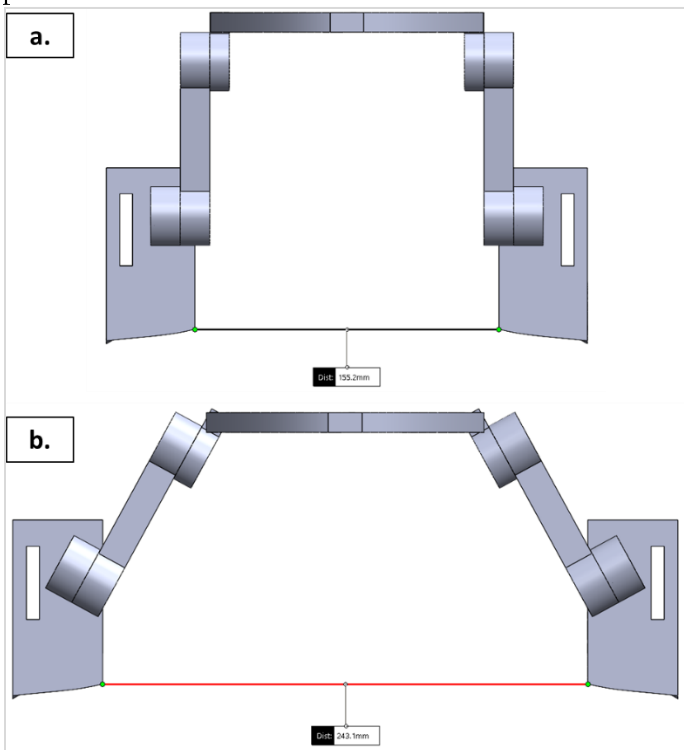


Figure 8 – Assembly of the Frontal Portion with the Improved Mandible Support: ***a****- Non stretched Structure;* ***b****- Stretched Structure*

Those positions can be non-stretched (Figure 8-a) and stretched (Figure 8-b) and in both cases, there hasn't been any deformation of the *Mandible Support* besides the allowed one in the y-direction (Figure 2).

Figure 9 shows an assembly with all the updated parts.

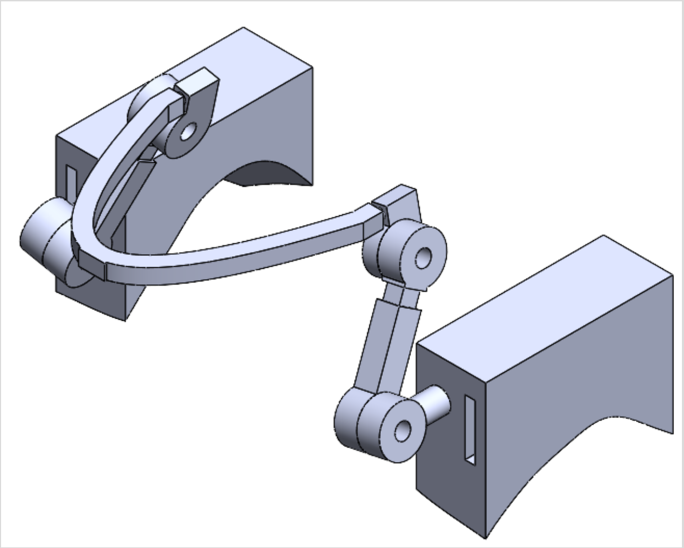


Figure 9 – Improved Possibility for the Front Portion

Appendix B

The Second Model is a continuation of the First one.

The First Model's *Shoulder Support* is now constituted by two parts, the *Shoulder Element* (Figure 1-1) and the *Telescopic Adjustment* (Figure 1-2), and there was added a *Back Portion Element* (Figure 1-3).

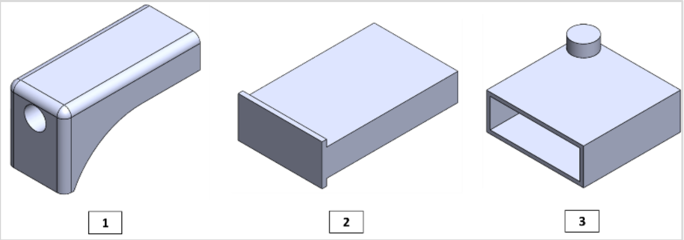


Figure 1 – Parts that were Included on the Second Model

The *Telescopic Adjustment* applied to the *Shoulder Element* is similar to the one applied to the Improved *Shoulder-Mandible Element* (Figure 4 – Appendix A). In this case, the *Telescopic Adjustment* has the function to be locked to the *Back Portion Element* and allow the further adjustment of the *Shoulder Element* against the patient's shoulder (Figure 2).

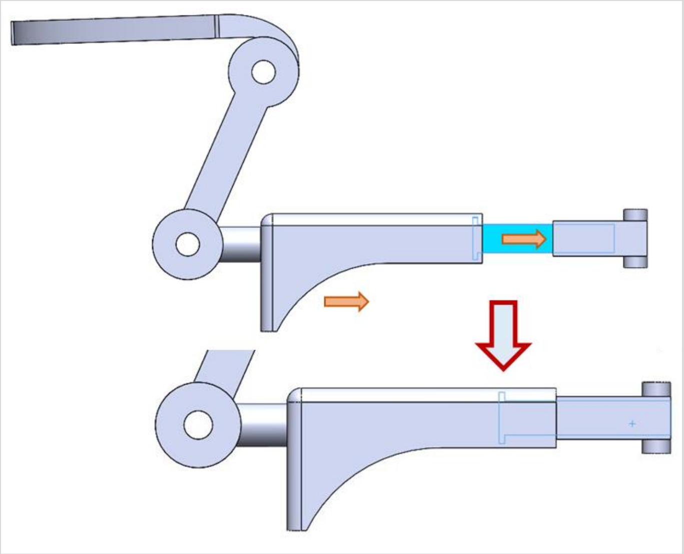


Figure 2 – Visual Explanation of How the Connection Between Frontal and Back Portion is Made and Subsequent Shoulder Element Adjustment

It is possible to change the dimensions of the *Shoulder Element* and *Telescopic Adjustment* to allow more distance of adjustment.

Figure 3 shows the assembly of the Second Model with one of the *Shoulder Elements*, *Telescopic Adjustment* and *Back Portion Element* in Cut View for a better understanding of the Structure's Mechanics.

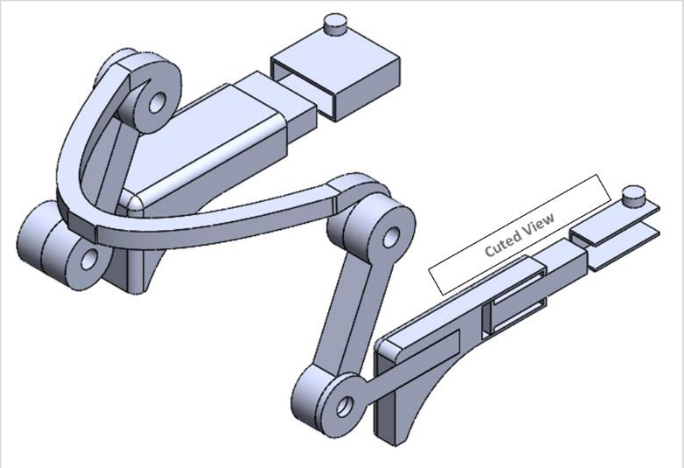


Figure 3 – Isometric View of the Assembly with a Cut View of the New Pieces

Appendix C

This Third Model is the first to present a complete structure. It follows the same principles as the first model in terms of positioning the patient on the structure but there have been some changes concerning the shape and even the mechanics of the assembly. These changes were performed mainly on the Frontal Portion as in the Back Portion was only added the final element for immobilisation. In this model, there are still missing locking mechanisms.

Figure 1 shows the non-closed cervical collar structure of the present model. The parts in grey colour are present on the previous models and haven't suffered any changes while the other ones have a variety of colours for better identification. In the case of equal or symmetric parts, the same colour is applied.

The pieces that have been changed are:
1. *Mandible Support*; **2.** *Chin Strap*; **3.** *Chin Attachment*; **4.** *Shoulder-Mandible Element*; **5.** *Back Portion Element*; **6.** *Main Back Portion*. The numbers that precede the parts' name are the ones that identify the parts in Figure 1.

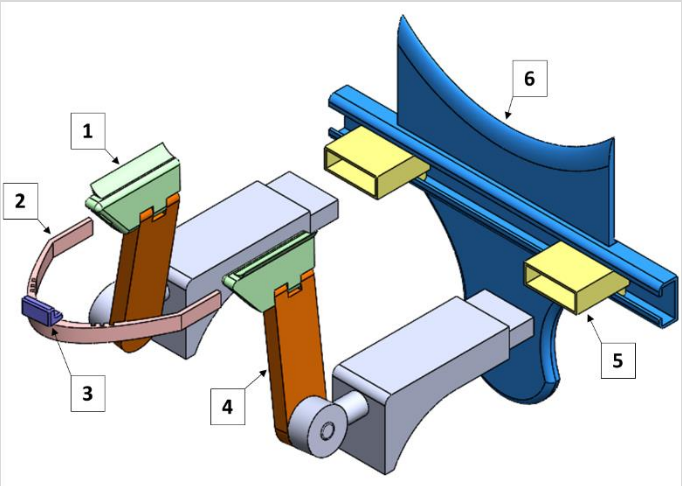


Figure 1 – Assembly of the Third Model

The *Mandible Support* was changed from an entire element like in the previous two models (Figure 1-4 – Appendix A) to two separate elements (green elements on Figure 1). In combination with locking mechanisms, these elements have the purpose of immobilising the patient in the following directions: flexion, lateral flexion, and lateral rotation (Figure 2).

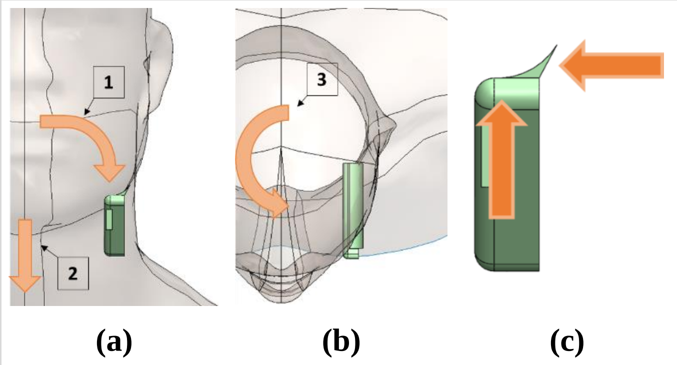


Figure 2 – Context and Purpose of the New Mandible Support.
a- Front View of Mandible Support's Isolated Application: 1- Lateral Flexion; 2- Flexion;
b- Top View of the Mandible Support's Isolated Application: 3- Lateral Rotation;
c- Ideal Reaction Forces from the structure

Following the change of the *Mandible Support*, this group of parts, besides the elements presented in figure 2, have now a *Chin Strap* and a *Chin Attachment*. These last ones, as a group, have the purpose of pushing the head backwards for immobilising the patient against the *Main Back Portion*. The connection hole on the *Mandible Support* is supposed to lock the *Chin Strap* (not represented), and to allow its adjustment (Figure 3).

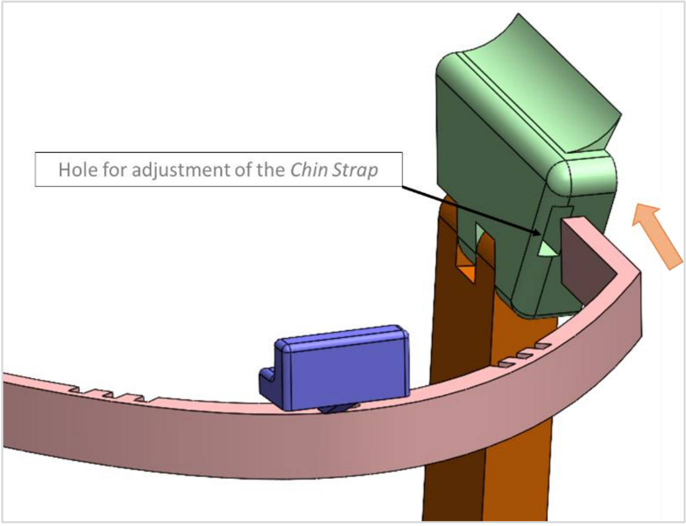


Figure 3 – General View of the Chin Strap Adjustment

There has been a change in the *Chin Strap* when considering the shape on the *Mandible Support* from the first model. The purpose of the changes on the *Chin Strap* when compared to previous models, is to accommodate different sizes of mandible and allow the "y-direction" adjustment like displayed in Figure 2 - Appendix A. The straight portion (Figure 4-1) on each end of the strap is to allow a correct adjustment because if there was a curved shape it could get damaged or not even be able to adjust on the *Mandible Support*. In this part, there is also a sequence of square cuts (Figure 4-2) to allow better elastic deformation from it. The round hole on the front (Figure 4-3) is to allow the insertion of the *Chin Attachment*.

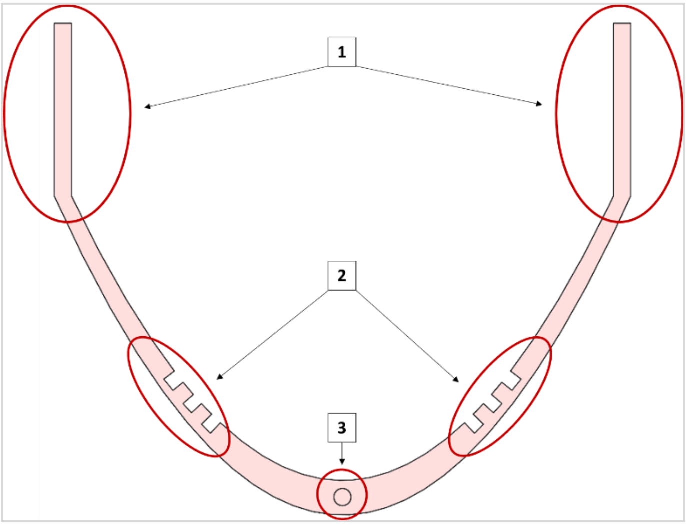


Figure 4 – Top View of the Chin Strap

The *Chin Attachment* is the part that is in contact with the chin and causes the backwards movement when it is adjusted. (Figure 5)

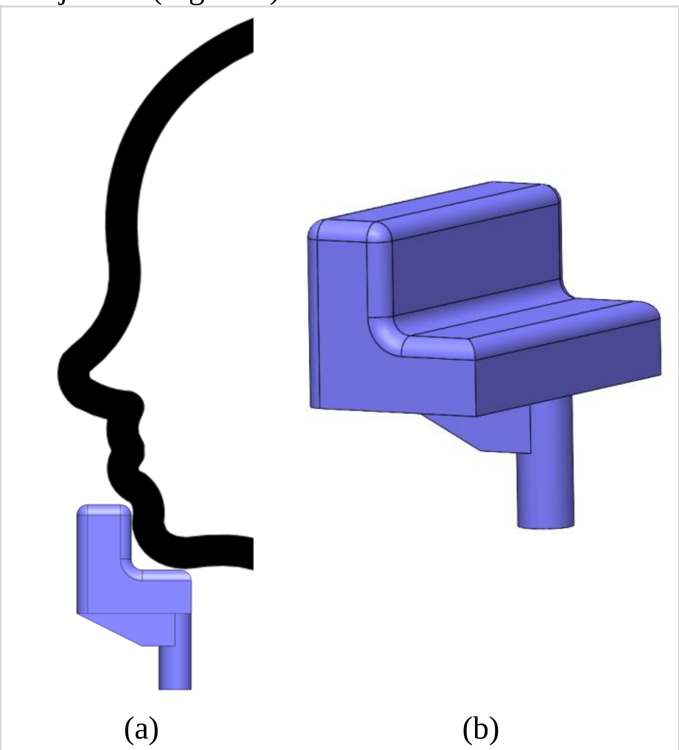


Figure 5 – Chin Attachment: a- Right View and Ideal Positioning; b – Isometric View of the Chin Attachment

The group of *Shoulder-Mandible Element*/*Mandible Support* is designed in such a way that when the *Shoulder Support* is fitted against the shoulder, the natural position of the mentioned group is aligned and parallel with the mandible region (Figure 6). As the *Mandible Support* is already aligned and parallel to the mandible, the only adjustments needed are to the inside (to fit them against the patient) by rotating the elements, as shown in Figure 7.

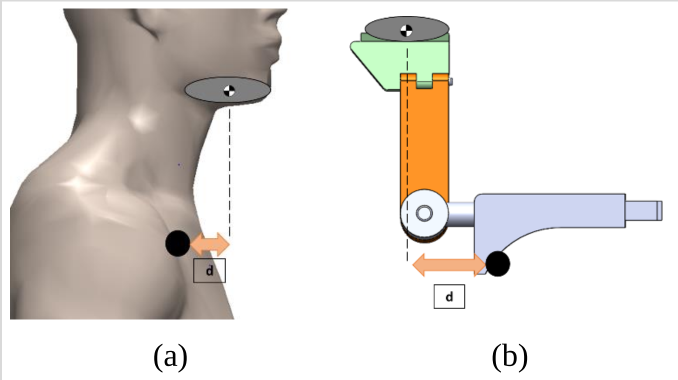


Figure 6 – Comparison of the Distance Between Shoulder and Mandible in a Patient and on the Structure. a – Patient Point of View; b – Structure Point of View

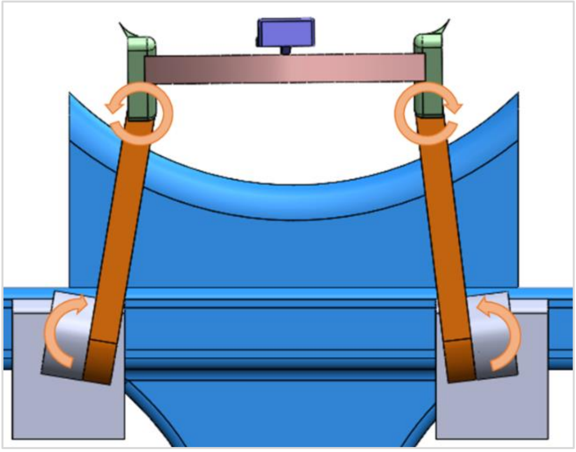


Figure 7 – Adjustments Needed to Better Fit the Patient When Applying the Cervical Collar

Considering what was mentioned, in this model it isn’t necessary any other kind of Rotational Element otherwise, any rotation of it would result in misalignment and bad support of the mandible. This part can be designed as one with the *Shoulder-Mandible Element* (Figure 8)

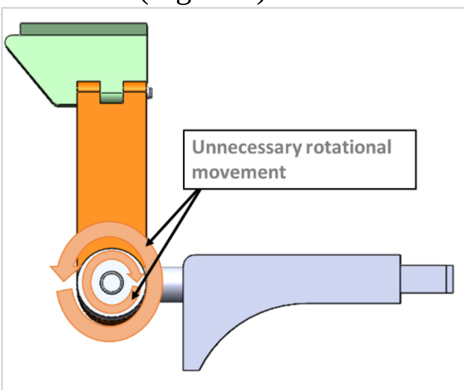


Figure 8 – Unnecessary Rotational Element

Concerning the Back Portion, another pin was added on the top and bottom side of the *Back Portion Element* in order to avoid the rotation of it when assembled on the *Main Back Portion*. (Figure 9)

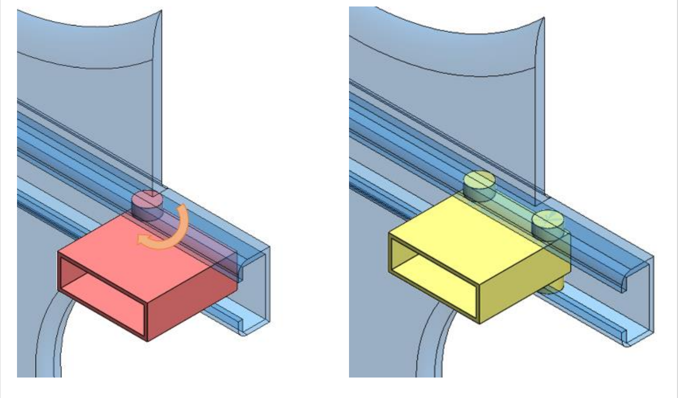


Figure 9 – Comparison Between the Back Portion Element with One and Two Pins. a- First Model's Back Portion Element with just One Pin; b- This Model's Back Portion Element with Two Pins.

The assembly allows for the *Back Portion Elements* to get several positions along with the sliding house of the *Main Back Portion* (Figure 10). This feature ensures suitability for different sized patients.

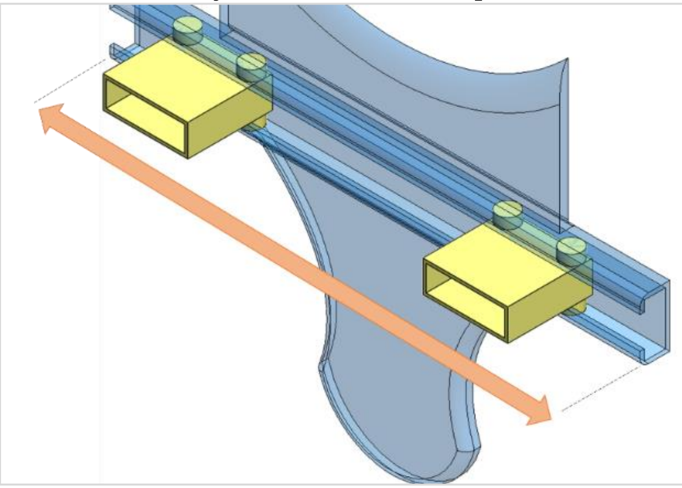


Figure 10 – Sliding Distance for Back Portion Element's Adjustment

To immobilise the patient, the *Main Back Portion* supports the head on the occipital region blocking the patient's extension movement. (Figure 11)

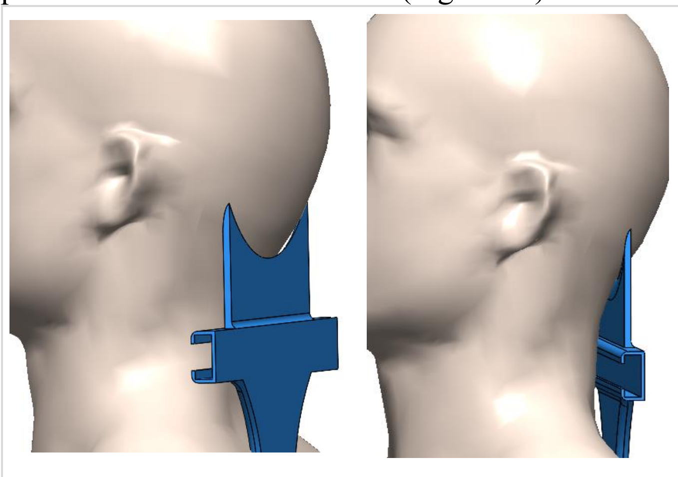


Figure 11 – View of Main Back Portion Applied to the Patient and Supporting Occipital Region. a- Back View; b- Frontal View

The lower part of the *Main Back Portion*, below the sliding house, fits between the scapula bones. (Figure 12) This allows for the structure to be balanced and immovable on the back. (Figure 13)

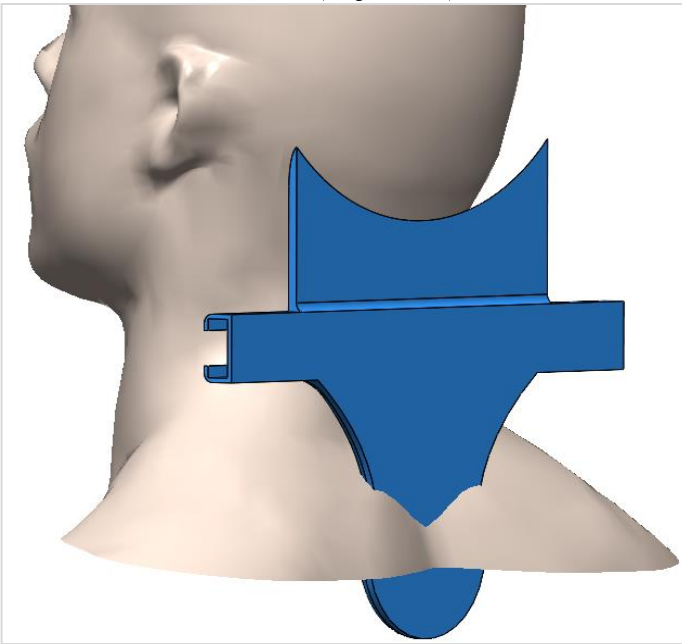


Figure 12 – Fitting of the Lower Part of the Main Back Portion Between the Scapula Bones

The *Main Back Portion* still needs some shape/size adjustments because for the balanced Action-Reaction scene presented in Figure 13, the sliding house needs to be on the level of the shoulders, which is not. The same for the lower part of the *Main Back Portion* as it is too large and might not fit between the desired bones.

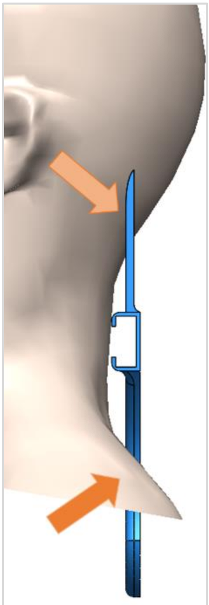


Figure 13 – Representative Action-Reaction Force in an Ideal and Well Fitted Back Portion

As mentioned in the main document, the non-existence of a telescopic adjustment on the *Shoulder-Mandible Element* causes a misalignment between the *Mandible Support* and the *Main Back Portion*

(Figure 14) which makes the structure not usable. In figure 14, the lines represent the two points that are supposed to be supported by the structure: the mandible – supported by the *Mandible Support*, and the occipital region - supported by the *Main Back Portion*. The yellow line represents the occipital-mandible direction based on a person, while the red line represents the same direction but based on the cervical collar's model. It is clear that the structure has the opposite direction of the desired to accommodate the patient. This can be corrected using a telescopic adjustment on the *Shoulder-Mandible Element* to lower the *Mandible Support*. Also, a Main Back Support Adjustment or re-design of the entire piece is advisable.

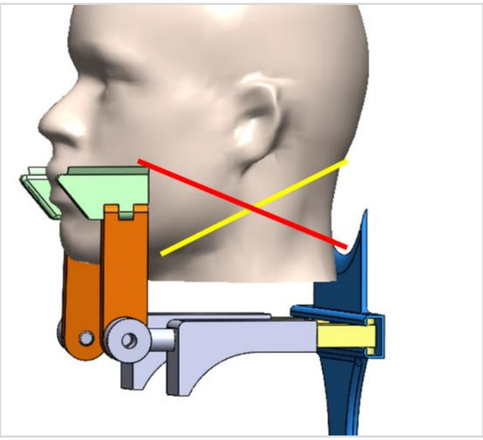


Figure 14 – Comparison Between Support Point Directions

Appendix D

The differences between the third and fourth models are noticeable, but the overall structure and support points haven't changed as it is possible to see in Figure 1.

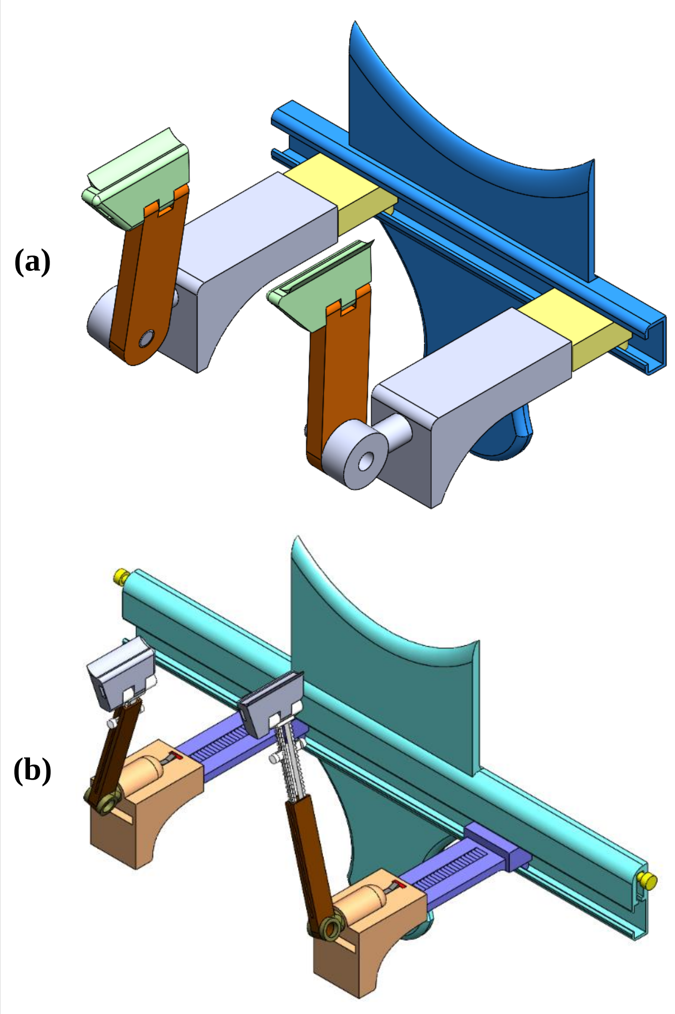


Figure 1 – Comparison between Third and Fourth Models. a- Third Model; b- Fourth Model;

Following the colour code established, the only element that hasn't suffered any changes was the *Mandible Support* (Standard Grey Colour). Since in this region nothing has been changed, the views presented don't show the *Chin Strap* and *the Chin Attachment*.

Shoulder-Mandible Telescopic Adjustment

The *Shoulder-Mandible Telescopic Adjustment* consists of two parts (Figure 2) connected on a teeth pattern mechanism that allows an easy adjustment in one direction and locks the position on the opposite one (Figure 3).

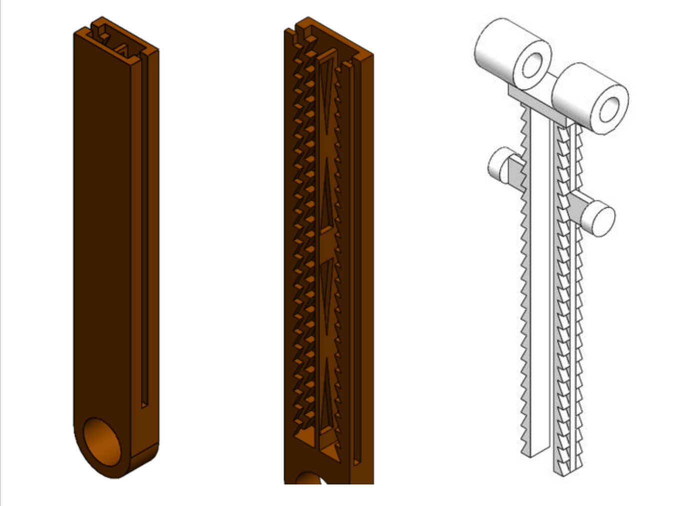


Figure 2 – Isometric View of the Parts that Constitutes the Shoulder-Mandible Element. a- Outer Part of the Telescopic Adjustment; b- Cut View of the Outer Part of the Telescopic Adjustment; c- Inner Part of the Telescopic Adjustment

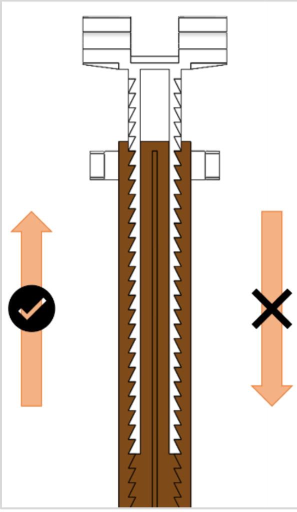


Figure 3 - Movement Directions of the Adjustment

It is possible to see in Figure 3 the two directions of movement that are possible on this mechanism. Both movements are possible due to the conciliation of shape and material choice on the Inner Part of the system, that needs to present an elastic deformation and rigidity balance, (white colour in figure 3) allowing to be compressed and deformed to disengage and to return it to its original condition when released.

On the upward movement the adjustment is easy, as only by pulling the element it changes its position increasing the height of the *Mandible Support*. When the pulling stops, the teeth engage again, and the opposite movement doesn't happen. The group and shape of the teeth pattern allow for consecutive increases of 3 mm in length as it is the distance between two teeth. (Figure 4)

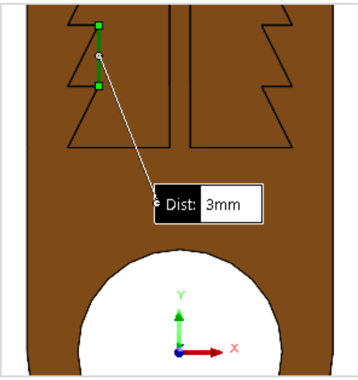


Figure 4 – Distance Between Two Consecutive Teeth on the Outer Part

To unlock the mechanism and return it to its lower positions, is required the application of a transversal force on the inner part. (Figure 5) When the force is applied, the teeth disengage allowing both movements to lower and to increase the length of the group.

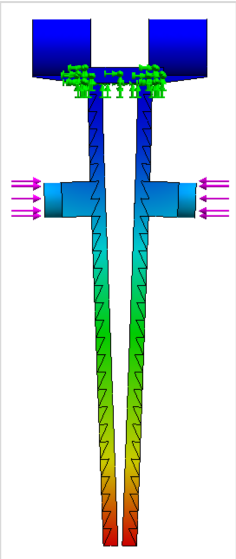


Figure 5 – Displacement Chart of the Simulation when Applying Transversal Forces to the Inner Part to Unlock the Mechanism

The blue region shows small displacement and the red region the higher displacement, and since the top region of the part is almost unbendable there is no necessity for teeth there. In their presence, it isn't possible to introduce the entire part inside the outer one as they collide. So, above the line of the transversal forces, there shouldn't be any teeth.

Shoulder Support and Back Portion Connection

The main changes concerning the previous model are the opposite mean of connection. While in the previous model the *Shoulder Support* inserts a portion on the *Back Portion Element*, in this case, the *Back Portion Element* has an extension that will go inside a square hole on the *Shoulder Support*. This change allows for a simplified mechanism and a wider range of positions to adjust. (Figure 6)

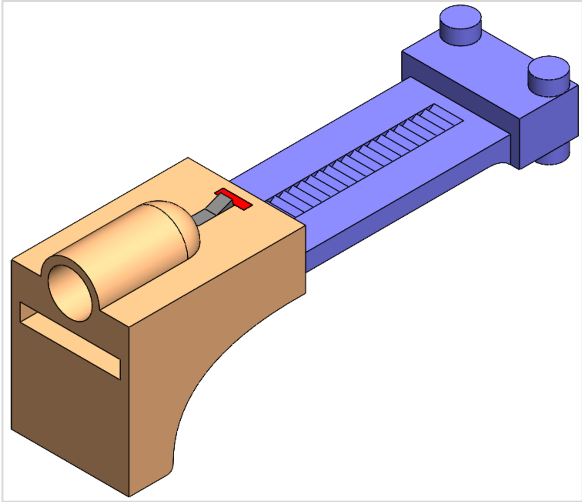


Figure 6 – Isometric View of the Mechanism Group

As the *Shoulder Support* is meant to go against the shoulder of the patient and lock that position, the direction in which the teeth pattern mechanism is designed allows it. (Figure 7)

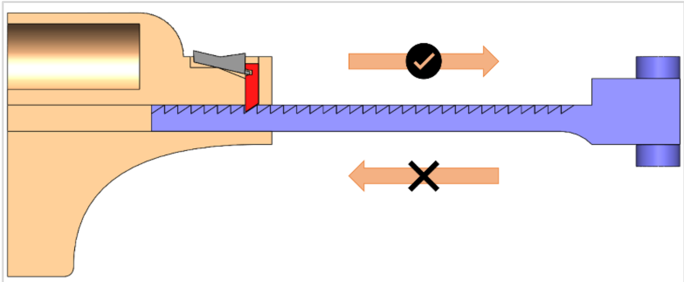


Figure 7 – Movement Directions of the Adjustment

The Shoulder Support now accommodates a manually actuated button system that allows for locking the positions (Figure 8).

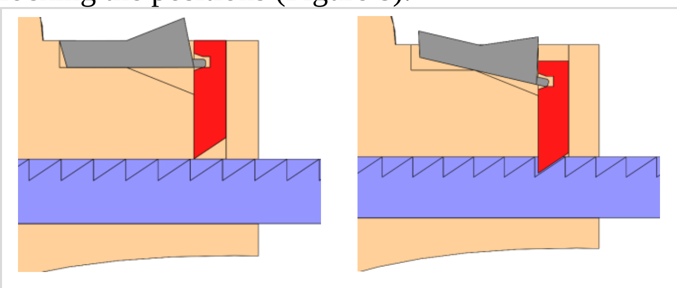


Figure 8 – Button Locking Mechanism. a- Position: Open; b - Position: Locked

Back Portion Locking Mechanism

The locking mechanism on the *Back Portion* consists of a *Sliding Element* (inside a housing on the *Main Back Portion*) that secures a variety of *Small Elements* (all equal) moving them up and down depending on what is intended (lock/unlock). Its purpose is to immobilise the *Back Portion Element*.

Figure 9 shows the positioning of one of the *Small Elements* along with the *Sliding Element*.

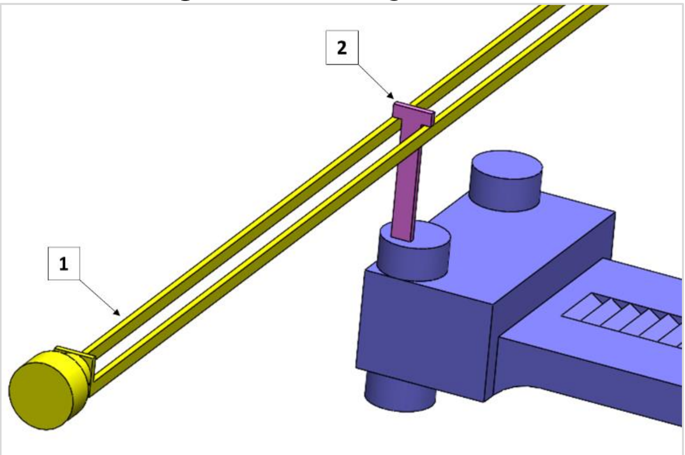


Figure 9 – Demonstration of the Small Element and Sliding Element Assembly. 1- Sliding Element; 2- Small Element.

The *Sliding Element* is the same length as the *Main Back Portion* (Possible distance between shoulders) having 450 mm. (Figure 10)

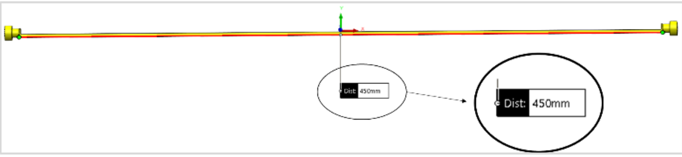


Figure 10 – Sliding Element's Length

As the thickness of the *Small Elements* is only 1 mm (Figure 11) and for the purpose of the mechanism is needed the full length of the *Sliding Element* to have those ones, it is needed 450 Elements. This small thickness of the Small Elements allows adjustments of the *Back Portion Element* of 1mm.

Figure 11 – Assembly of the Sliding Element and the 450 Small Elements

This group is supposed to move up and down on the sliding housing of the *Main Back Portion*. The upper movement unlocks the position of the *Back Portion Elements*, and the downward movement locks their position. (Figure 12)

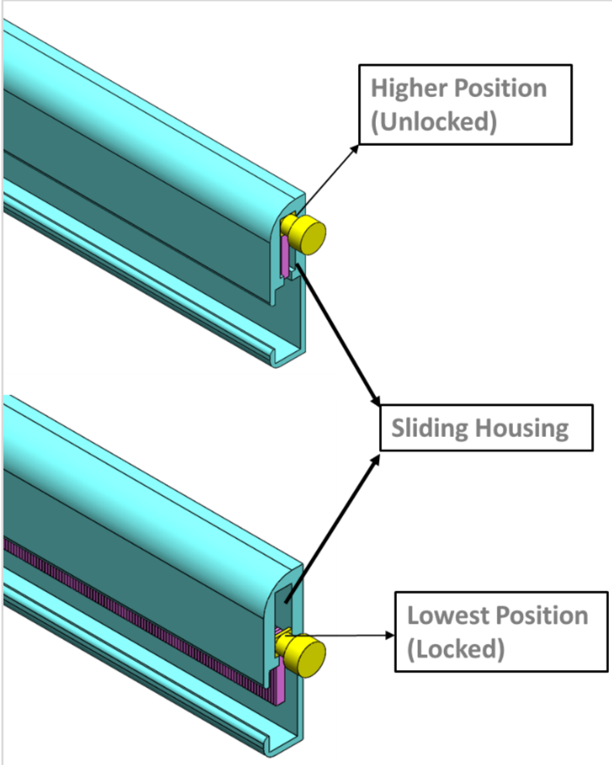


Figure 12 – Difference Between Highest and Lowest Position of the Group Sliding Element/Small Elements

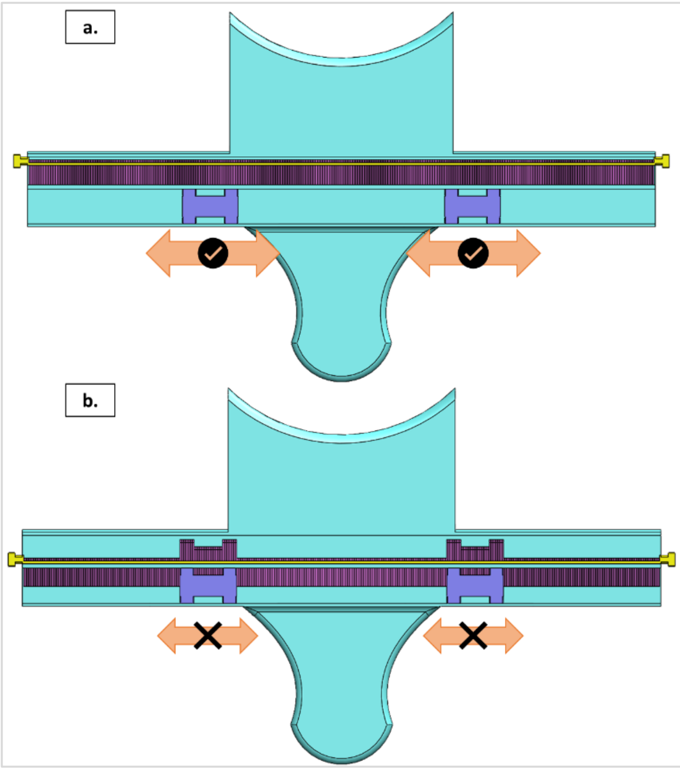


Figure 13 – a- Sliding Element on the Highest Position (Unlocked); b- Sliding Element on the Lowest Position (Locked)

When the group is in its lowest position, the separate *Small Elements* contour the *Back Portion Elements*, surrounding them and blocking their movement. Figure 14 shows in detail the delimit of the *Back Portion Element*. As the *Small Elements* are against the endings of the *Sliding Element*, they will not have any further movement as they are stuck, blocking this way any other movement from the *Back Portion Element*.

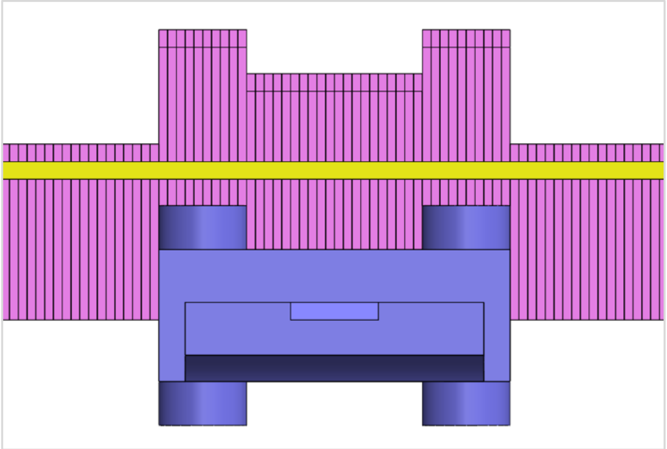


Figure 14 – Detailed View of the Delimit of the Back Portion Element by the Small Elements

The *Back Portion's* locking Mechanism has obvious problems due to its number of components. Despite being small, a large amount consists of an increased weight when compared to simpler mechanisms. This weight might even cause an excessive flexion on the *Sliding Element*, due to its length, affecting its normal function.

Another problem is that there isn't any kind of covers or guides to prevent the *Sliding Element* to move longitudinally which makes it get out from the place. The transversal movement is the only one required. (Figure 15)

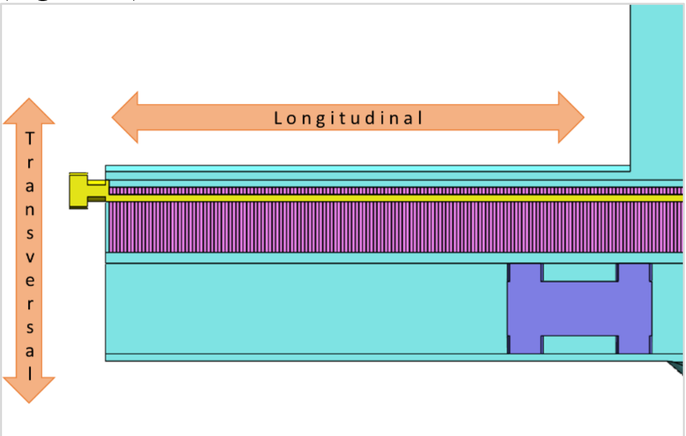


Figure 15 – Longitudinal vs Transversal Direction

Appendix E

Model five is the model in which the biggest change is the *Back Portion*. It comes in two versions, the first where there is a *Chin Strap* connected to the *Mandible Support* (Figure 1 – a) and a second version with the *Chin Strap* connected to the *Back Portion* (Figure 1– b).

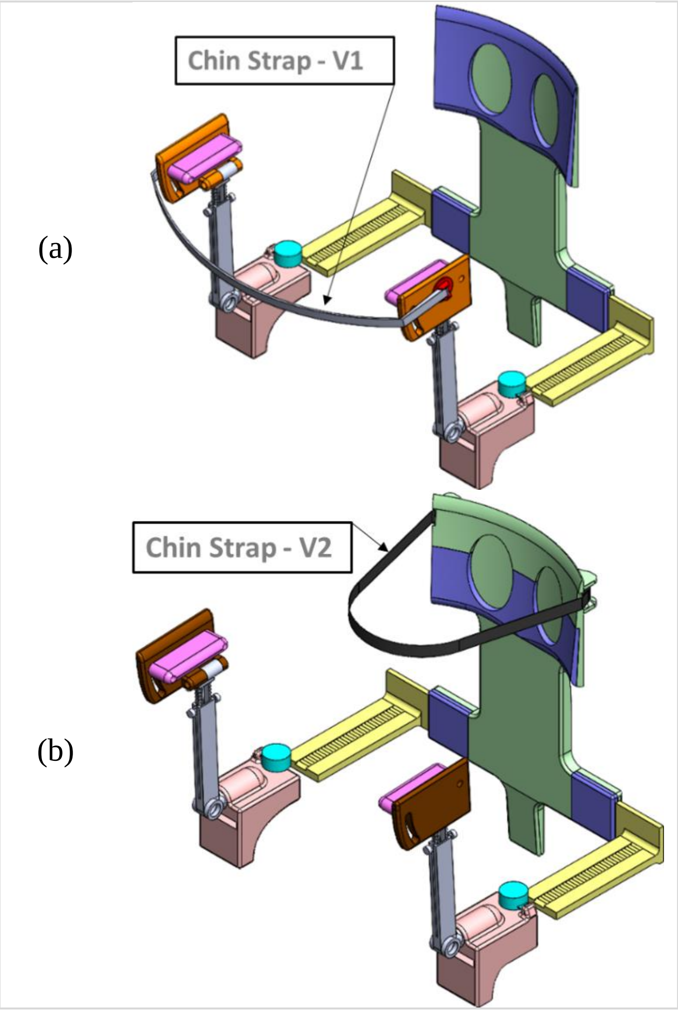


Figure 1 – Presentation of the Two Versions of this Model with the Chin Strap Identified. a- Version 1 (V1); b- Version 2 (V2)

Both models share the same mechanism on the connection of the front and back portions. It was changed from a button to a rotatable element (*Cover*) that has the locking tooth inside. (Figure 2)

Due to the tolerances between the *Tooth's pin* (White part) and the *Cover* (Blue part), the second rotates around the pin and in combination with up and down movement allows it to lock and unlock the mechanism (Figure 3). The holes on the *Shoulder Support* must have a small tolerance for the *Cover* to be stuck on them in the higher (unlocked) and lower (locked) position. (Figure 4)

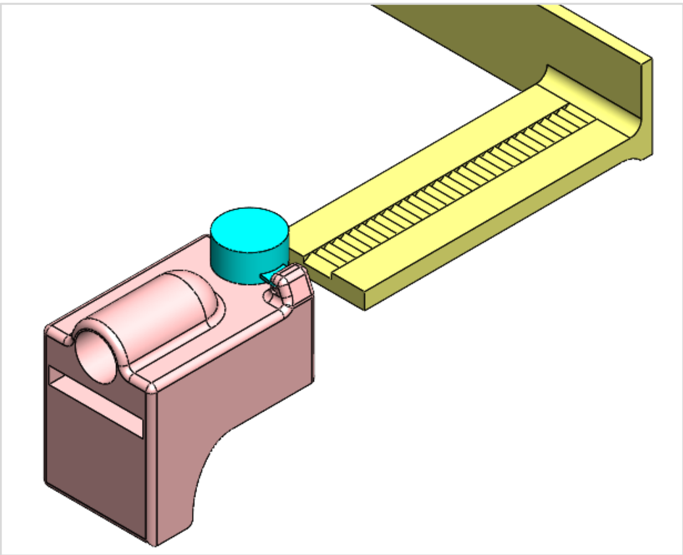


Figure 2 – Isometric View of the locking mechanism

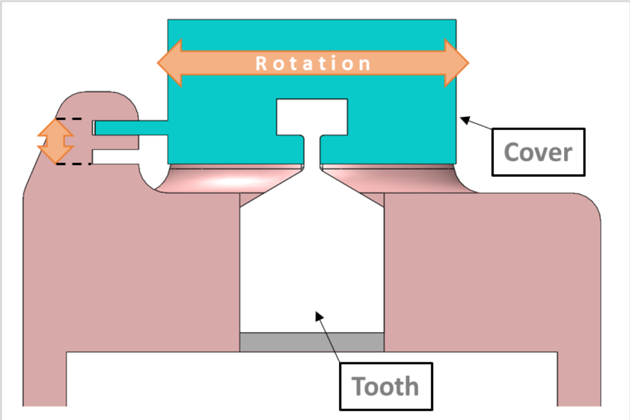


Figure 3 – Relation Between the Cover and the Tooth

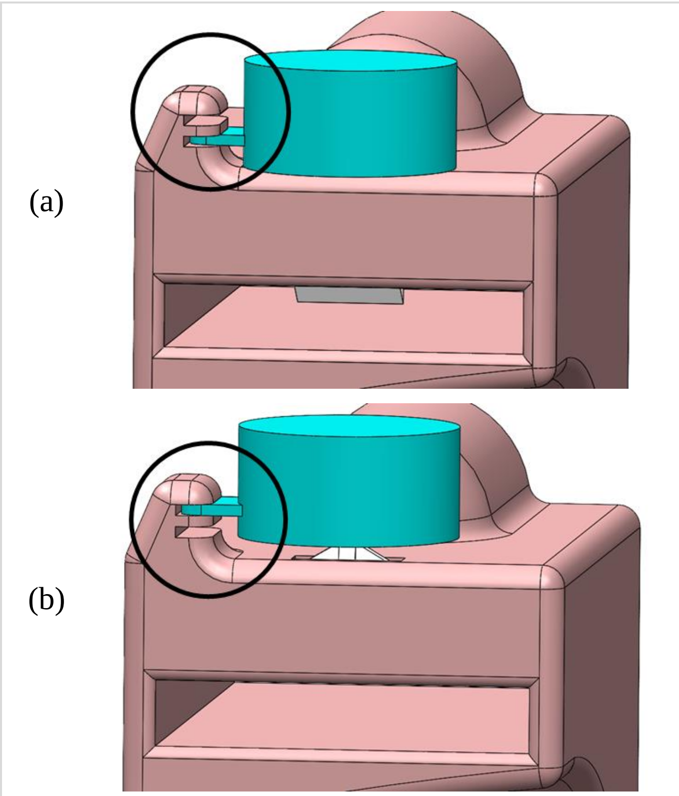


Figure 4 – Locked and Unlocked Position. a- Lower Position – Locked;
b – Higher Position - Unlocked

The lower region of the *Back Portion* is also equal for both versions and now accommodates two *Sliding Elements* (yellow parts) that replace the *Back Portion Element* (purple parts). (Figure 5) It is like the *Back Portion Element* but instead of the two pins for sliding, it has now a flat rectangular portion that slides inside the *Main Back Portion* (Green part). The new design also has in consideration the assembling process. Due to this concern were placed two covers on both ends (purple parts figure 5-b) to allow the *Sliding Elements* to be inserted.

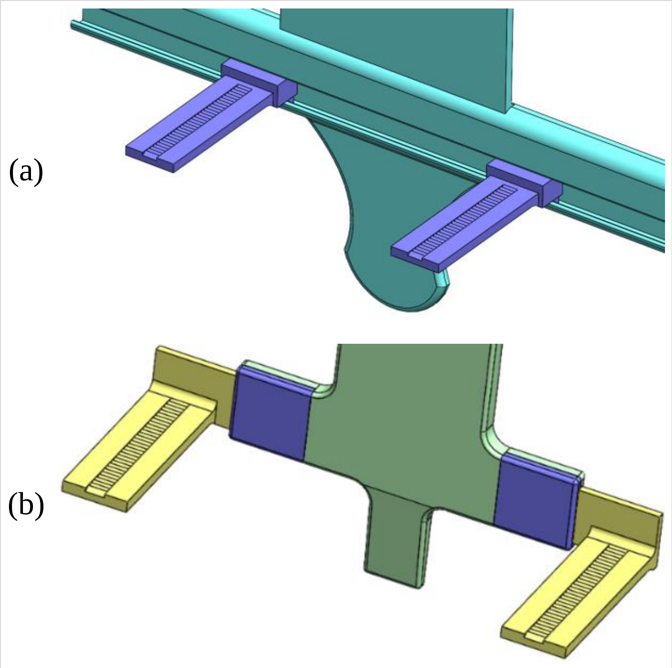


Figure 5 – Replacement of the Back Portion Element from the Previous Model to Sliding Elements in the Fifth. a- Fourth Model; b- Fifth Model

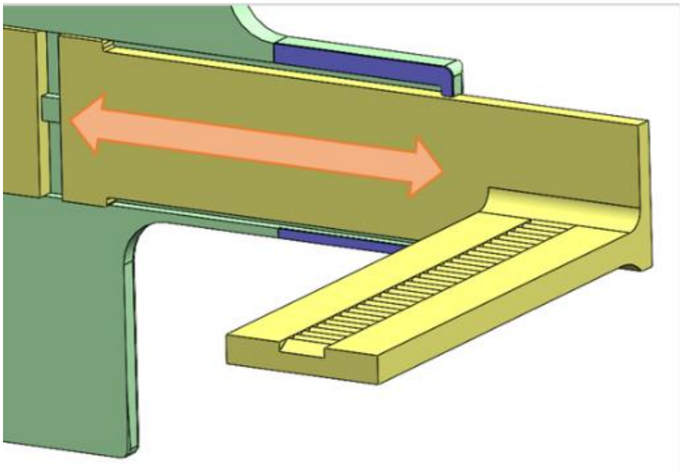


Figure 6 – Cut view of the Back Portion

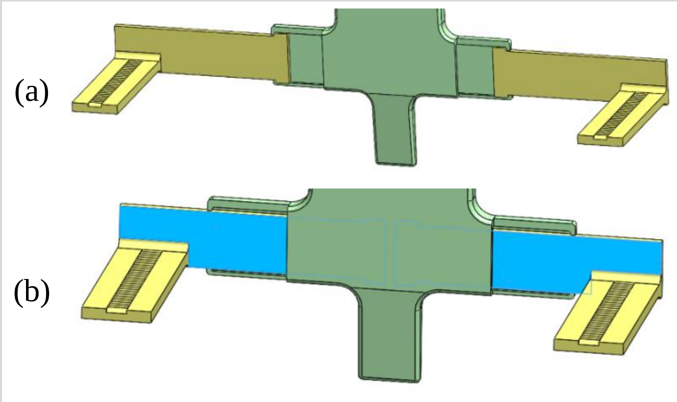


Figure 7 – Wider Position and Closed Position View of the Sliding Elements without Covers on the Main Back Portion. a- Wider Position; b- Closed Position

About the top region of the *Main Back Portion*, the front of this part is also common to both models, but the back of it it's different as in the second version there is a *Chin Strap* connected to it. Both have two round holes (Figure 8) ready to accommodate two *Balloons* that will be used to measure the pressure when fastening the cervical collar. The only thing distinguishing both models on the front, is the size of the cover. In the first version the cover is complete, and in the second one is only half it. As for the back, the presence or absence of two cylindrical elements to connect the *Chin Strap* is the way of distinguishing both parts.

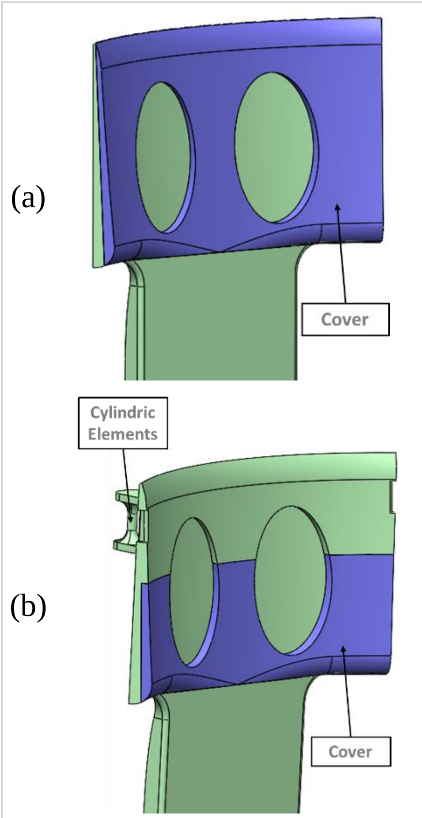


Figure 8 – Difference between the Front View of the Main Back Portion on Version One (a) and Version Two (b)

The *Balloons*' Development, its fundamentals and other topics related will be discussed in Chapter 3.2 in the main document.

The element that will force the head backwards (against the *Balloons*), beside the head's weight, is the *Chin Strap*. In Figure 9, it is possible to understand the direction of the forces that the *Chin Strap* makes on the patient's head. The directions represented, link the two support points for each version. On the first version it links the patient's chin and the *Mandible Support*, and on the second one links the patient's chin and the *Main Back Portion*. (Figure 9)

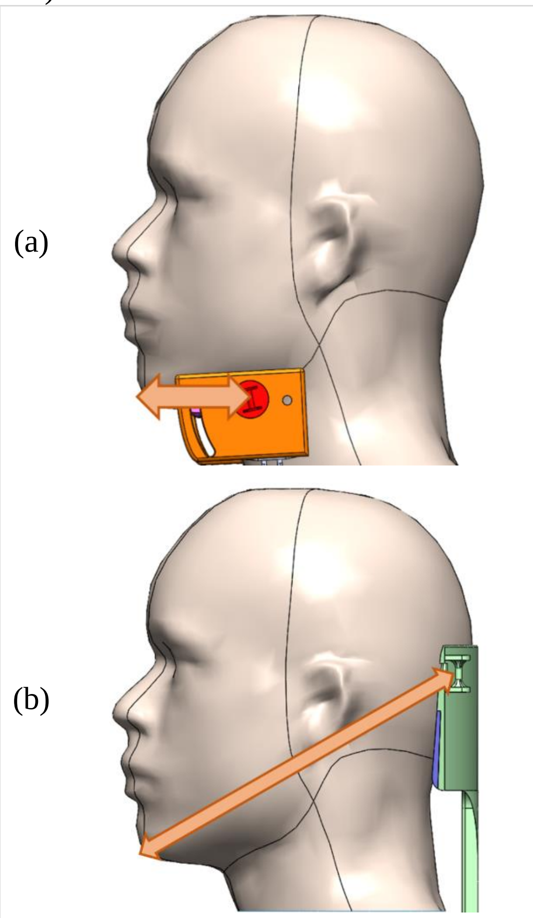


Figure 9 – Representation on Both Models of the Chin Strap Effort Direction. a- First Version; b- Second Version

As it is possible to see in figure 9, the version that can push the head backwards in a better way is the second. This happens because on the first one the *Chin Strap* might not apply enough effort to push the head back, as the *Mandible Support's* dimensions might reduce the ability of the strap to contour the chin and tighten it, and that way, not immobilise the patient efficiently. Another advantage of connecting the *Chin Strap* to the *Main Back Portion* is that when it is "closed" to force the head backwards, it is connected to an entire piece (*Main Back Portion*) and not a group of pieces that will be dependent on their locking mechanisms to keep the position when forces are applied.

Another feature of this model (both versions) is the different angled mandibles that it can support. (Figure 10) The *Mandible Support* is now built as two pieces, besides pins and locking mechanisms, and are presented on the figures with the orange (first version), brown (second version), and purple colour. As the *Chin Strap* is connected to a *Rotatable Element* (red part) on the outside of the *Mandible Support*, this is the only difference between both models (Figure 11).

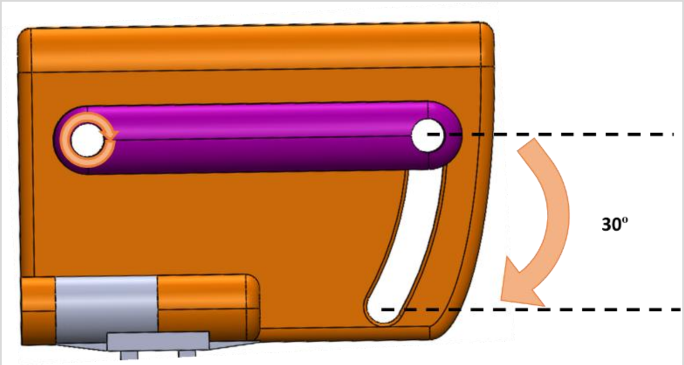


Figure 10 – New feature of Different Degrees Possibility on the Mandible Support

Figure 10 shows how the pink portion rotates in relation to the brown one around a pin hole and this movement allows for opening the patient's mouth or to better fit the different shaped mandibles (still missing the locking mechanisms). Its maximum degree capability is around 30 degrees from the horizontal position.

Figure 11 shows the opposite view of the *Mandible Support*.

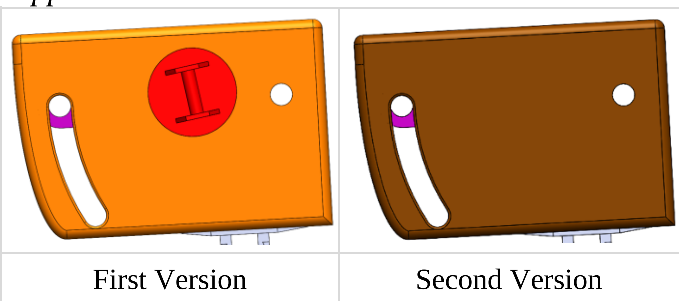


Figure 11 – Right View of the Mandible Support on Both Versions

For the following models, Version Two is the one applied due to the better characteristics represented in figure 9 and discussed in the subsequent lines of text.

Appendix F

In this model was changed the *Shoulder Support* for one that can offer a better immobilisation in combination with the structure, due to its extended contact area. It also benefits from two thin features on the shape that allows for the part to have increased elasticity, to better delimit the patient's shoulder shape, as well as not hurting it, due to its increased possibility to elastically deform. (Figure 1) On the other hand, because the top part of the Shoulder Support (the rectangular region on the side view) is locked on the *Sliding Elements* of the Back Portion, that elasticity will not affect the rigidity of the structure.

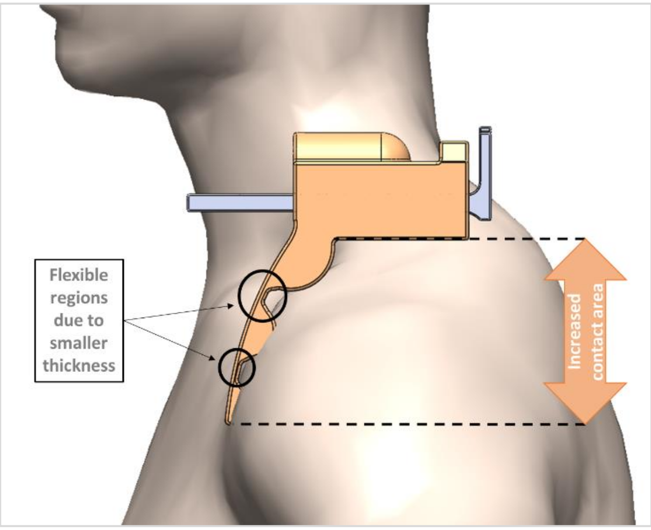


Figure 1 – Right View of the Shoulder Support

The absence of thin features as presented in Figure 1 would result in a much more rigid region affecting the concept of universal size as it wouldn't fit all the different shaped chests due to low deformation and pain caused.

To provide extra comfort for the patient can be added pieces of closed-cell foam on the flexible region, mainly on the contact region with the patient.

Appendix G

The seventh model represents the model with simplified locking mechanisms. These mechanisms are based on friction because they apply bolts.

Figure 1 is the assembly of this model in which the dark blue coloured parts represent all the parts that need to be moved for locking or unlocking the positions of the adjustments. The parts that had no changes remain with the standard grey colour.

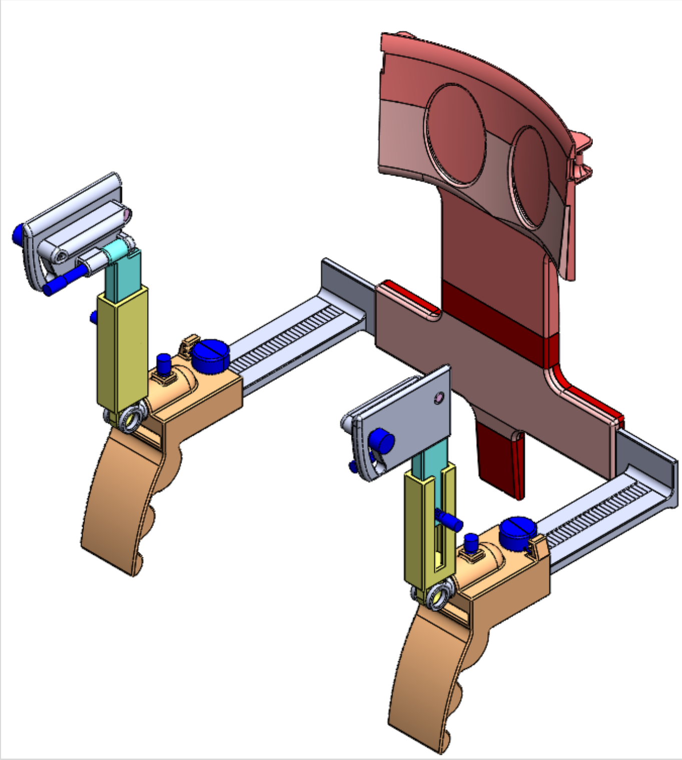


Figure 1 – Isometric View of the Seventh Model

There are still missing two locking mechanisms, on the *Rotational Element* (or eliminate this component as it was described as unnecessary on the third model), and on the *Sliding Elements* of the *Back Portion*.

From a printing and assembling point of view, the *Back Portion* will be split into four parts. Two that represent the *Covers*, one for assembling the *Sliding Elements* and the other to assemble the *Balloons* (Figure 2), and the remaining two are mandatory because the overall size of the *Main Back Portion* is impossible to print as one part on the used printer (bed size: 20x25 cm). (Figure 3)

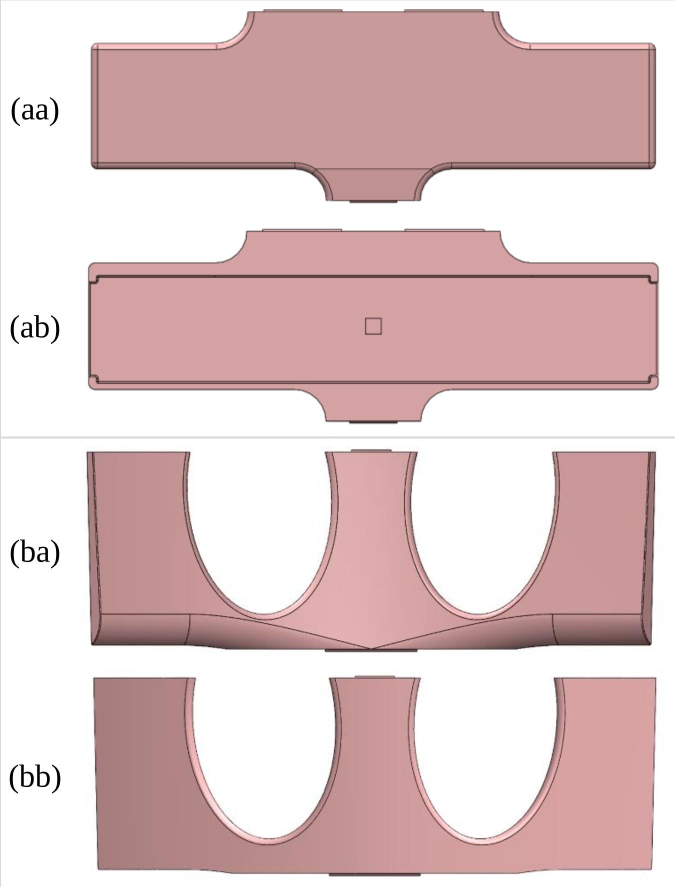


Figure 2 – Front (aa, ba) and Back (ab,bb) View of the Covers

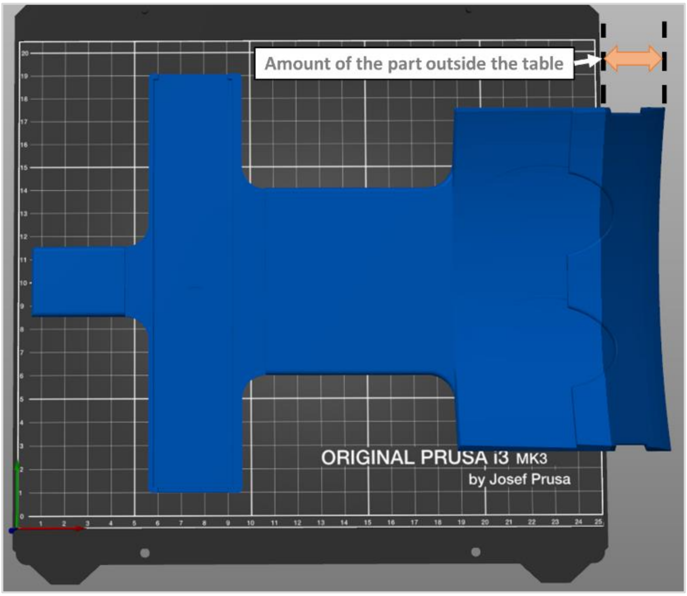


Figure 3 – Entire Main Back Portion on Prusa Software

Both *Covers* and the two separate parts of the *Main Back Portion* can be glued during the assembly. On the other hand, the *Main Back Portion* has some slots where small extensions of material on the *Covers* will fit and lock these parts (snap-fit), (Figure 5) which without glue, allows for the covers to be removed when the user wants to solve problems or replace components.

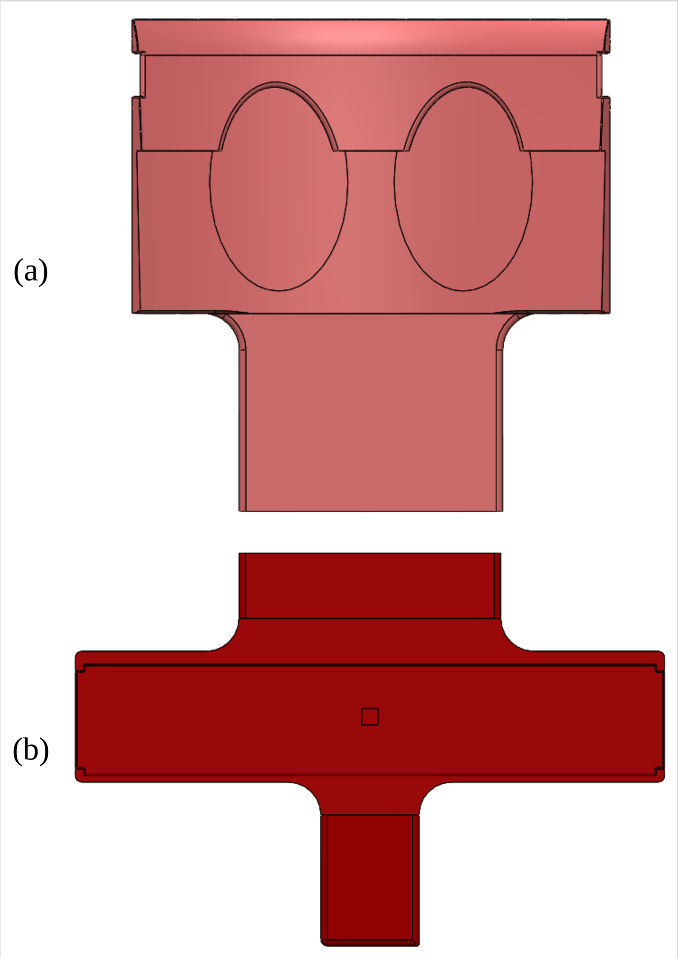


Figure 4 – Front View of the Top Part (a) and the Bottom Part (b) of the Main Back Portion

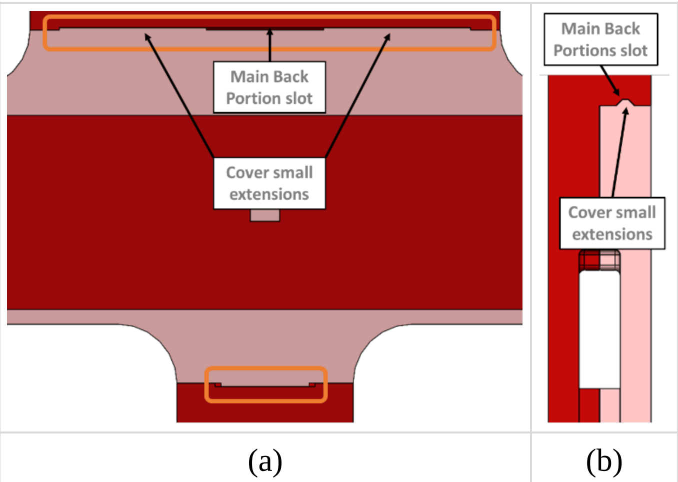


Figure 5 – Assembly of the Cover on the Main Back Portion. a – Front Cut View of the assembly; b – Left Cut View of the assembly

The *Button Cover* on the *Shoulder Support Element*, from the printing point of view, was split in half and is supposed to be glued on the assembly process. If this part wasn't split in half, when printing it, the *Tooth* needed to be printed inside it, which could result in printing errors like the fusion between the two parts, due to its reduced tolerances.

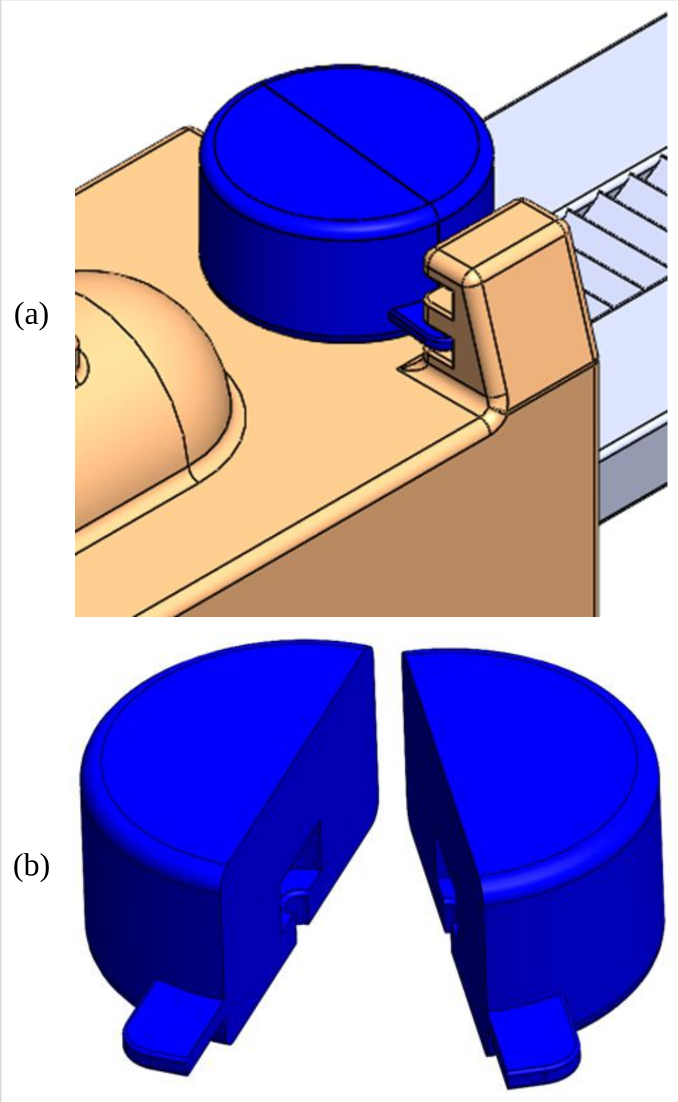


Figure 6 – Button Cover in the Assembly (a) and Split View (b)

Concerning the *Shoulder Support* and its locking mechanism, in this case, it is guaranteed with the application of a bolt. This bolt will have two functions: not allow for the *Rotational Element* to get out from its housing (Figure 7 –a), and to lock its rotation by applying some effort against it (Figure 7 -b). The mechanism will rely on friction which means that the surfaces can be worked (design or post-processing) in order to increase it. The region that must be worked is delineated in Figure 7 – c with a green colour and it concerns all the parts, the *Bolt*, the *Shoulder Support*, and the *Rotational Element*.

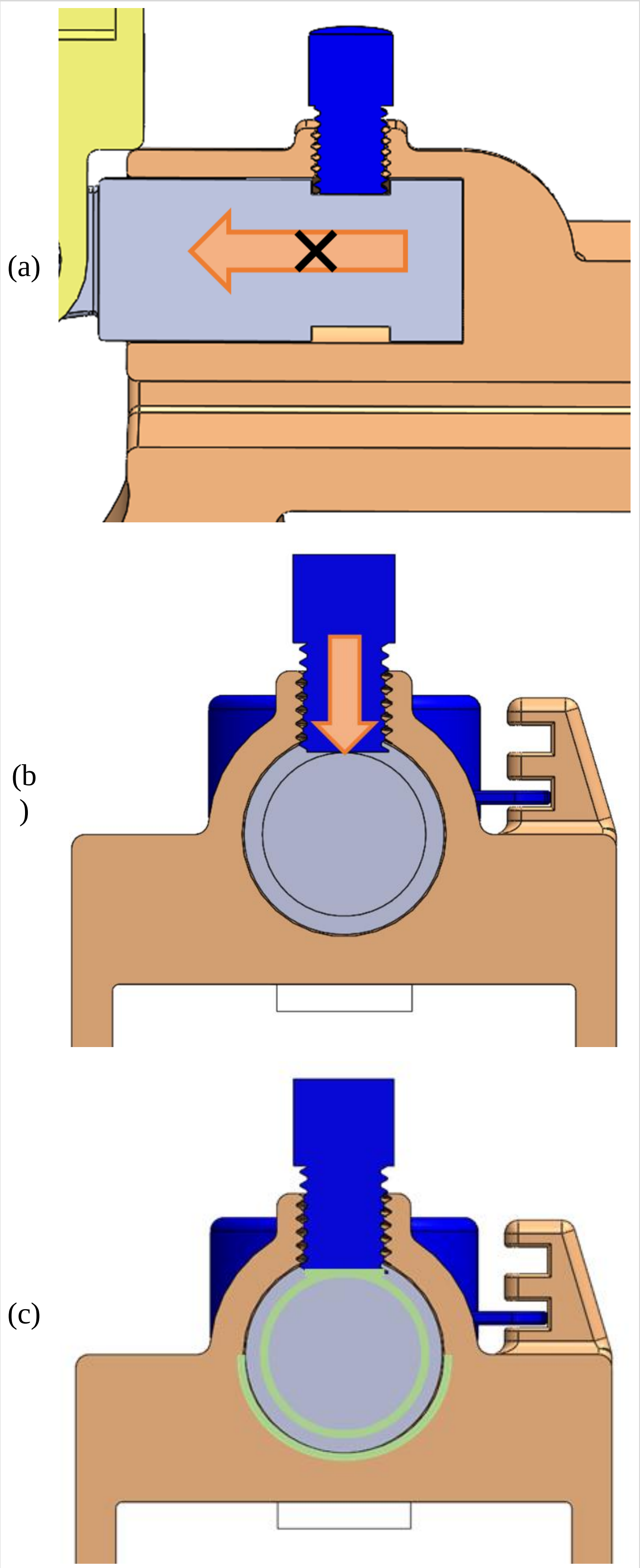


Figure 7 – Different Views of the Locking Mechanism. a – Right View Cut; b – Front View cut; c- Front View Cut with Green Marks

For the *Shoulder-Mandible Element*, the same bolt method was applied. (Figure 8) In this case, the bolt is supposed to lock the inner part of the telescopic adjustment relative to the outer one. In this group, the surfaces can also be worked to increase friction. The regions that need friction improvement are presented in Figure 9 with green colour.

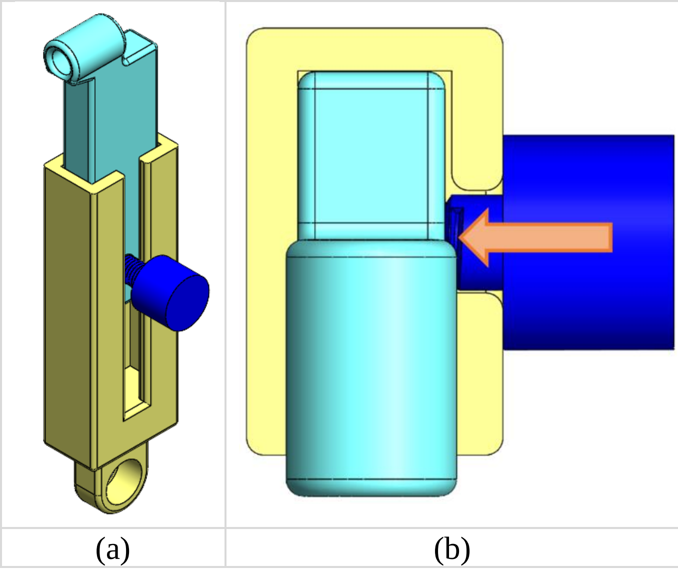


Figure 8 – Isometric (a) and top (b) view of the Shoulder-Mandible Adjustment Mechanism

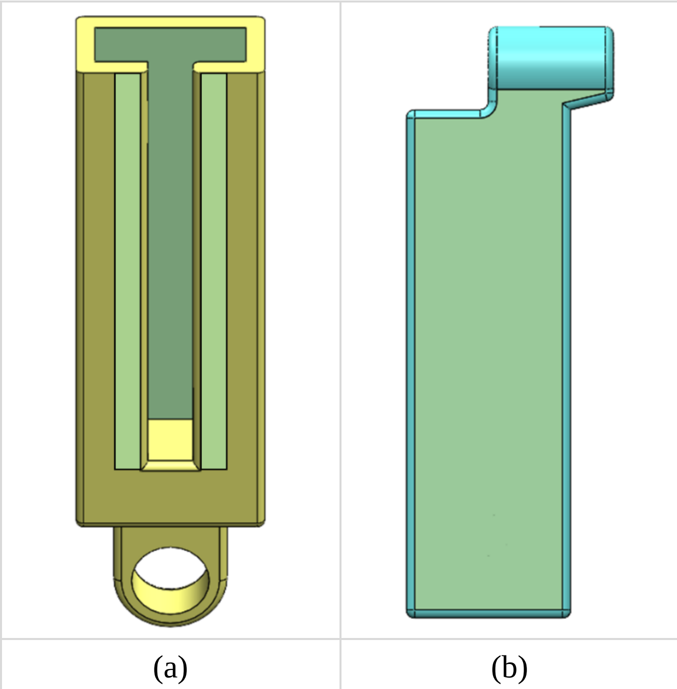


Figure 9 – Regions that Might Need Work in order to Increase Friction Between Parts. a – Front View of the Outer Part of the Shoulder-Mandible Element's Telescopic Adjustment; b – Back View of the Inner Part of the Shoulder-Mandible Element's Telescopic Adjustment

The *Mandible Support* has two locking regions, in the connection with the *Shoulder-Mandible Element*, and to lock the rotation of the *Mandible Adjustment Element*. In this case, the *Bolt* from the mentioned connection occupies the space that is needed for the 30 degrees adjustment on the mandible. Due to its volume and space occupied, that 30 degrees range is reduced. As this is a temporary solution, this problem isn't alarming. (Figure 13)

Figure 10 shows the *Bolts* on the assembly (dark blue parts) and their position relative to the remaining assembly.

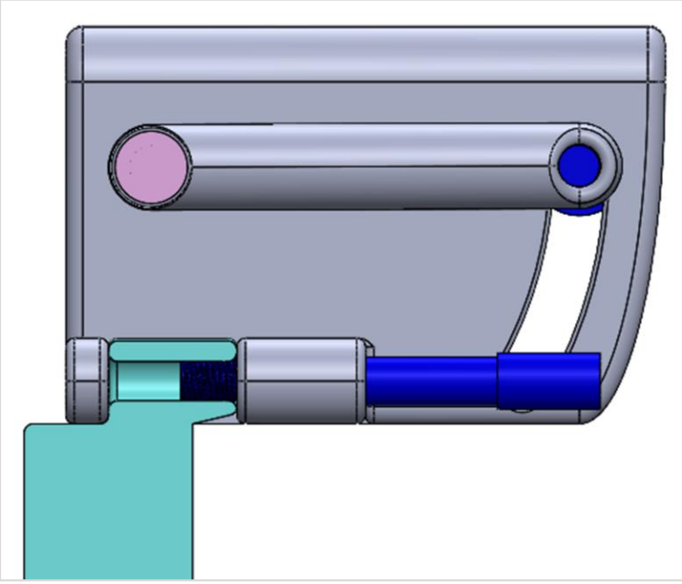


Figure 10 – Left View of the Mandible Support assembly

The *Bolt* on the connection is supposed to pull the threaded region (Figure 11 – 1), relying on the elastic properties of the material, and tighten the *Shoulder-Mandible Element* in order to lock the rotation. Once again, the locking mechanism will be based on friction and torque applied. (Figure 11)

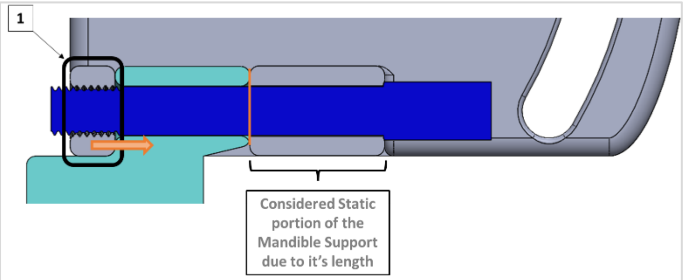


Figure 11 – Bolt Tighten Effect on the Structure

The region where the friction should be increased to difficult the movement between pieces is shown in Figure 12 with green colour. The lines refer to the whole circle that is in contact in this region and to both parts.

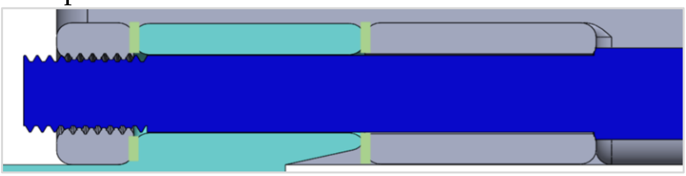


Figure 12 - Regions Where the Friction Should be Increased

As mentioned, the positioning of the bolt relative to the remaining *Mandible Support* parts, decreases the degree of rotation of the *Mandible Adjustment Element* from 30 to ≈19.4 degrees. (Figure 13)

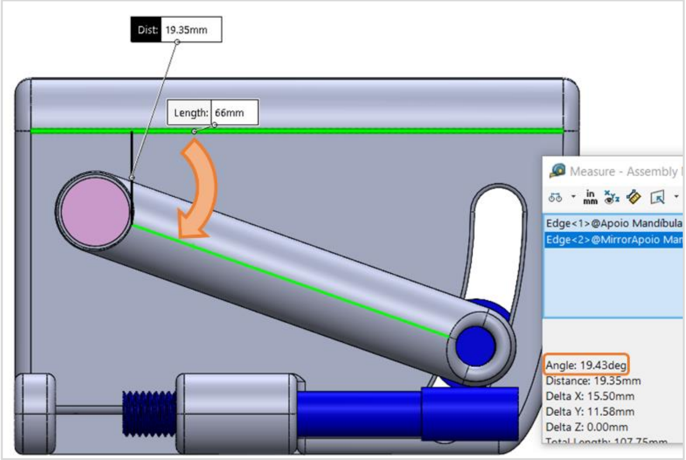


Figure 13 - Degree of Rotation of the Mandible Adjustment Element

Concerning the production of this model, the *Main Back Portion*, the *Mandible Support* and its mechanisms, the *Shoulder-Mandible Element*, and a portion of the *Sliding Elements* were printed for testing purposes. The colours on the CAD model and the printed pieces may not match as they are just for testing purposes.

As mentioned, the *Main Back Portion* is printed in two parts. Figure 14 shows the lower part of the Main Back portion printed. It was printed with guiding pins for a perfect fit when this part and the top one are glued.

Figure 14 – Lower Part of the Main Back Portion Printed

The *Main Back Portion* fully assembled is presented in figure 15. It shows some problems like the ability for securing the *Lower Cover*, which is too loose on both ends as the snap-fit is only in the middle (can be solved with glue or a new design).

Figure 15 – Main Back Portion Assembled with the Loose Regions Signalled with Orange Contour

About the *Shoulder-Mandible Element* and the *Mandible Support*, they were printed and assembled. Independently, they work how they are supposed to but, when assembled, some conditions aren't verified. The problem found was the degree of rotation that the *Mandible Support* can have in relation to the *Shoulder-Mandible Element.* These elements shock at a certain angle reducing their ability to fit every person. (Figure 16)

Another problem that can be identified is the non-existence of a locking mechanism that prevents the inner part of the telescopic adjustment to come out on its maximum position. (Figure 17)

One already presented problem (Figure 13) is the reduced angle of rotation from the *Mandible Adjustment Element*, as the *Bolt* that is supposed to lock the rotation between the *Mandible Support* and the *Shoulder-Mandible Element* is in its way. If we use a shorter bolt, it will be too difficult to tighten or loose it as the fingers won't be able to rotate the bolt due to a lack of space and grip. (Figure 18)

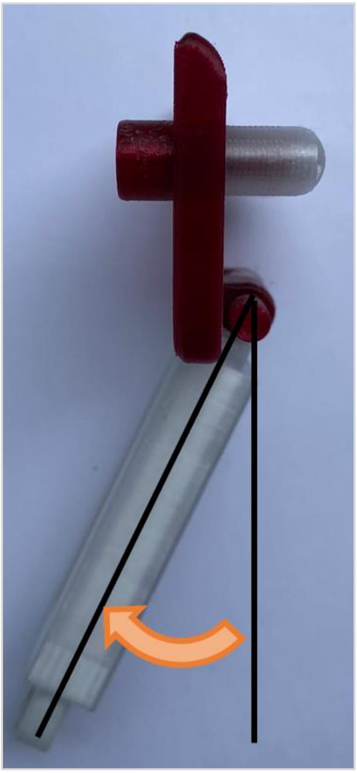


Figure 16 – Rotation Angle Between Mandible Support and Shoulder-Mandible Element

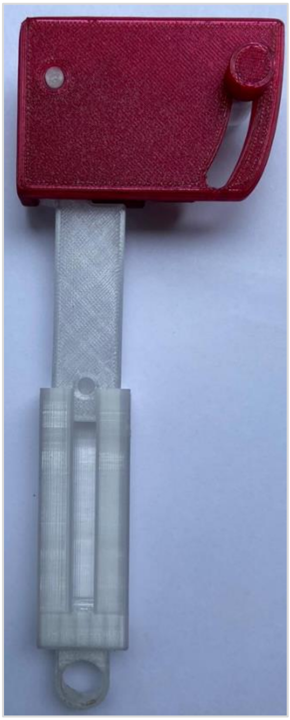


Figure 17 – Mandible Support and Shoulder-Mandible Element Assembly

Figure 18 – Mandible Support's Reduced Angle Adjustment

The last point to be noticed is the grip that the *Bolt's* shape offers. As they are smooth, sometimes the job of tightening or loosening the bolts might get difficult.

In Figure 19 it is possible to see a printed portion of the *Sliding Element*.

Figure 19 – Sliding Element Portion

Appendix H – Final Prototype

The Final Model is the combination of improvements and final versions of many intermediate parts.

As is possible to see, many of the adjustments made to those intermediate parts were due to the existing production method. It also matches in time the development of the other hardware components for the electronic improvements, like the balloons, and many changes were made to accommodate them.

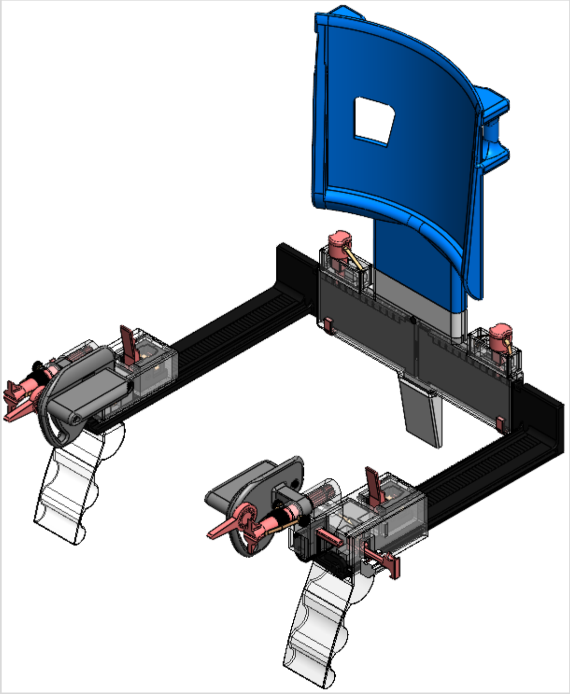


Figure 1 – Final Model's Assembly Without the Balloons

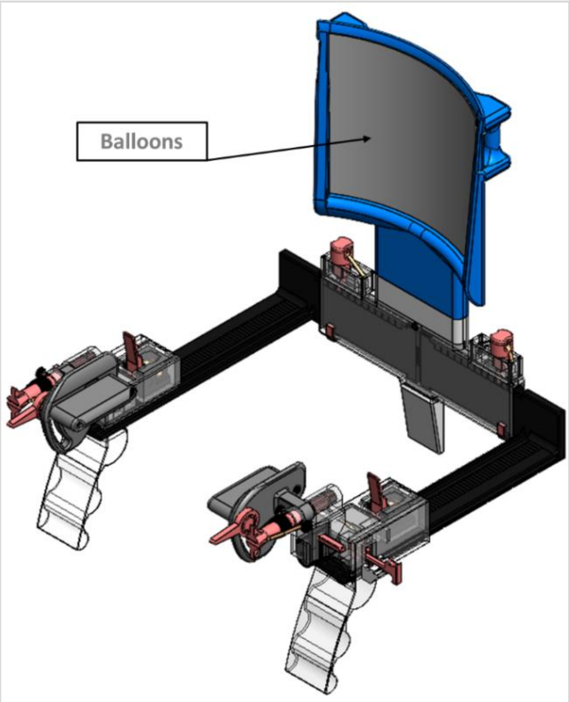


Figure 2 - Final Model's Assembly with Balloons (Not Inflated)

Figure 2 presents the eighth and final model with the balloons (grey part) assembled. They are displayed in their empty condition (not inflated) and present a round but straight surface that when inflated, gives form to the balloons. (Chapter 3.2 of the Main document).

The development process passed through various intermediate versions until achieving the final prototype configuration. The presented models (1-7) suffered severe changes/improvements between each other, representing big steps and differences in every model. When compared to the Final Prototype, it also presents a severe change, but at this point, the improvements were achieved in combination with production and testing.

Every part will be presented and explained by sections, usually where a locking mechanism is needed.

Back Portion (Main Back Portion and Sliding Elements)

On this portion, as the structure itself was already defined, the most important changes that are needed when relating to the previous models are the locking Mechanism for the *Sliding Elements*, the redesign of the top part to accommodate the *Balloons*, and to solve the cover's loose problem diagnosed on the previous model print.

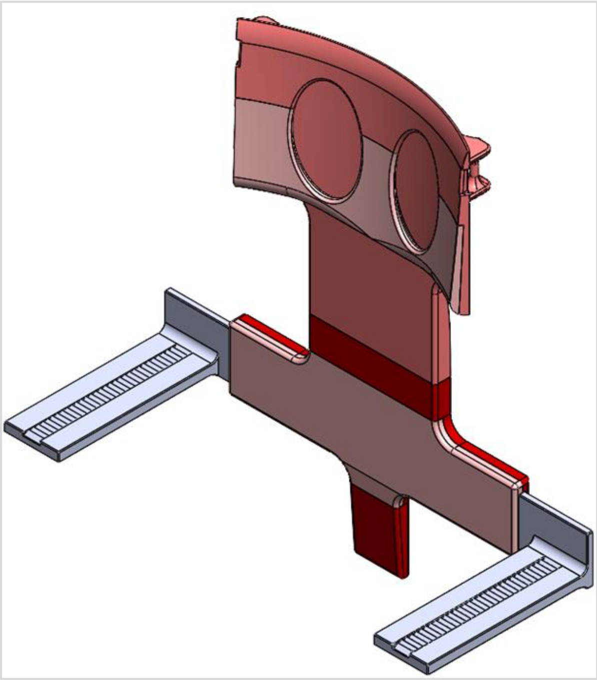


Figure 3 – Model Seven Back Portion Assembly

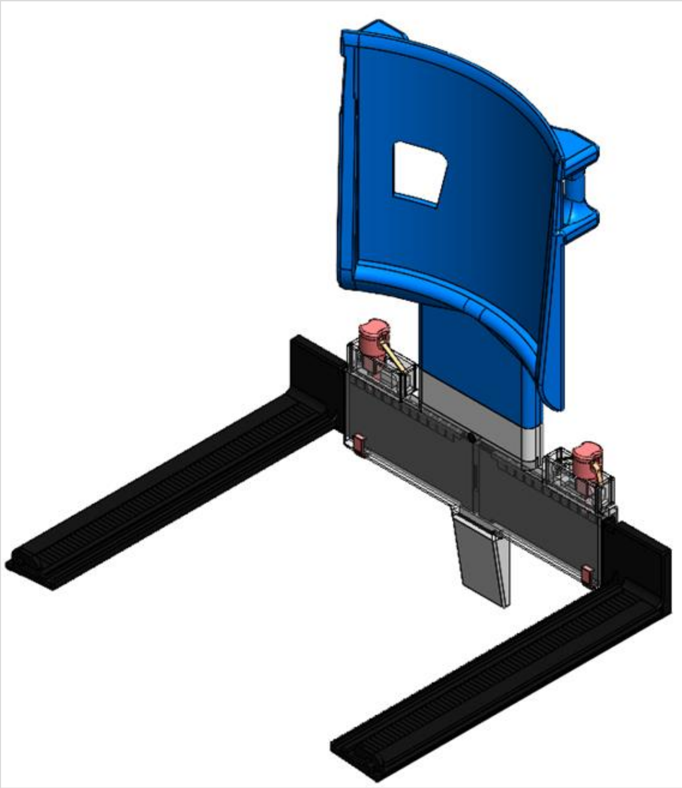


Figure 4 – Final Model's Back Portion Assembly

Concerning the *Top Part* of the *Main Pack Portion* (Blue part Figure 4), this last prototype doesn't present any cover to secure the balloons as they were designed with a tight fit that doesn't allow them to move. In this case, the part was designed for them to slide through guiding slots on each side (Figure 5). As the balloons must be inflated with air they must have an inlet, so the Top part presents a hole (Figure 5) to allow an after-positioning connection to the balloons. This will be achieved with a hose that will pass through it.

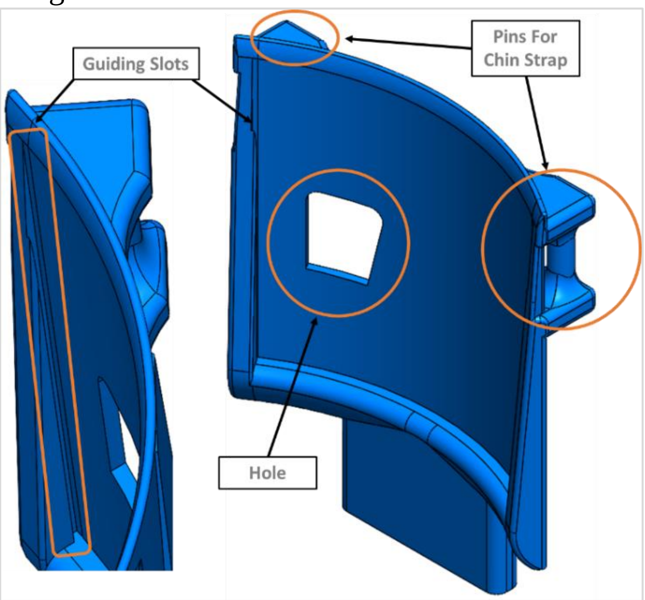


Figure 5 – Detailed Top Part of the Main Back Portion

The remaining characteristics of this part, like the pins for connecting the Chin Strap on the Back, were kept.

For printing the *Top Part*, it was positioned on the printer bed in its standing position. It required some supports for the back pins and for better detail in the top wall of the hole (despite not being necessary because its quality isn't relevant), as well as for printing the region that creates the bottom of the T letter (Figure 6). The direction of printing was the most favourable for keeping tolerances on the guiding slots as the layered deposit doesn't present any degree that might condition or change the CAD model dimensions.

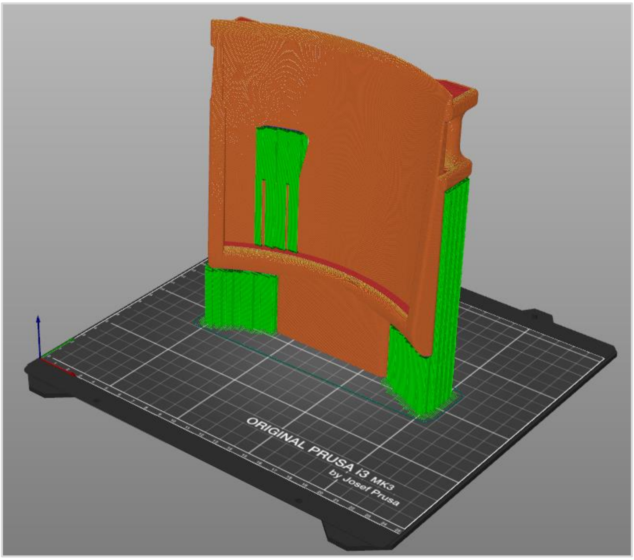


Figure 6 – Printing Preview on PrusaSlicer Software

Figure 7 – Printed Top Part of the Main Back Portion

Concerning the *Lower Part* of the *Main Back Portion*, it is now possible to lock the position of the *Sliding Elements* and to secure the cover in its full length.

The *Lower Part's Cover*, which on the previous model was assembled with a snap-fit, is now assembled by sliding it. (Figure 8) It has reduced tolerances and big interference regions with different shapes ensuring that the cover has a tight fit. This allows for the remaining structure to be more rigid and so to perform better its function.

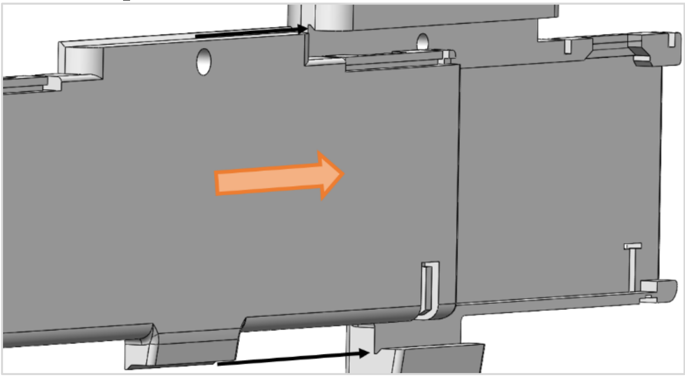


Figure 8 – Sliding Direction of the Cover for Assembling

The interference between both parts ensures that the *Cover* on that region doesn't move in the perpendicular direction of the sliding movement (Figure 9). To lock the cover on the desired position and to prevent further movement in the sliding direction, was added a pin (Black Colour Figure 10) that intersects both parts locking its movement between each other.

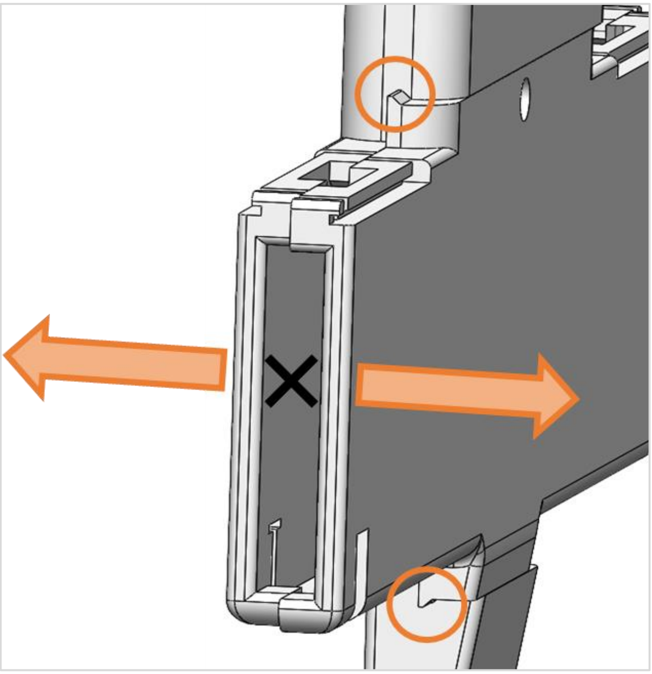


Figure 9 – Perpendicular Movement to the Sliding One Not Allowed

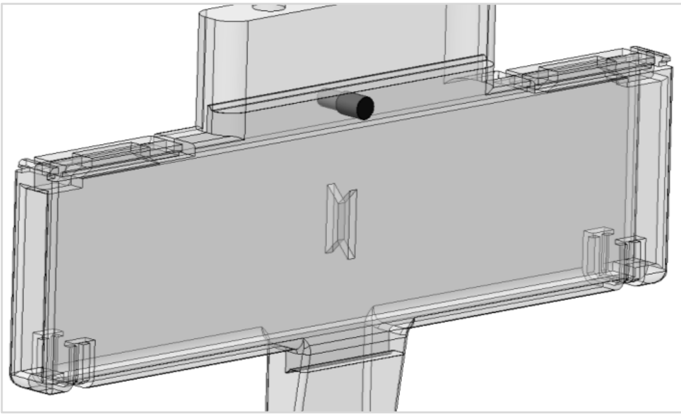


Figure 10 – Lower Part of the Main Back Portion and its' Cover Assembled with the Pin

For the locking mechanism, the solution found was to create small slots on the *Sliding Element* and to add a *Tooth* (pink part on Figure 11) that would engage in those slots. As the *Tooth* would be static when in the locked position, there wouldn't be any further movement from the *Sliding Element*. To unlock the movement, the *Tooth* just needs to be pulled or removed.

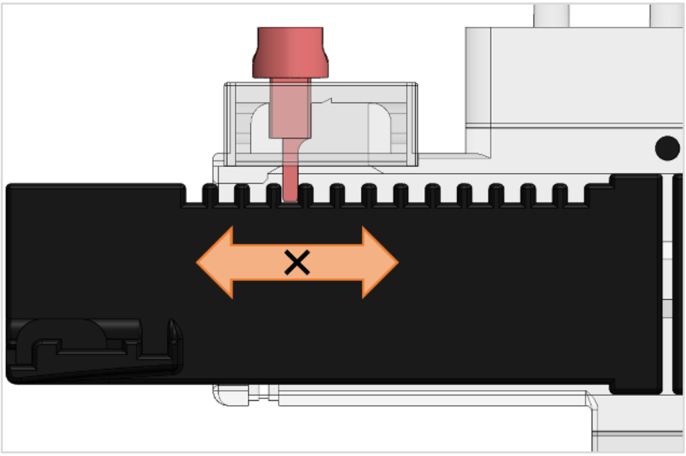


Figure 11 – Final Prototype's Sliding Element with the Tooth Engaged

To prevent the *Sliding Element* from escaping from the sliding house on the *Main Back Portion*, both parts present extensions that will shock when in their maximum extended position (Figure 12). Also, due to its tight fit and constraints applied, the misalignment between the *Sliding Element* and the sliding movement direction is very low. The only misalignment verified on the printed assembly is due to the tolerances given for printing. Figure 13 shows the misalignment about a straight line (ruler). In total it presented a vertical variation of around 5mm on its extended position which is the most fragile position and probable of having a bigger variation.

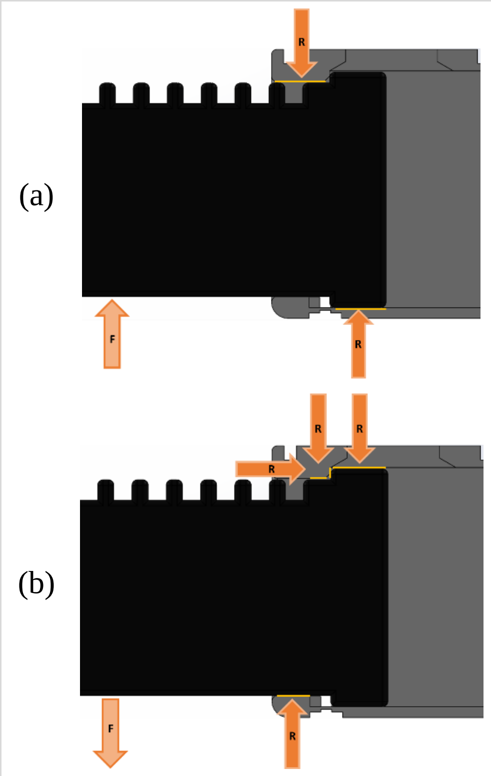


Figure 12 – Movement Constraint When Forces are Applied to the Sliding Element in Different Directions (Only Main Reactions Signalled)

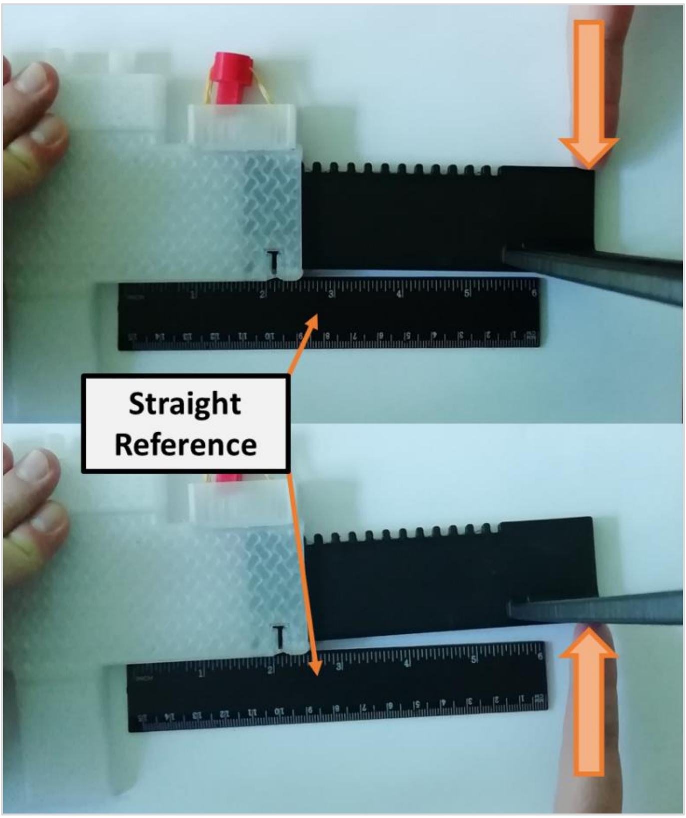


Figure 13 – Position Variation with the Reference According to each Force Direction

For keeping the *Tooth* static when in the locked position (engaged) was created a *Structure* that allows for the pin to be lifted and secured. This *Structure* also creates a support for the *Elastic Bands* and eliminates the loose verified on the ends of the cover as was possible to see in Figure 15 from Appendix G.

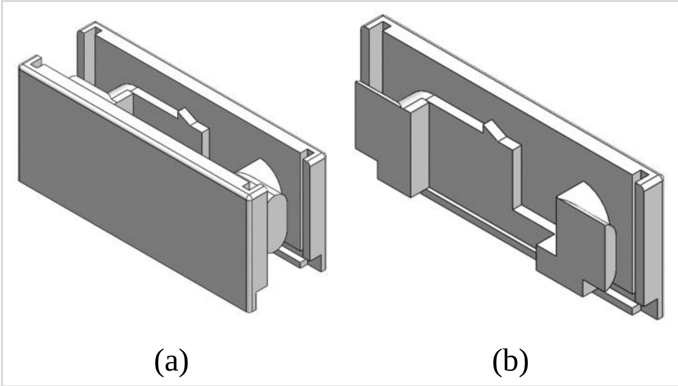


Figure 14 – Isometric (a) and Cut (b) View of the Structure

First, understanding the method for assembly of this *Structure* will help understand how it eliminates the loose ends as well as how it offers a securing mean to the tooth. Like the *Cover* in Figures 8 and 9, this *Structure* is also slid to its position so, as it is an entire piece and due to the way that it is assembled on the remaining cervical collar's structure, it compresses the ends of the *Cover* and the *Lower Part* of the *Back Portion* against each other. (Figure 15 and 16)

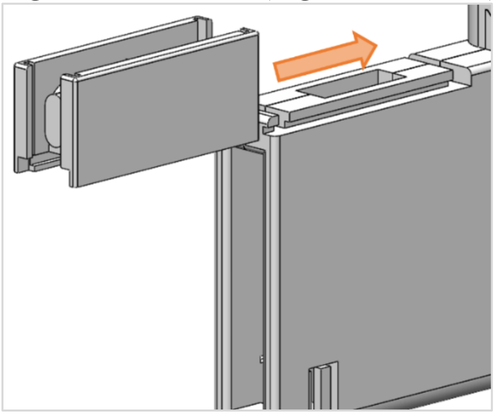


Figure 15 – Tooth Structures Assembly Direction

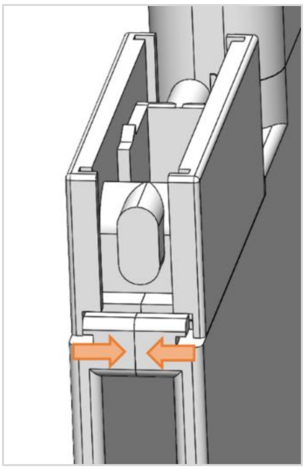


Figure 16 – Cover and Lower Part Compressed Against each Other

This *Structure* allows for lifting the *Tooth* and locking the position. On the other hand, as the cervical collar is a device that has some movement (when being applied or even when transporting the patient) is needed a security that prevents the *Tooth* from disengaging or getting lost. The application of an *Elastic Band* allows not just to secure the *Tooth* on the assembly as well as for fast locking caused by their spring effect. When considering the *Elastic Band* size, there should be aware of the fact that it must be tensioned when the *Tooth* is in its locked position. Figure 17 shows how the *Elastic Band* (brown colour) is secured on the Structure and how it secures the *Tooth*.

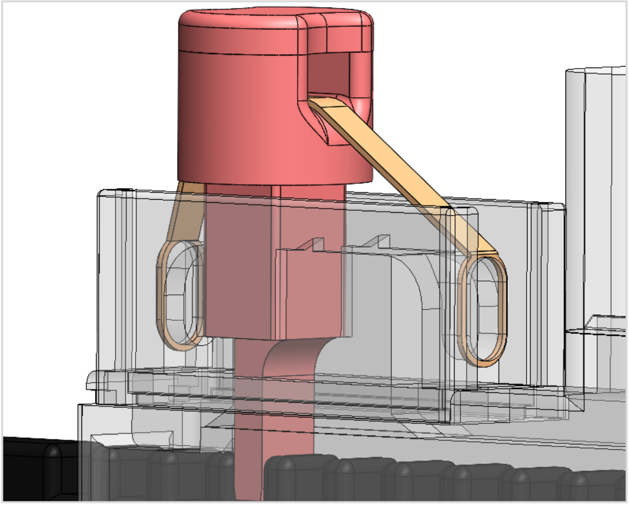


Figure 17 – Elastic Band Securing the Tooth in the Locked Position

Figure 18 shows a cut view of the *Structure* with the button in the locked and unlocked position. As it is possible to see, on the unlocked position figure, there is a small indentation whose function is to prevent the *Tooth* from sliding into the locking position. Due to the *Elastic Band* tension, the tooth gets locked against the indentation.

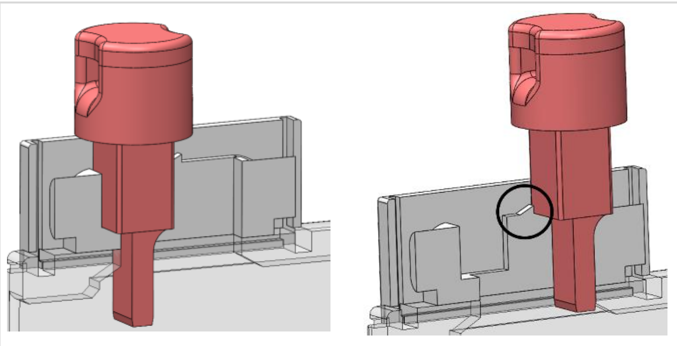


Figure 18 – Locked and Unlocked Position of the Tooth on the Structure

To lock the *Structure* in the sliding direction two *Covers* on each side of the structure were added. These *Covers* allow to secure the structure in relation to the remaining parts and to prevent the *Elastic Bands* to get out of position. (Figure 19 and 20)

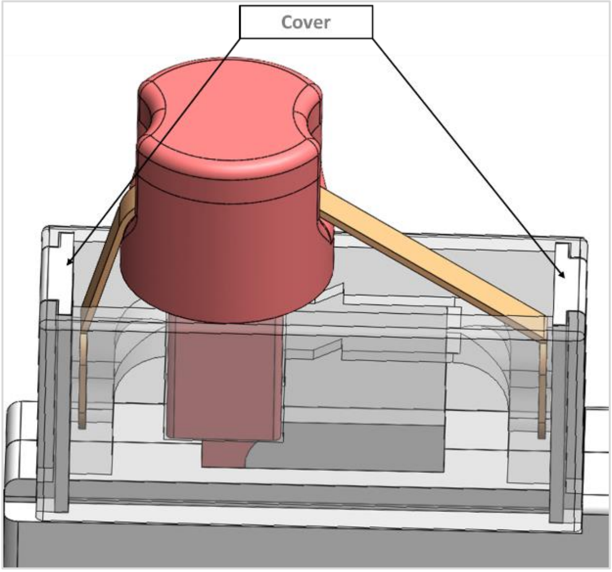


Figure 19 – Full Assembly of the Sliding Elements' Locking Mechanism

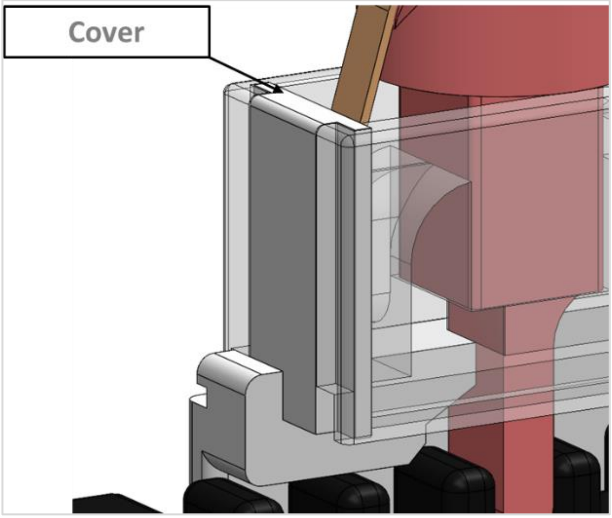


Figure 20 – Better View of How the Cover Fits the Assembly

Since the *Tooth Structure* ensures that in that region the *Lower Part* and the *Cover* are compressed (which after tests is enough) there was also added two *Clips* that ensure that the bottom of the *Lower Part* doesn't get loose, compressing both mentioned parts against each other. (Figure 21)

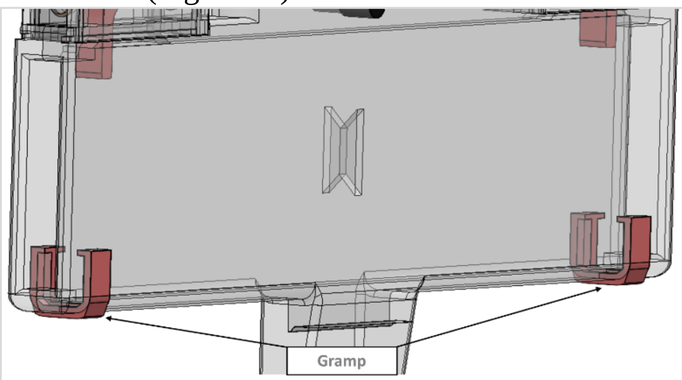


Figure 21 – Gramps to Compress the Lower Region of the Assembly

Concerning the dimensions of the *Back Portion* fully assembled, figure 22 shows the overall dimension of the *Main Back Portion*, and figure 23 the dimensions of the *Main Back Portion* with the *Sliding Elements* on their closed and extended position.

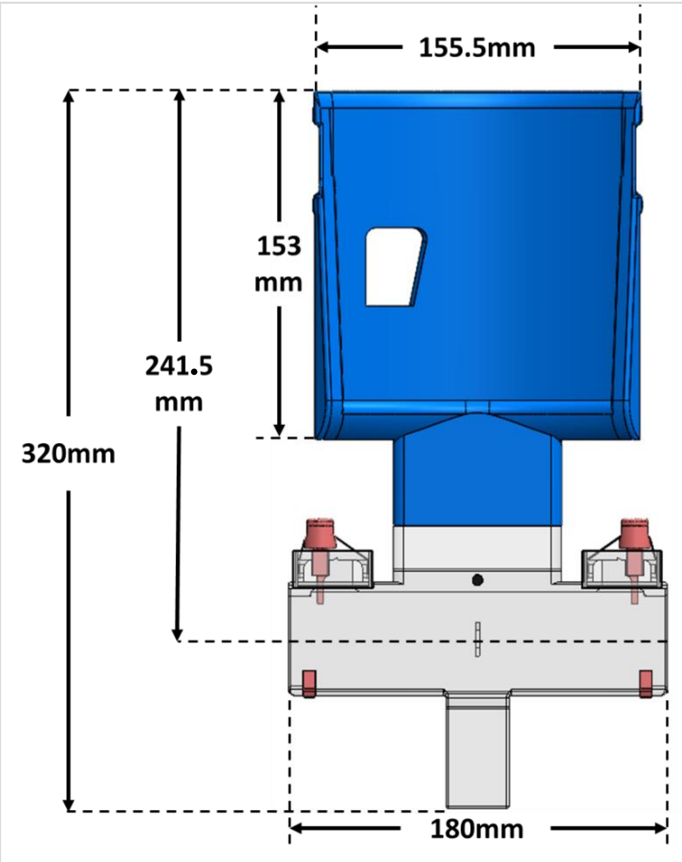


Figure 22 – Overall Dimensions of the Main back Portion Assembled

These dimensions were based on the measures taken by Knowing, 2017 (Annex 6). For the shoulder dimension, the minimum and maximum values for Women and Man were respectively 365 and 495 mm.

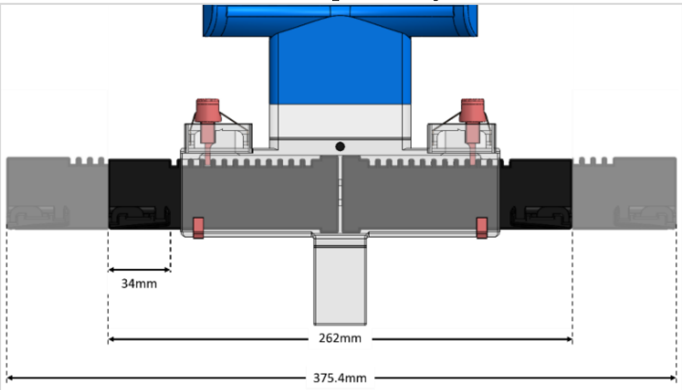


Figure 23 – Closed and Extended Dimensions of the Sliding Elements

As the *Sliding Elements* will settle between the end of the shoulders and the neck/head (knowing that the neck in healthy conditions is smaller or equal to the head diameter), it is important to also know that distance. The maximum value is 165 mm and the minimum 135 mm. Calculating the distance between the inner region of the sliding elements on its closed position, it is around 196 mm (distance=262-34-34), which means that on the closed position, the distance can accommodate people on the presented range. The remaining adjustment allowed it to better settle on different shoulder widths. For the top part of the *Main Back Portion*, its dimension is not that important as the patients won't rest their heads directly on it, but on the balloons.

Concerning the printing position of the parts, the biggest concern was to keep the tolerances by trying not to print them with supports on sliding guides or in such a position that the material weight could cause any warp. In some cases, it is inevitable, and the part needs to be printed in one of those conditions. For those, it is needed longer post-processing because apart from the removal of the supports, in some cases, as the supports affect the tolerances it is necessary to file to achieve the desired dimensions. This is the case of the *Lower Part* and its *Cover* where there were needed supports on the sliding guides and some extra work to re-establish the desired tolerances. (Figure 24)

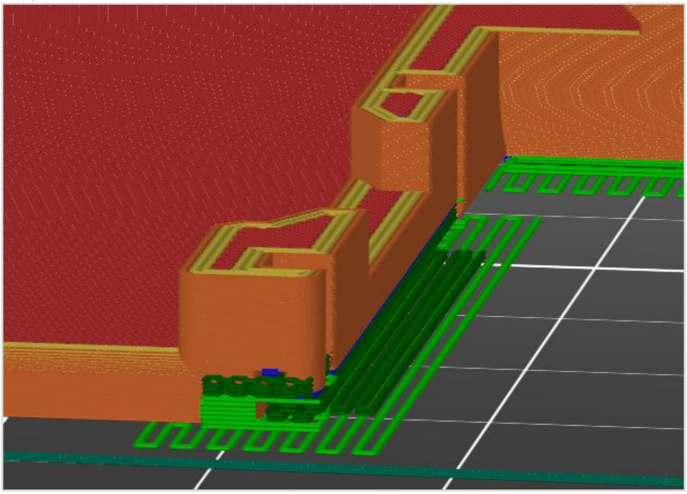


Figure 24 – Detailed View of the Supports (Green) on the Sliding Guides

It was chosen to print this part with its largest flat area against the printer bed as they are the touchable parts, and this position increases surface quality. Any other position would require a bigger amount of support material. (Figure 25)

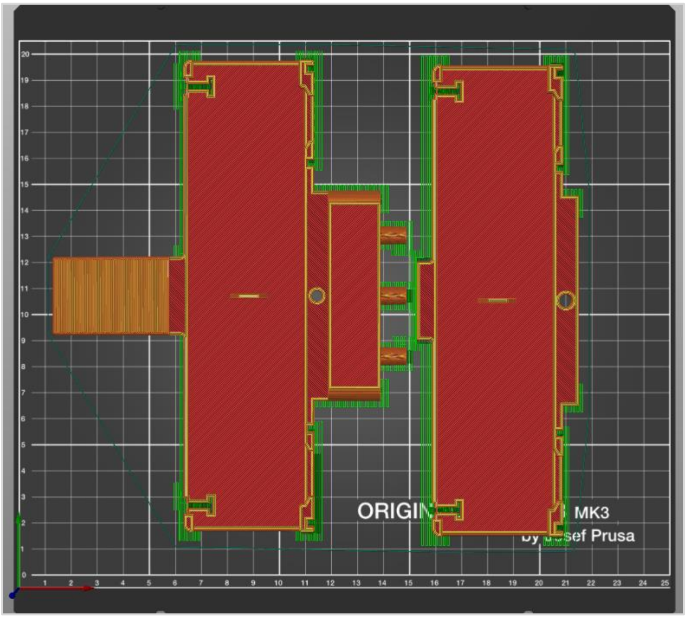


Figure 25 – PrusaSlicer's Software Print with the Parts Positioning on the Table

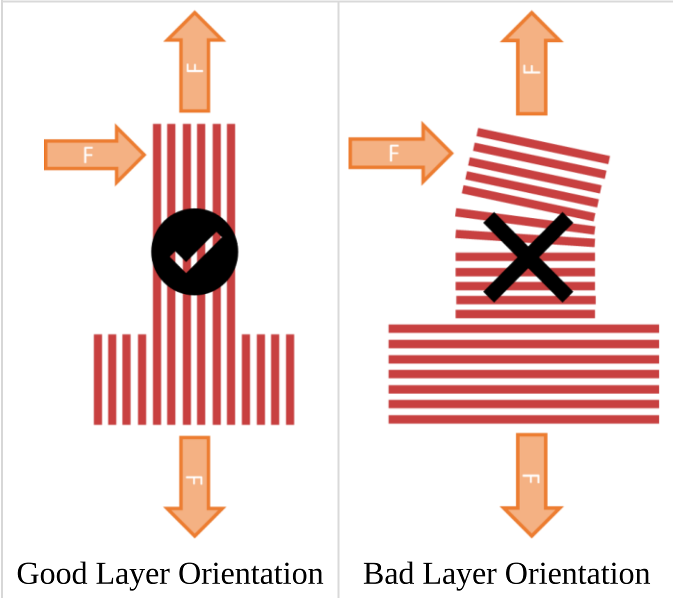


Figure 27 – Differences Between Good and Bad Layer Orientation

Figure 26 presents PrusaSlice's software prints of the parts that don't need any support material position. Besides that, the ideal print for the tooth and the pin is on its longitudinal position due to the transversal efforts verified on the application and caused by the slide efforts of the *Sliding Elements*. (Figure 10) In this case, the difference in the orientation of the layer's deposition benefits the strength of the part as it doesn't rely on adhesion properties but material ones. This happens because the molecular bonds created by the extruder are always stronger than those created by layer deposition. (Figure 27)

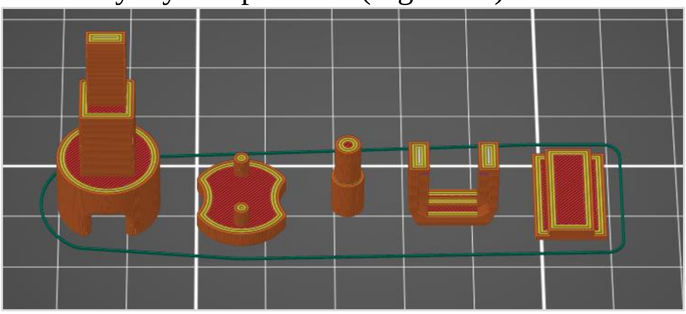


Figure 26 – Positioning of the Non-Supported Parts on the Bed

Some parts of figure 26 have bridging regions where the software recommends support. The decision was to print them without any supports as the bridging regions don't have any tolerance necessity or where it was considered that the printer was able to bridge without many warps. This saves post-processing time and doesn't affect the prototype's final purpose.

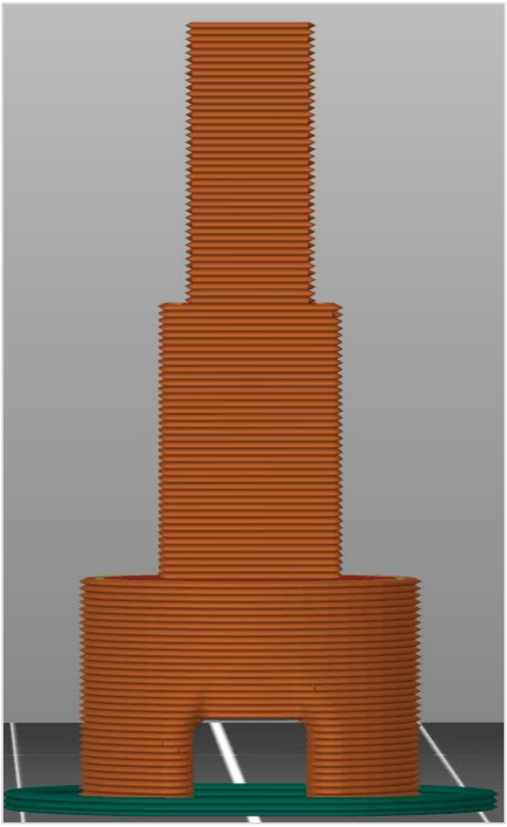


Figure 28 – Detailed View of Layers orientation

The *Tooth's structure* due to its complex shape needs to be printed in such a way that will receive supports on the sliding guides conditioning, once again, the tolerances and adding extra post-processing time. (Figure 29) Other positioning and options of this part were printed as it is possible to see in Figure 30, but the one presented in figure 29 is the best option.

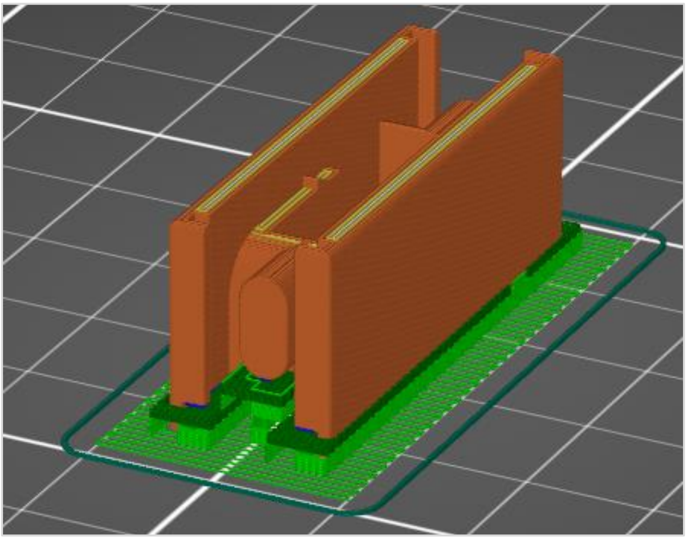


Figure 29 – Detailed View of the Structure's Printing Position

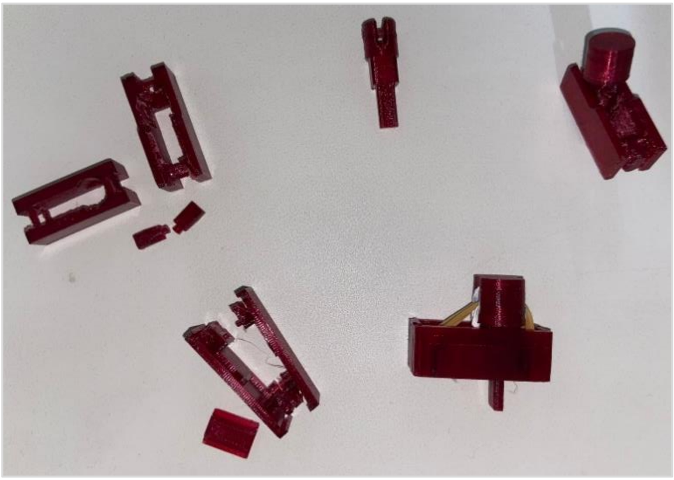


Figure 30 – Different Printed Versions of the Structure

Concerning the *Sliding Elements*, the first one to be printed (seventh model version) was printed with supports and in its lying position, benefiting the layer orientation on the extension that settles on the shoulders which provide higher resistance to transversal efforts. (Figure 31 and 32-1) Although this position benefits the layer deposition, it prejudices the tolerances on the sliding guides (explained in the subchapter "*Sliding Element* and *Shoulder Support*" on this appendix) which made necessary post-processing to re-establish them. After the update for the last prototype version and after some attempts for printing in the same position, it resulted in warped parts on the same region (Figure 32-2, 32-3 and 33) which turned mandatory to print this part on its up-standing position (Figure 34).

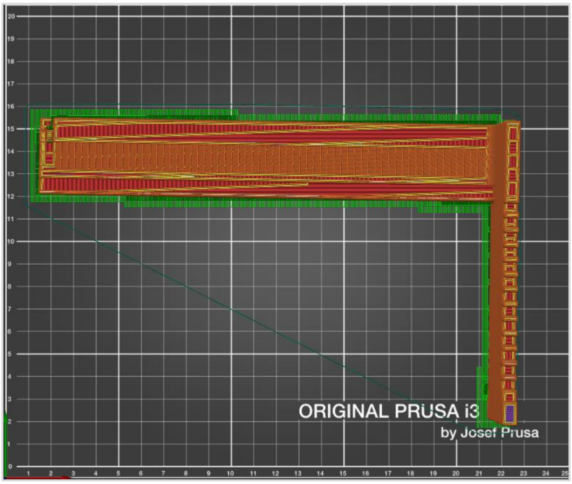


Figure 31 – Lying Position of the Sliding Element on the Printer Bed

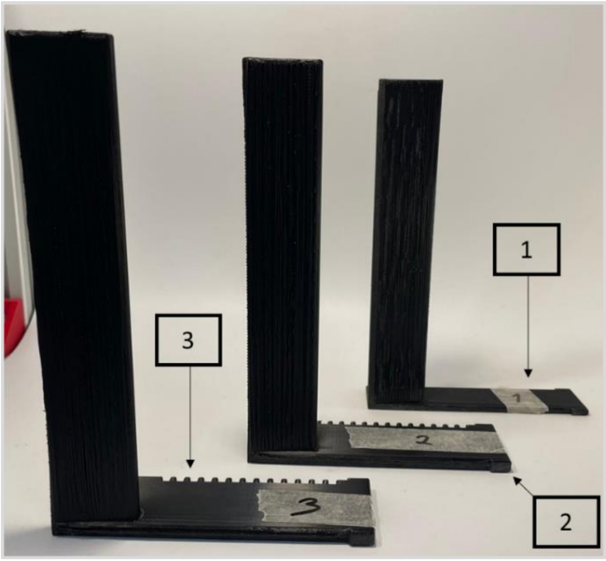


Figure 32– Printed Sliding Elements: 1 – Seventh Model Version; 2 and 3- Print attempts of the Final Version

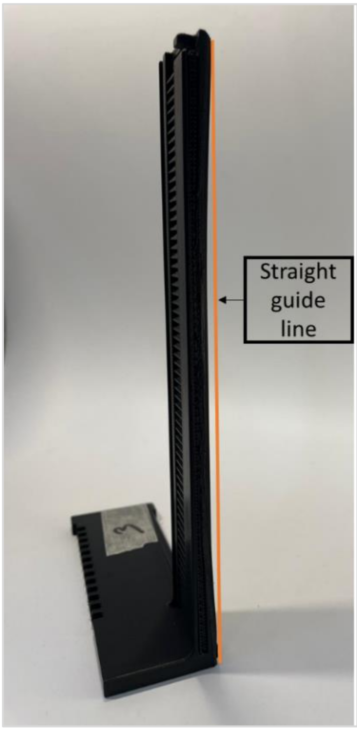


Figure 33 – Detailed View of the Warped Sliding Element

Figure 34 shows the up-standing position of the *Sliding Element* and despite not having printer's software supports, was created on the CAD model a small support to prevent one airborne region to collapse (Figure 35) being then cut and removed on the post-processing. This printing position ensures that the tolerances on the sliding guides (explained in the chapter "Sliding Element and Shoulder Support" in this appendix) are kept.

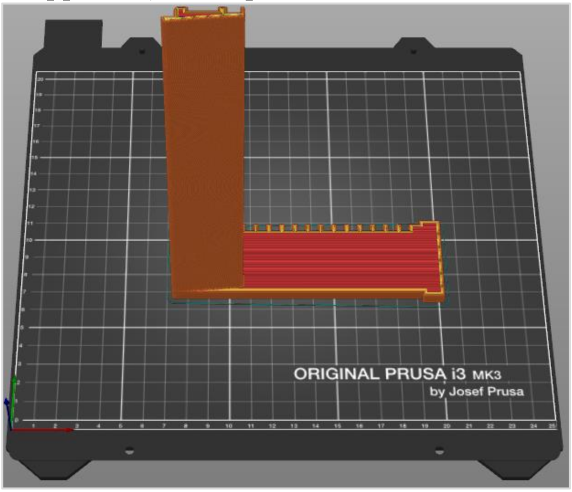


Figure 34 – Final Prototype's Sliding Element Printing Position

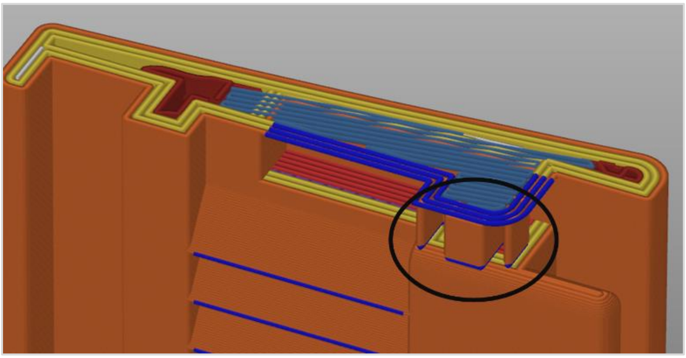


Figure 35 – Cut View of the Printing Model with the CAD Support Signalled

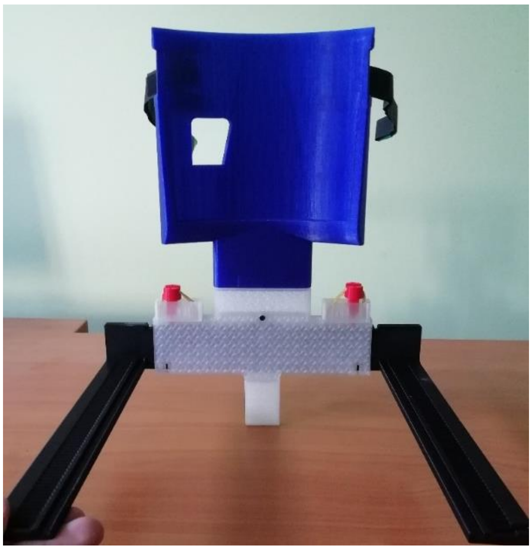


Figure 36 – Back Portion Assembled

Sliding Element and Shoulder Support

Model Seven presented a worrying detail that could have conditioned the application of the cervical collar or made it unsafe to use. When pushing the *Shoulder Support* against the patient (like in appendix F), since it slides along the *Sliding Element*, it touches the patient's body on the sliding region before the intended contact area. (Figure 37) Due to this, the adjustment can injure the patient, get stuck on the clothes, and for a complete adjustment is needed to lift the structure a few millimetres for the Shoulder Support to fit in the right place.

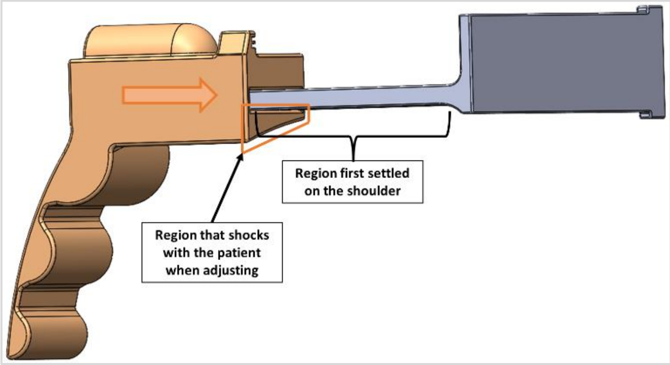


Figure 37 – Shoulder Support Collision on the Previous Model

To solve this problem, the design of the *Sliding Element* was changed. The changes made on the region that slides inside the *Back Portion* were already presented, and in figure 38 is possible to see the Sliding guides created on this element. Figure 39 shows the Sliding Element and a Shoulder Support assembled. The colour of the parts was changed on both figures for a better view of all the details.

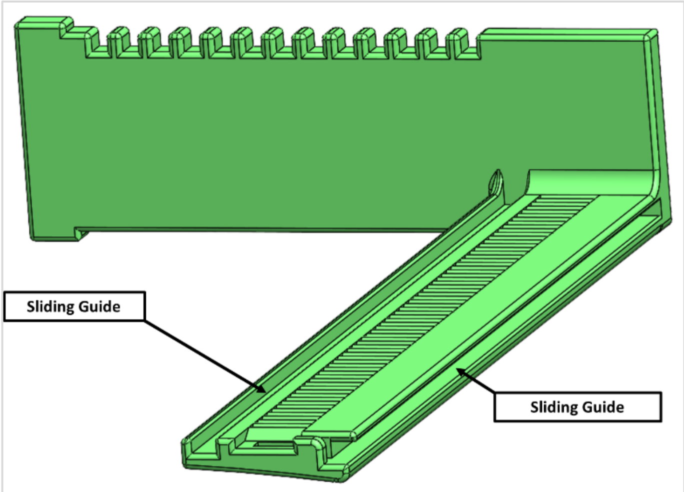


Figure 38– Sliding Guides of the Sliding Elements

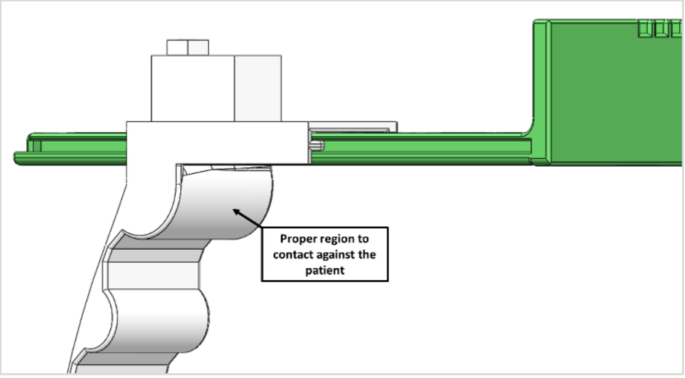


Figure 39 -Final Prototype's Sliding Element assembled with a Shoulder Support

Comparing Figures 37 and 39 is possible to verify that the region that used to shock with the patient no longer exists and on the second model there is no need to lift the structure to complete the adjustment.

The existence of two sliding guides on the *Sliding Element* matches the necessity for guaranteeing that the *Shoulder Support* wouldn't disengage from it. Figure 40.

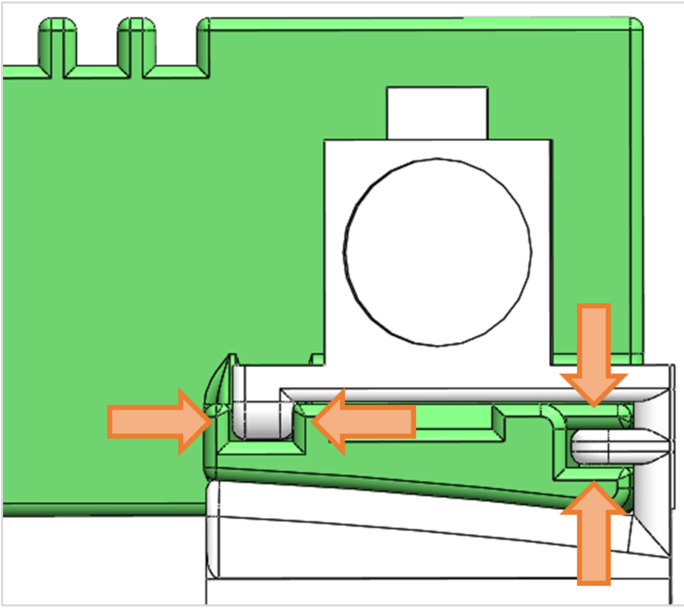


Figure 40 – Restrictions of Movement Created by the Sliding Guides

Concerning the *Shoulder Support*, its design evolution follow-up the development of the locking mechanisms. In this case, the locking mechanisms are two and were already presented in the previous models. The purpose of the mechanisms is to lock the *Shoulder Mandible* in relation to the *Sliding Element*, and to lock the rotation of the *Shoulder-Mandible Element* in relation to the *Shoulder Support*. As for the improvement of the first mechanism, it was created a *Box* (29.2 (l) x 24.5 (w) x 22.2 (h) [mm]) with *Elastic Bands* (Figure 41) that allow for the movement in one direction to be made with only a pull and automatically locking the position. For the opposite movement, a *Lever* must be pulled to unlock it and then by pulling the *Shoulder Support*, the position can be changed. (Figure 42) For the examples shown on the figures, the colours may be different than those on the CAD model assembly as the Black colours on the model present a hard view of the different parts.

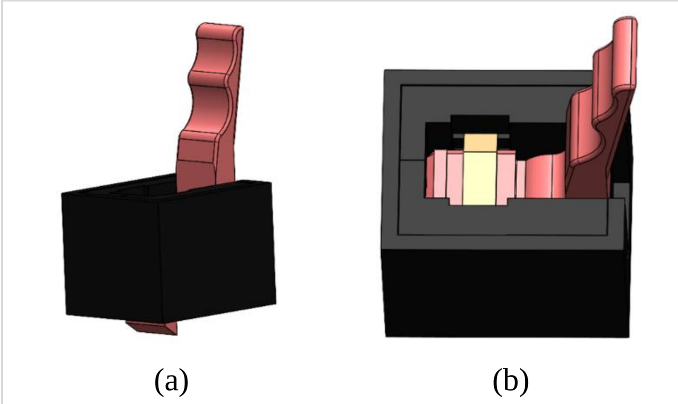


Figure 41 – Different Views of the Box Locking Mechanism Assembled

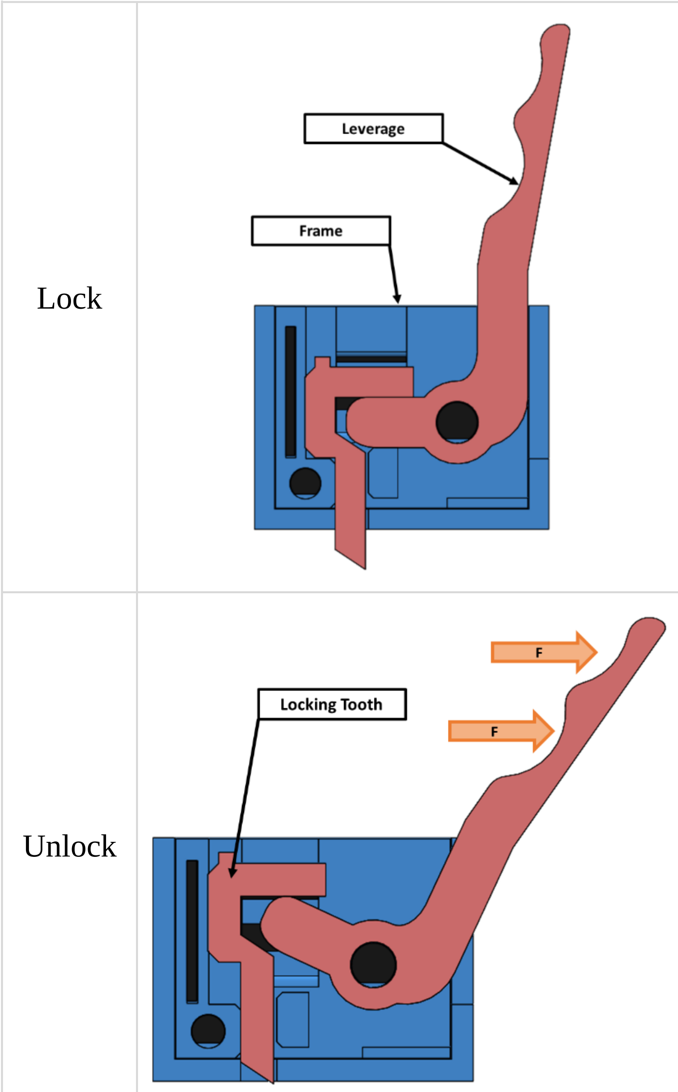


Figure 42 – Box Cut View of Locked and Unlocked Position

The *Box* is composed of eleven parts (including the elastic band). The parts are presented in Figure 43 on an exploded view of the assembly. The parts that constitute the box are: 1- *Outside Box*; 2- *Frame*; 3- *Pins*; 4- *Sheet*; 5- *Elastic Holders*; 6- *Lever*; 7- *Tooth*; 8 – *Elastic Band*.

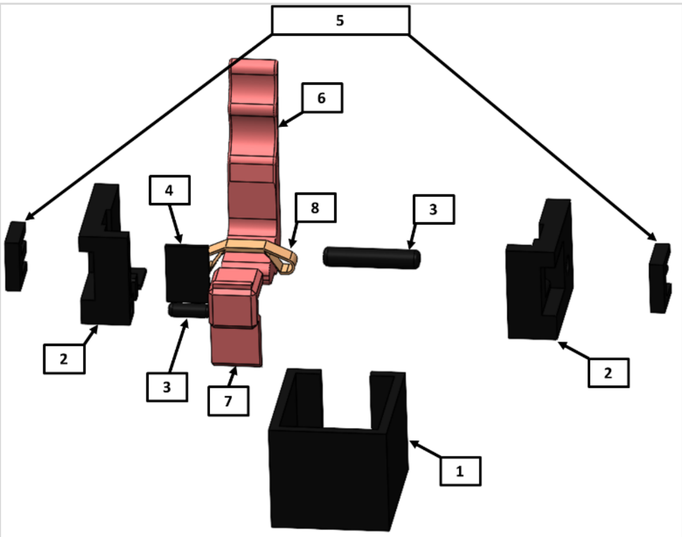


Figure 43– Exploded View of the Box

The *Frame* corresponds to the housing where the mechanism itself works, while the *Outside Box's* purpose is to ease the assembly on the *Shoulder Support*. Due to its thickness, it also protects the *Frame* and the mechanism to be compressed which could cause changes on the tolerances and might compromise the mechanism. The *Smaller Pin* on the *Frame* is a guide for assembling the two parts in the right position. After the first test, it was realised that wasn't enough and there would be needed an anti-rotation element (*Sheet*) as both parts were used to rotate around the pin. (Figure 44)

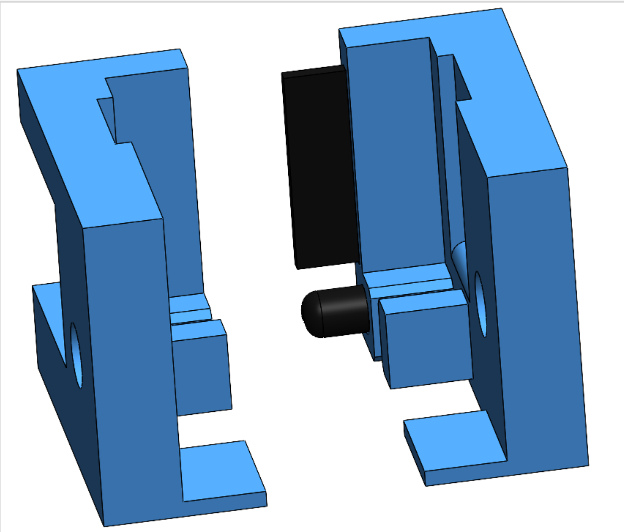


Figure 44 – Frame, Sheet, and pin Assembly

The *Lever* and the *Tooth* move completely free inside the *Frame* as the tolerances given between them are considerable. This reduces friction and increases the performance of the *Elastic Brand* spring effect for locking and unlocking. On the other hand, the *Pin* around which the *Lever* rotates has a tight fit on the *Frame* walls. (Figure 45)

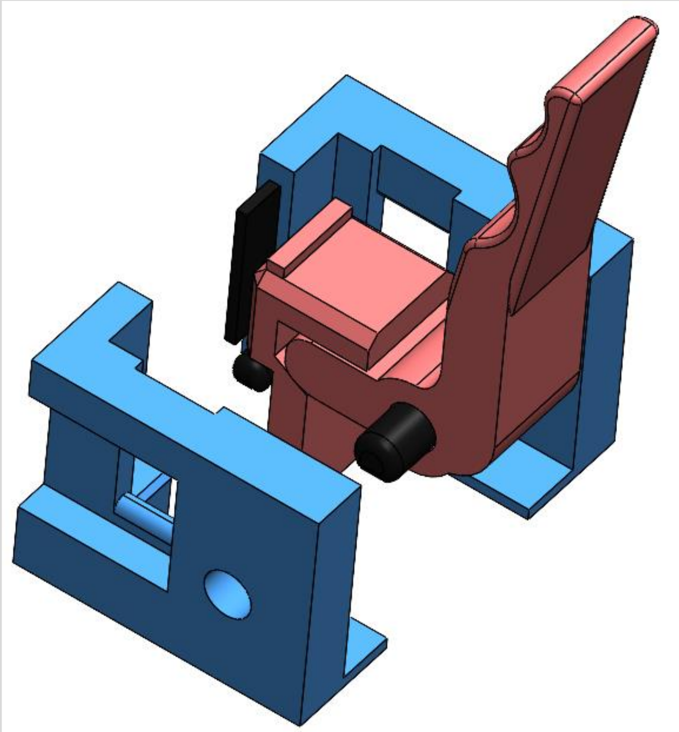


Figure 45 – Frame complete assembly

For applying and securing the *Elastic Band*, two holes were created on the outside of the *Frame* walls to assemble two E-shaped Elements (*Elastic Holders*). (Figure 46)

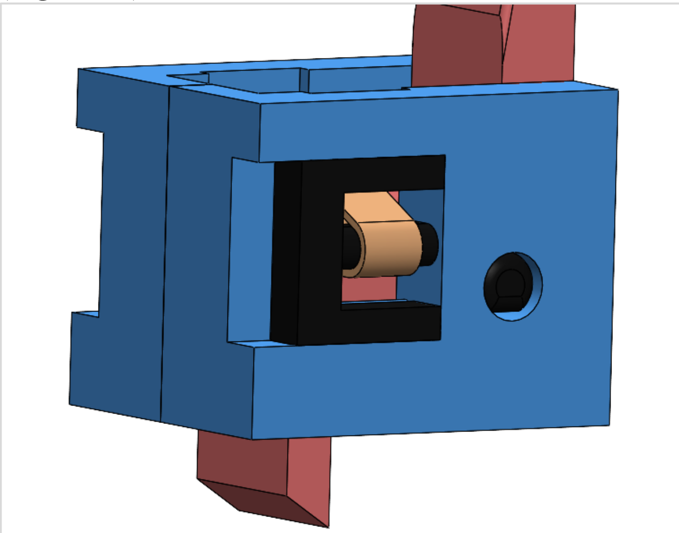


Figure 46 – Elastic Holders and an Elastic Band (Brown) Assembled on the Frame

The way the *Elastic Band* passes through the *Frame* and on the top of the *Tooth* allows it to create tension downwards. This tension increases when the *Lever* is pulled pushing the group downwards and locking the position when it is released. This creates the fast-locking mechanism intended (Figure 47)

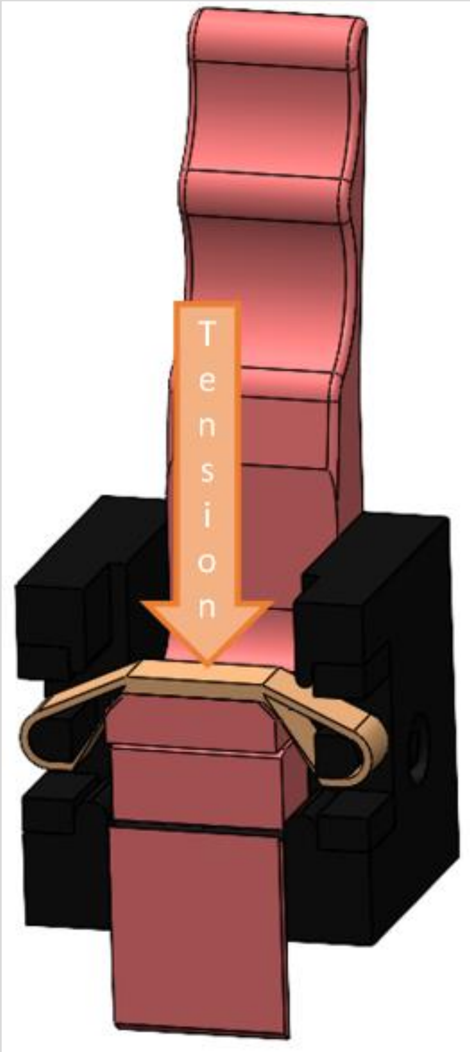


Figure 47 – Box Cut View and Elastic Band Tensioned

The orientation of the box when assembling on the *Shoulder Support* will allow for that spring effect to actuate when pushing it along the *Sliding Element*. The *Tooth* should be in the same orientation as the one explained in Figures 6, 7 and 8 from Appendix D – Model Four. The *Elastic Band* will stretch when achieving the top edge of any adjustment tooth of the pattern on the *Sliding Elements* and rebound when passing to the next tooth, locking its position, and preventing movement in the reverse direction (Appendix D-Model Four – Figure 7).

Concerning the printing of the parts from this mechanism, only the *Frame* required supports (light green on Figure 48). The remaining components were printed in their lying position, and for the *Pins*, which in their circular shape only present a line of contact with the bed, were cut to present a flat surface to lay on the printer bed. The profile shape of this part can be seen in figure 42.

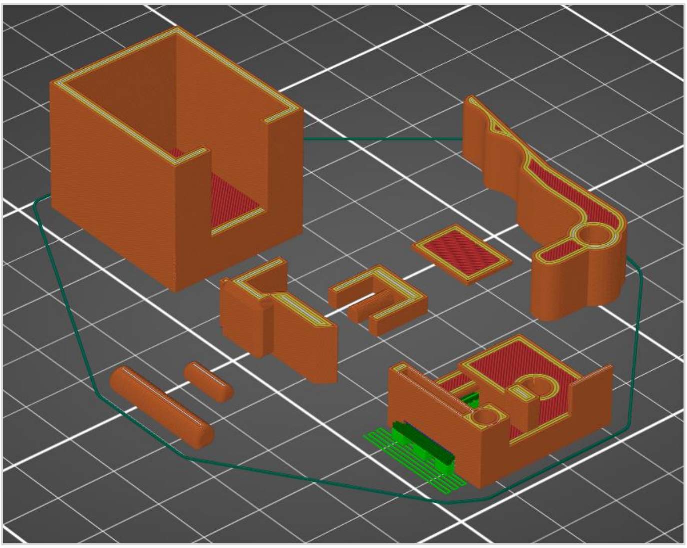


Figure 48 – PrusaSlicer's Printing Positions for the Box's Parts

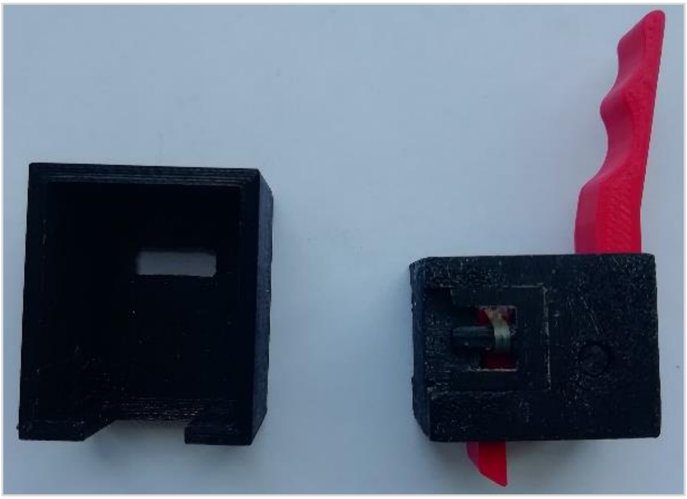


Figure 49 – Box Printed and Assembled

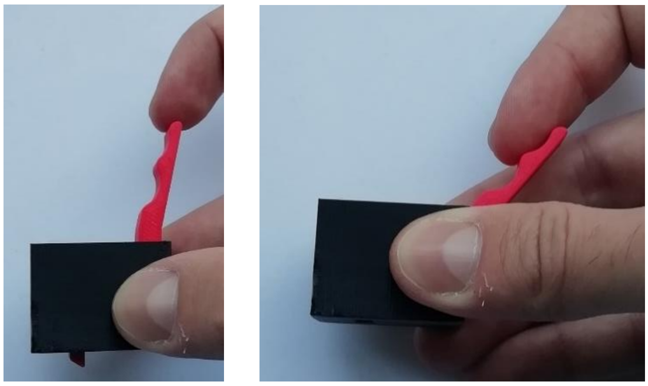
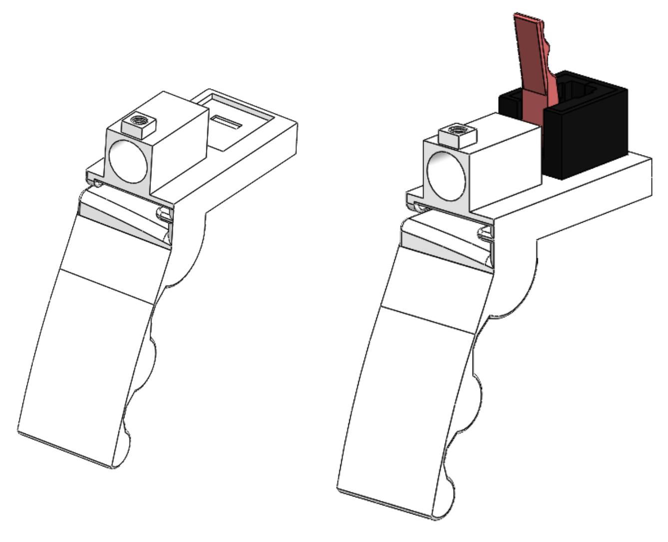


Figure 50 – Locked and Unlocked Position on the Assembled Box

As mentioned, the *Shoulder Support* follow-up these mechanisms' evolution so some changes were made in order to accommodate the *Box*.

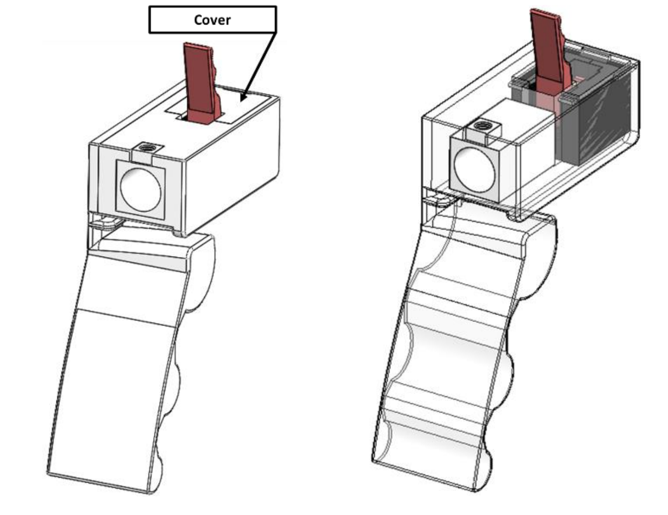
The first *Shoulder Support* that was able to receive the *Box* derived directly from the one on Model Seven. This support can now accommodate the locking *Box* and already presents the feature to slide on the sliding guides of the *Sliding Element*. (Figure 51)



(a) (b)

Figure 51 – Shoulder Support Replacing the Old Manual Mechanism with the Box Fast-Locking Mechanism

Understandably, a small hole won't secure the box unless it is glued (which is not the intended because if the *Elastic Band* breaks, the box can be removed and repaired), so there were built walls on the top of the entire *Shoulder Support* surrounding the *Box* and creating a housing for it. (Figure 52) To allow the assembly and removal of the *Box*, the top of the housing is open and posterior to the assembly covered. The cover is secured with a snap-fit. (Figure 53)



(a) (b)

Figure 52 – Second Version of the Shoulder Support

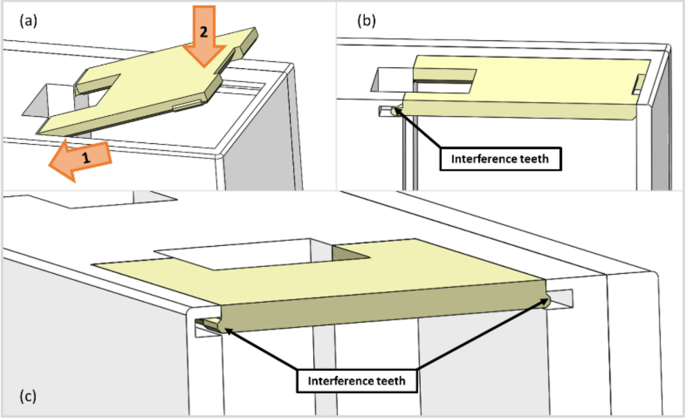


Figure 53 – Different Views of the Cover. a- Movements for Assembling the Cover; b, c – Cut View of the Interference Teeth

As the Shoulder Support presents a complex shape, the parts were split to reduce the amount of wasted material in supports and to keep the tolerances. Otherwise, it would be impossible without many hours of post-processing. Regardless of all the changes, some parts will be printed with supports as there isn't any other option to keep the remaining requirements.

Figure 54 shows the exploded view of the CAD model and the different parts that are going to be printed separately. In this figure, it is possible to see that the *Box* where the *Shoulder-Mandible Element* has a rotating *Pin*, is printed separately. This is due to the thread for the *Bolt Locking Mechanism*. There were two options, to print with a hole for inserting a nut, or a thread directly on the part (option used). For a nice tolerance and good quality, the part must be printed on the hole axis direction.

In Figure 55 it is possible to see the orientation in which the parts were printed as well as where the supports were set.

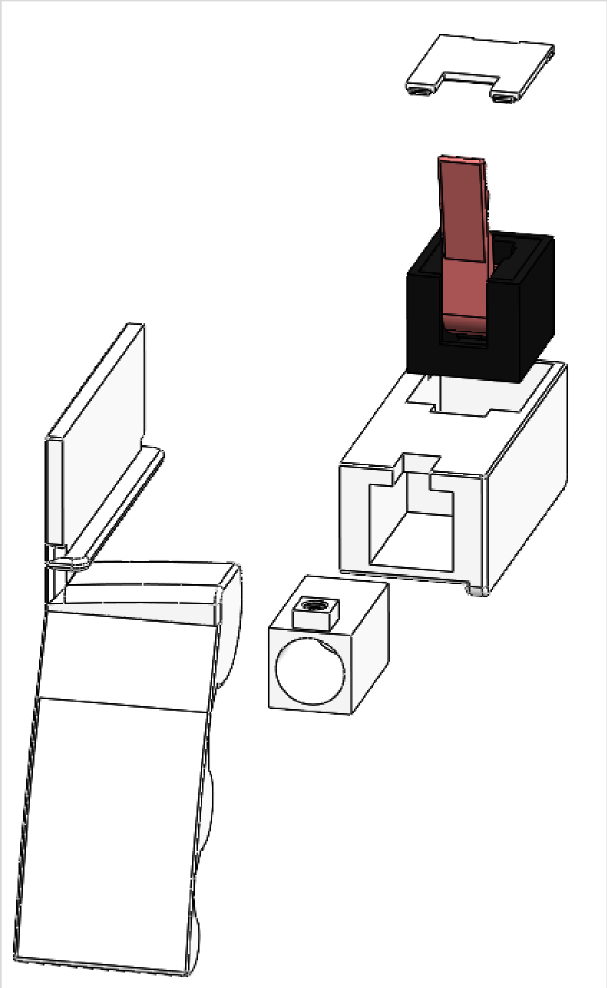


Figure 54- Exploded View of the Separate Parts from the Shoulder Support

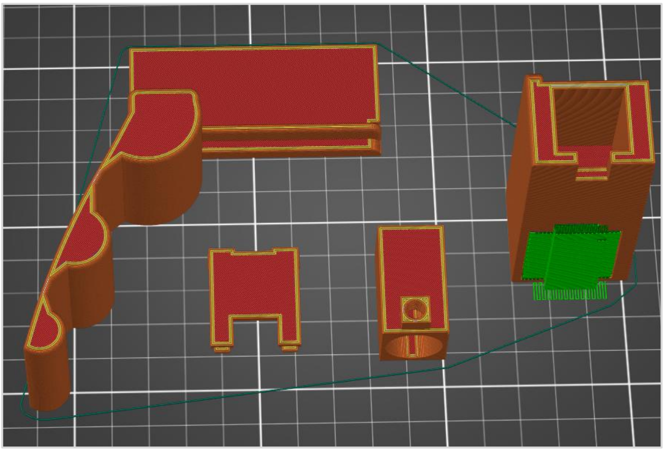


Figure 55 – Shoulder Support Parts' Positioning on the Printer Bed

The main structure of the *Shoulder Support* is then glued to achieve the shape in Figure 56. After printing, the group was assembled and tested. (Figure 56) As the results were the expected, the development of a fast mechanism to replace the bolt one was started.

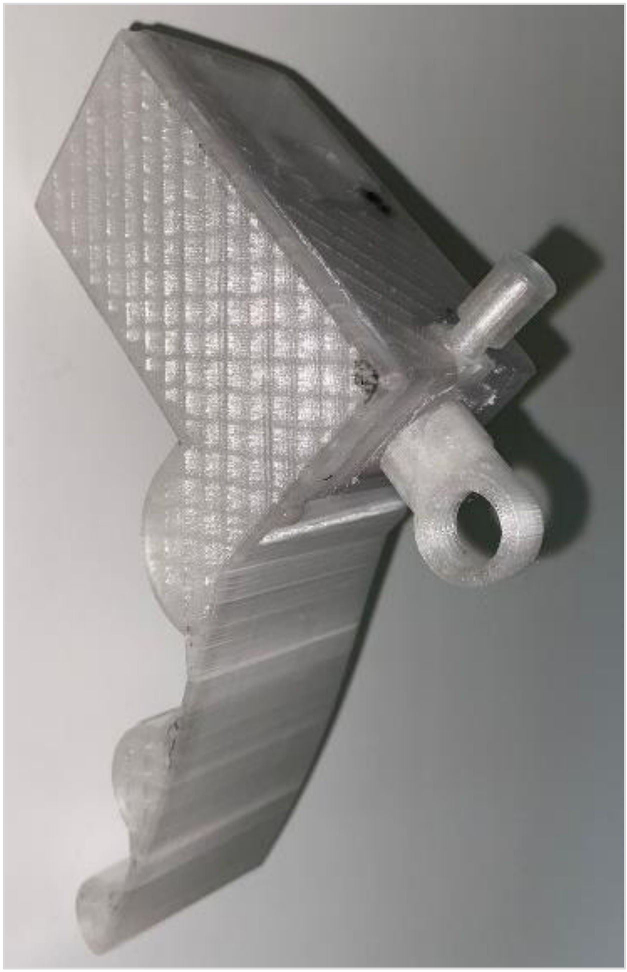


Figure 56 – Printed Shoulder Support

The solution found to lock the *Rotatable Pin* consisted of changes on both the *Shoulder Support* and the *Pin*. The concept to be reproduced is a geared locking mechanism trying, as on the *Box* locking mechanism, to introduce the spring element to allow for fast and easy locking.

To achieve it, the *Pin* was changed from a smooth geometry to a toothed one in a defined region. (Figure 57)

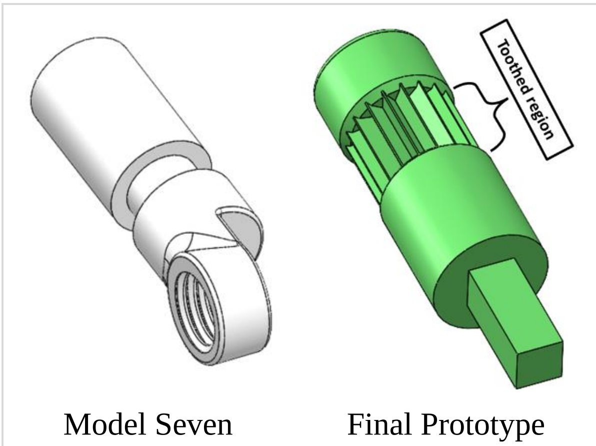


Figure 57 – Difference Between the Model Seven and the Final Prototype's Pin

A small element with three teeth was also developed to match those teeth patterns. When that small element gets static by engaging them, it locks the rotation of the *Pin*. (Figure 58)

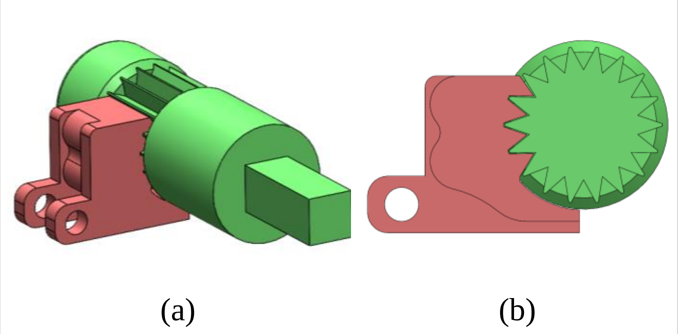


Figure 58 – Assembly (a) and Cut View (b) of the Gear and Lock

It was impossible to create a *Lock* with a higher number of teeth as the idea was to rely on a flat surface to slide the *Small Toothed Element* to lock or unlock the position of the Pin. (Figure 59)

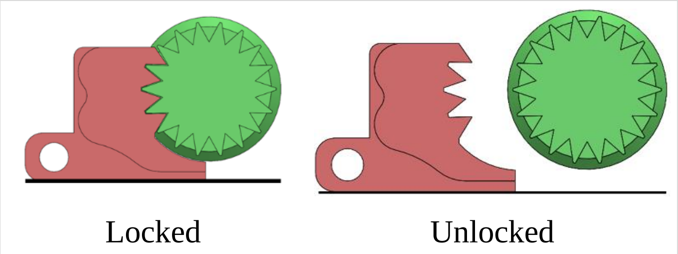


Figure 59 – Locked and Unlocked Position of the Pin

To put the mechanism on the same height level, the box strategy was used like on the previous mechanism. The *Box* was prepared to accommodate the *Elastic Bands* in order to create tension on the *Lock*, pushing it against the *Pin*. This will allow for the rotation movement to not disengage the *Small Toothed Element* even due to the teeth angle. (Figure 60 and 61)

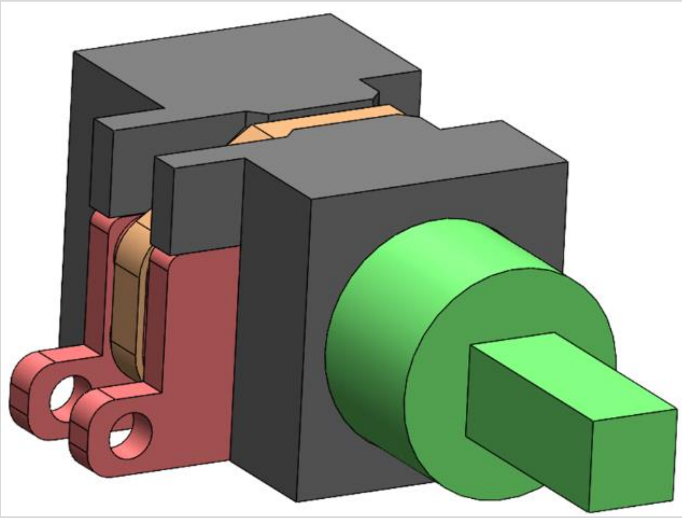


Figure 60 – Assembly of the Mechanism with the Elastic Bands

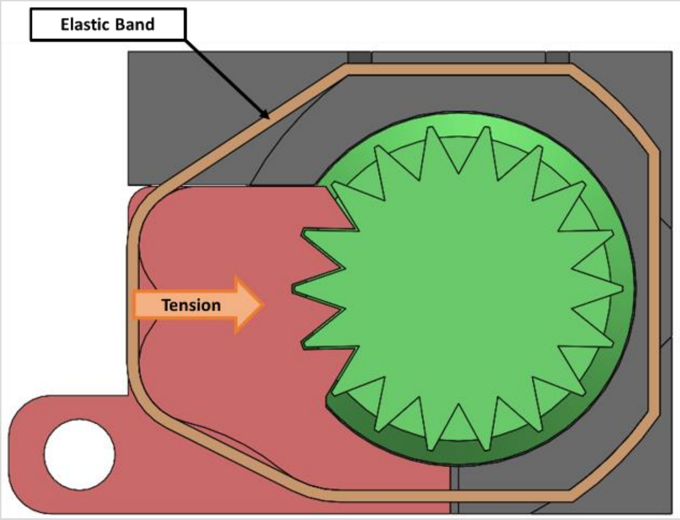


Figure 61 – Tension Created by the Elastic Band

The presented *Box* in combination with a housing on the *Shoulder Support* will allow for the *Small Toothed Element* to be guided in such a way that only the slide direction movement is allowed (turning the *Lock* theoretically static when locked). (Figure 62 and 63)

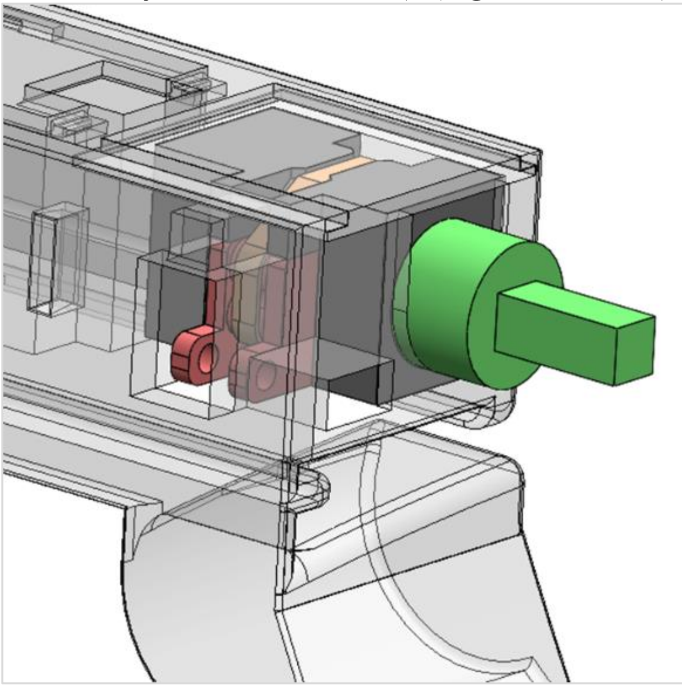
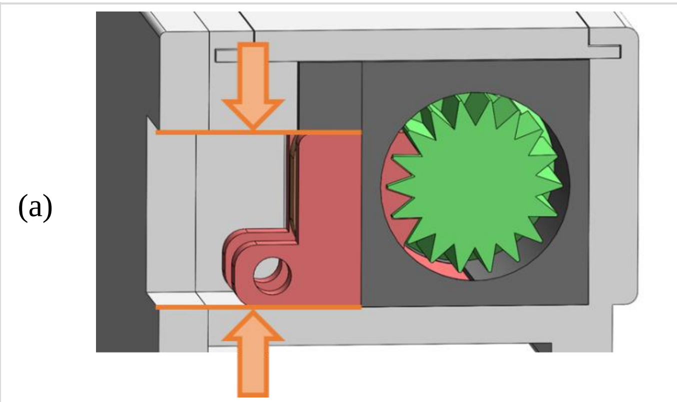


Figure 62 – Assembly of the New Mechanism on the Shoulder Support



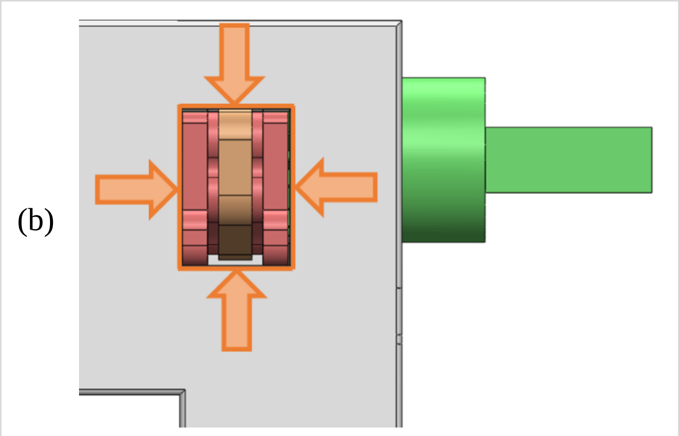


Figure 63 – Wall Restrictions that Turn into Guides for the Lock to Slide Oriented

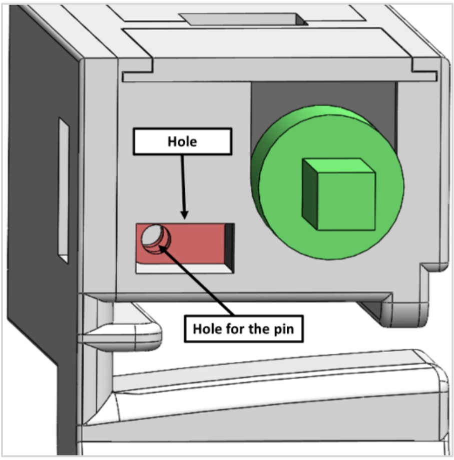


Figure 65 – Detailed View of the Hole Left for Assembly Purpose

To secure the *Box*, on a first attempt a cover with a snap-fit, like the one applied on the previous *Box* mechanism, was applied but, in this case, one direction of rotation causes some effort on it and releasing it, meaning that a stronger fit for the cover was needed. To solve this a *Sliding Cover* with considerable interference on the guides was created and was able to secure it.

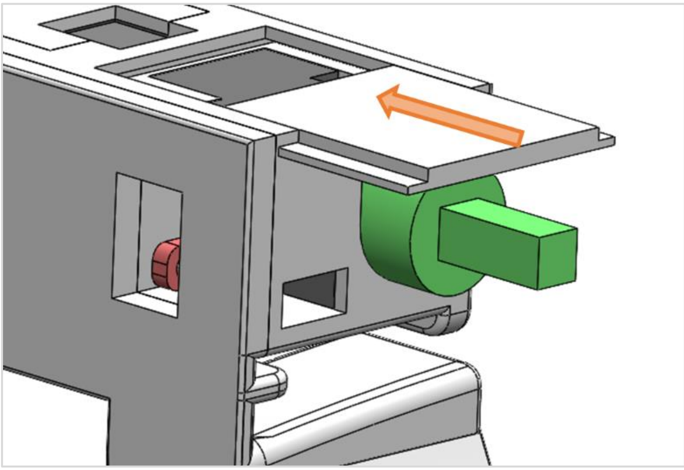


Figure 64 – Detailed View of the Cover

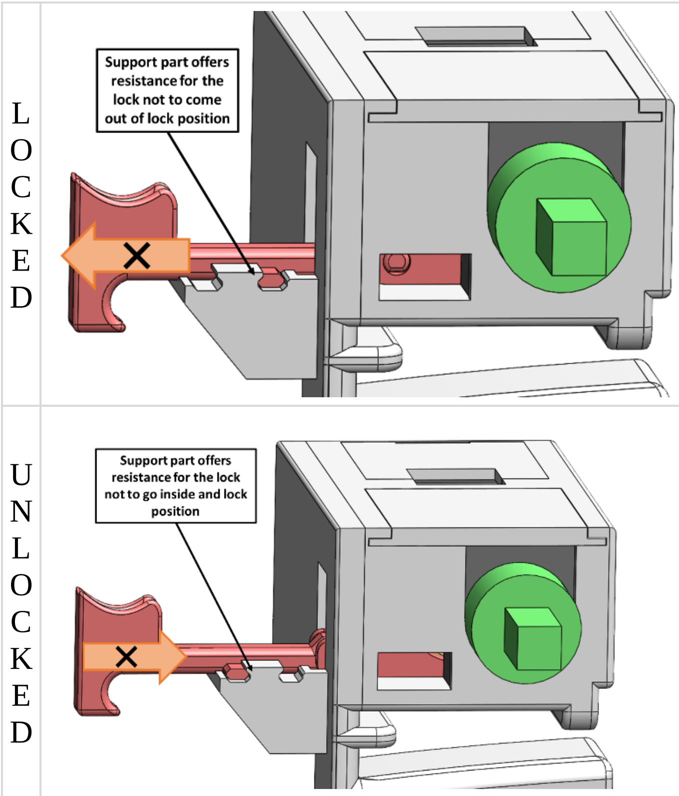
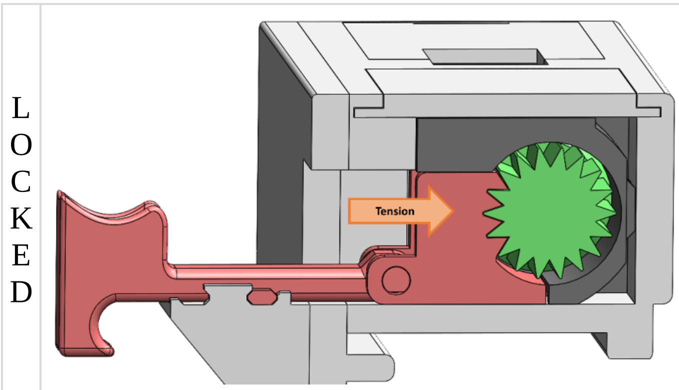


Figure 66 – Locked and Unlocked Position on this Mechanism



The *Shoulder* Support was also prepared for the assembly details like the rectangular hole on the front left that allows to insert a *Pin* that will connect a *Lever* and the *Small Toothed Element*. (Figure 66) The *Lever* will allow to lock or unlock the rotation of the mechanism. On the outside of the *Shoulder Support*, right where the hole for sliding the lock is located, was added an *Outside Support* that helps to keep the locking position but also to secure the lock on an unlocked position, if intended. The tension that the *Elastic Band* creates by being stretched will return the *Small Toothed Element* to the locked position immediately and automatically when the *Lever* gets released with a pull-up, from the unlocked position. To unlock the mechanism the user must also pull up the *Lever* and pull it to the unlocked position in these two movements described. (Figure 65 and 66)

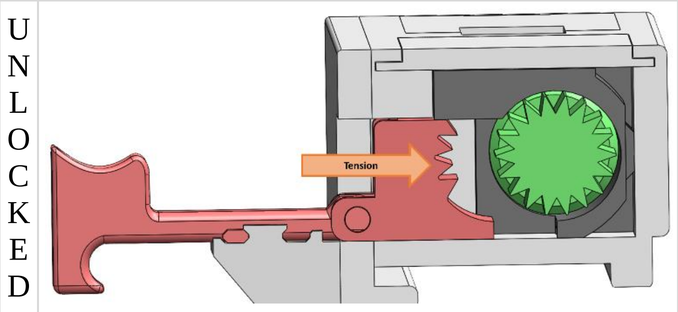


Figure 67 – Cut View of Locked and Unlocked Position on this Mechanism

Concerning the printing of these parts, almost everyone was necessary post-processing due to the use of supports. Post-processing was also performed in some parts to increase the tolerances to ease the assembly as they wouldn't affect the performance of the structure.

For the *Shoulder Support*, the parts were positioned like on the previous printed one but this time with more supports. There was also added a guiding extension to allow for better positioning between the parts before glueing them. (Figure 68)

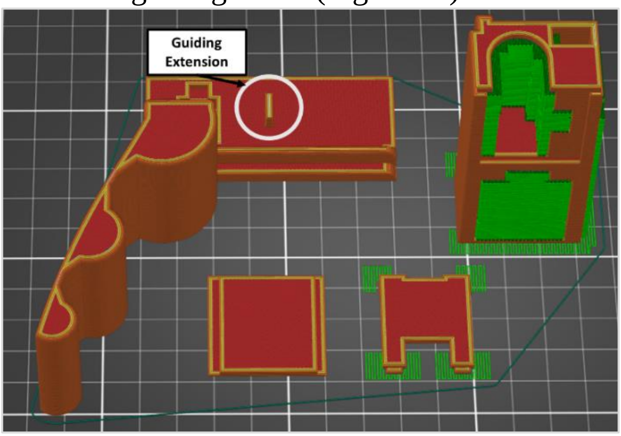


Figure 68 – Parts' Printing Position

As for the remaining parts, its positioning is presented in Figure 69.

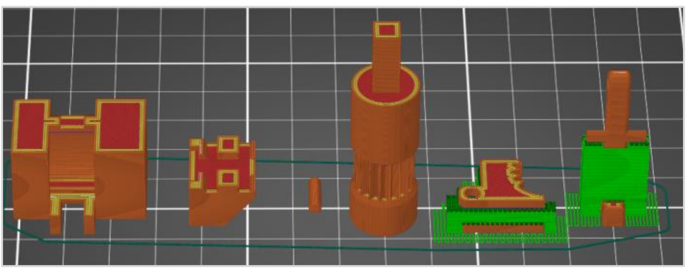


Figure 69 – Remaining Parts' Printing Position

On all the designs was considered the ability of the printer concerning prints of angled walls. The designs had the detail of keeping angled walls with no less than 45 degrees with the horizontal line of the printer bed. This is possible to see on the second part (the *Outside Support*) counting from the left in Figure 69.

As in the first part of this figure the top of the hole exceeds those 45 degrees on the walls due to the circular shape it needs to be rectified using a mill as post-processing (15 mm).

Figure 70 – Post Processing of One of the Shoulder Support Parts

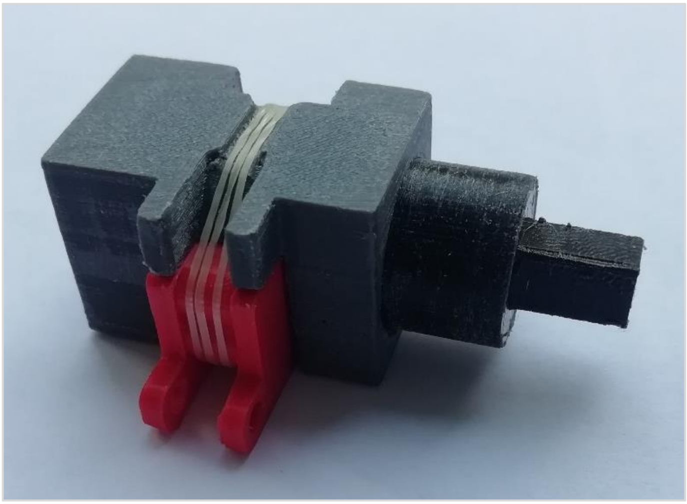


Figure 71 – Locking Mechanism Box with the Elastic Bands

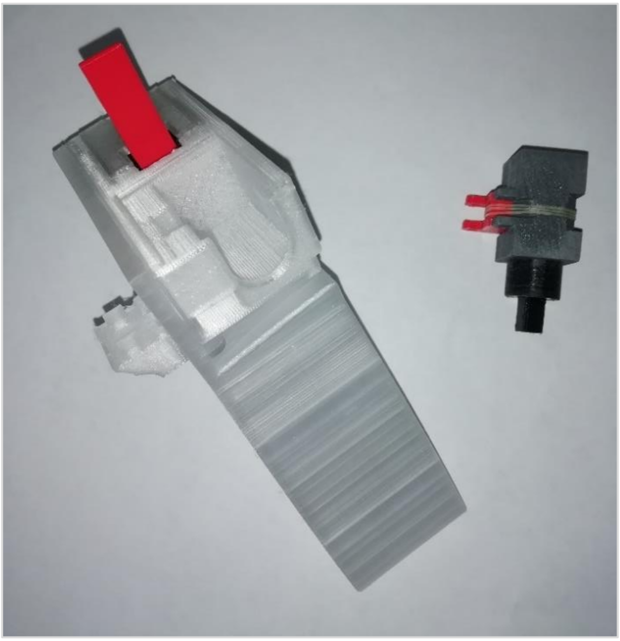


Figure 72 – Shoulder Support and Box Assembled

Shoulder-Mandible Element and Mandible Support

The *Shoulder-Mandible Element* presents on the Final Prototype a totally different solution than the one presented on Model Seven. The final version is the improvement of an intermediate version created, printed, and tested that didn't present the behaviour desired, being too rudimentary.

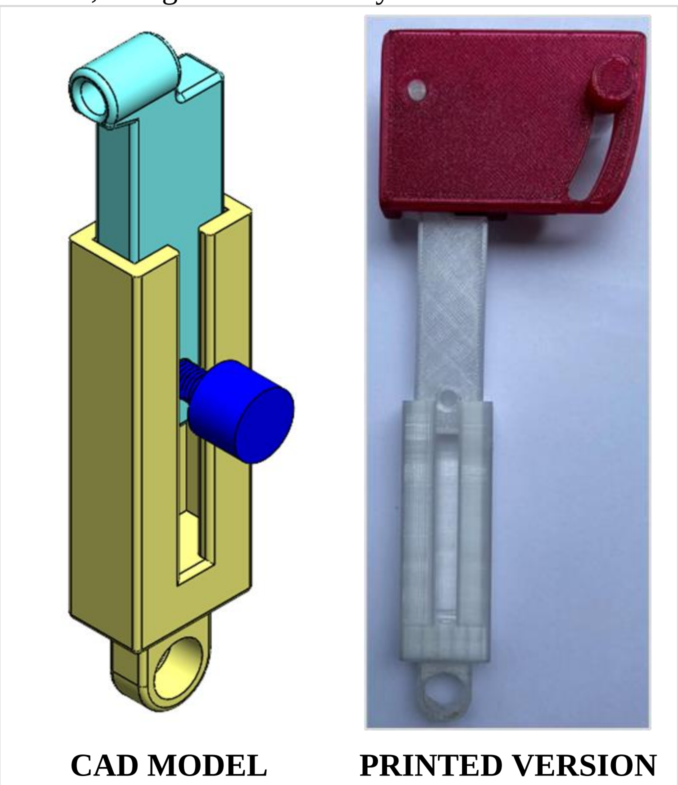


Figure 73 – Seventh Model Shoulder-Mandible Element

As for the intermediate model and even for the final one, the *Rotation Pin* (black part), which was developed for the rotation locking mechanism, is prepared to assemble the *Shoulder-mandible Element* as will be seen in Figure 74.

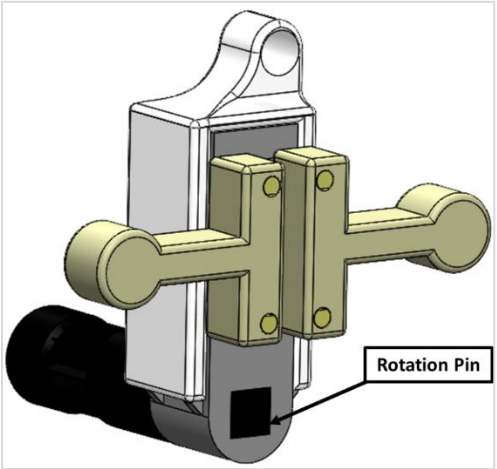


Figure 74 – Assembly of the Intermediate Shoulder-Mandible Element

The main purpose was to design a telescopic adjustment where the locking mechanism had *Elastic Bands* as spring elements like on the remaining locking mechanisms.

The grey *Structure* in figure 75 is the one where the *Elastic Bands* are kept. The solution achieved consisted of two *Toothed Pattern Locks* inside the *Inner Part* that are pushed against the *Outer Part* of the telescopic adjustment. (Figure 76 and 77) This, in combination with the *Teeth* orientation would allow for the *Outer Part* to move freely in one direction and get its position locked on the reverse one.

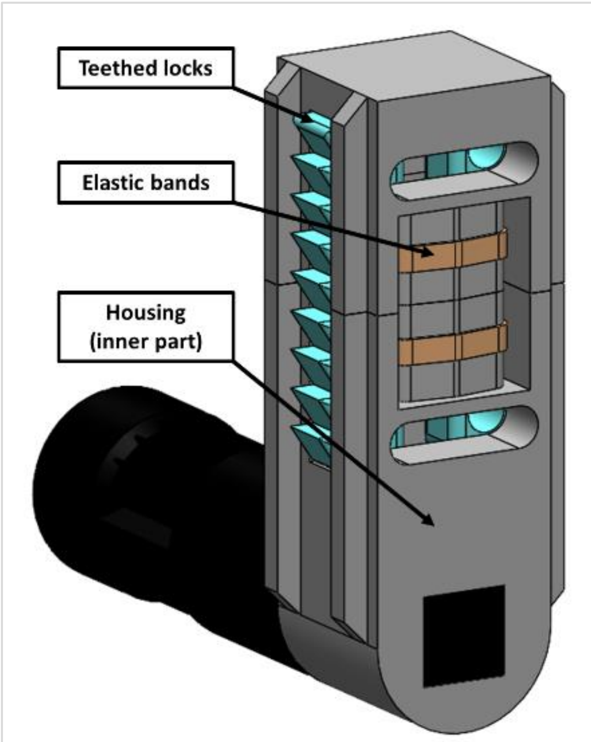


Figure 75 – Assembly of the Inner Part of the Telescopic Adjustment

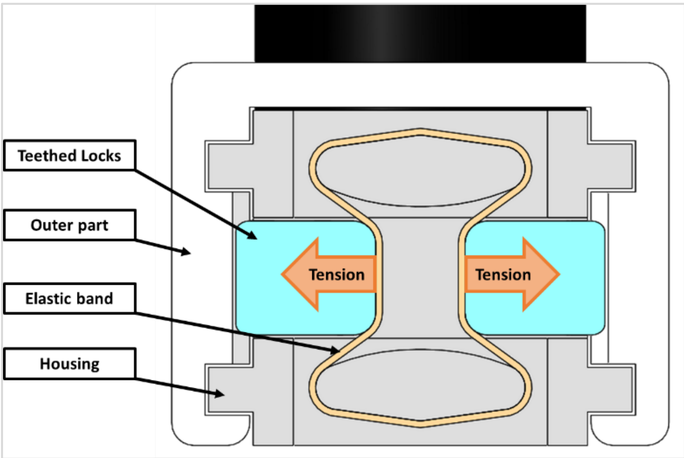


Figure 76 – Cut Top View of the Telescopic Adjustment

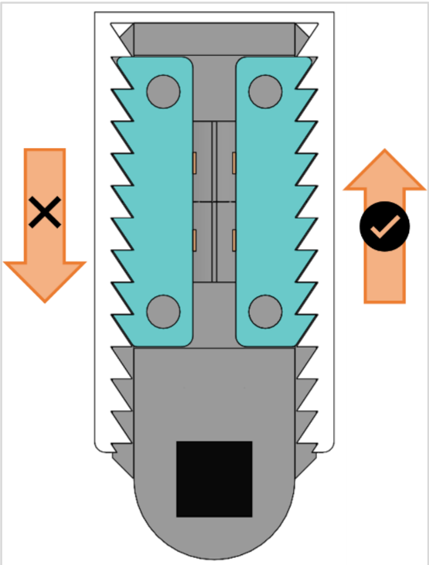


Figure 77 – Cut Front View of the Telescopic Adjustment

To be able to introduce the *Elastic Bands* on the mechanism, the *Inner Part* (Elastic Band Housing) was split in two and after assembling with the *Elastic Bands*, glued. (Figure 78) As this part is glued if the elastic band housing breaks the entire group needs to be replaced.

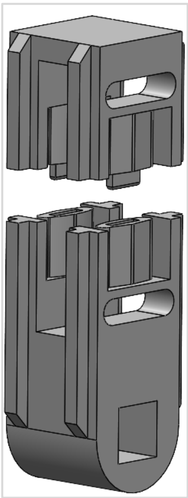


Figure 78 – Exploded View of the Inner Part

As on the *Shoulder Support*, the walls of the *Inner Part* and the tight fit offered to the *Toothed Elements*, turn the between walls onto guiding houses for the second. The edges on the *Toothed Element* were softened through fillets to reduce the friction between components. For the *Elastic Bands*, their positioning in relation to the *Toothed Elements* was also considered to input a balanced tension and keep these elements as straight as possible.

So, in the upward direction, the mechanism moves and automatically locks the position through the tension from the *Elastic Bands*. To unlock the position and return the height of the mechanism to the original one or to reduce its height, the solution found was with four *Pins* connecting two *Actuating Buttons* to the *Toothed Lock*. (Figure 79)

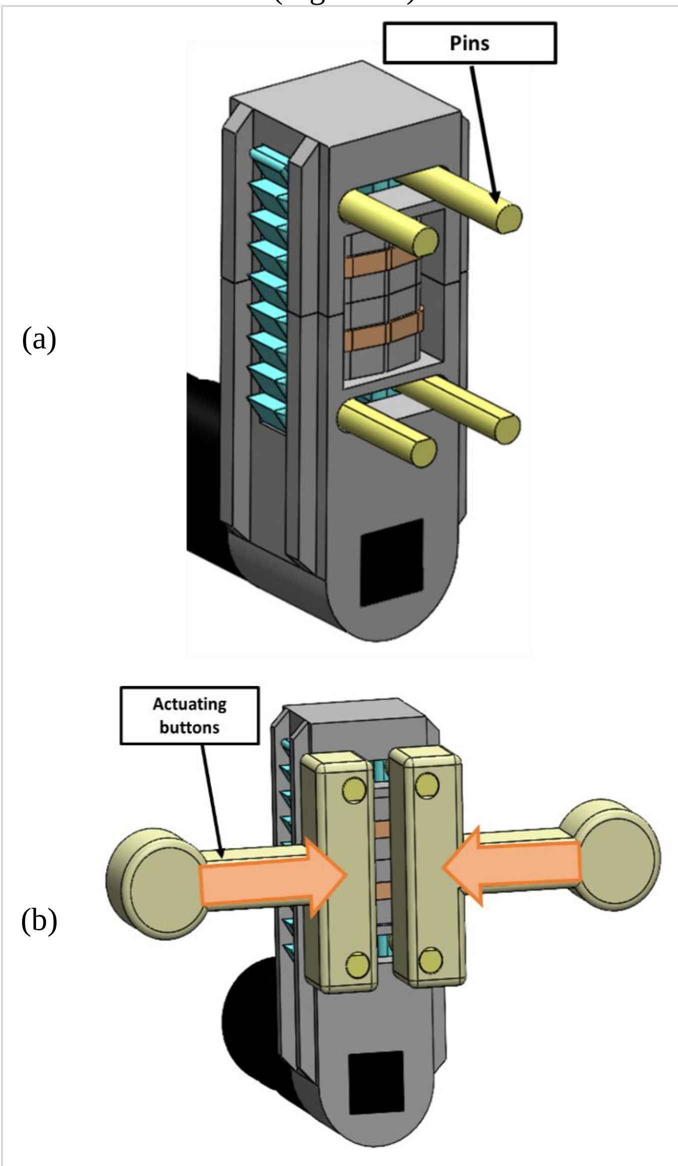


Figure 79 – Inner Part of the Mechanism with Pins (a), and with Pins and Button (b)

To connect this group to the *Mandible Support*, on the top of the *Outer Part* of the telescopic adjustment, a holed element that would receive a pin to make the connection to the *Mandible Support* was added. (Figure 80)

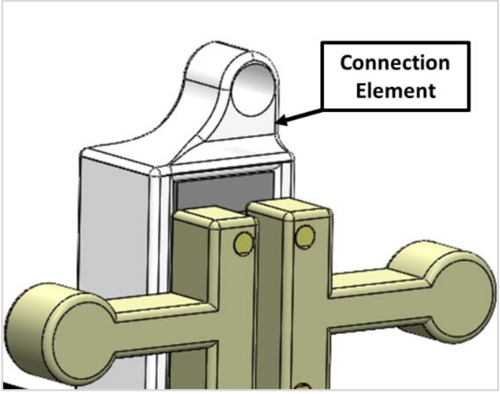


Figure 80 – Detailed View of the Connection Element

On its extended position this group of parts, from the gravity centre of the rotation pin, can achieve a total height of around 81.7 mm. Above the position presented in Figure 81, the assembly is not stable, and the *Outer Part* wagged too much and might bounce.

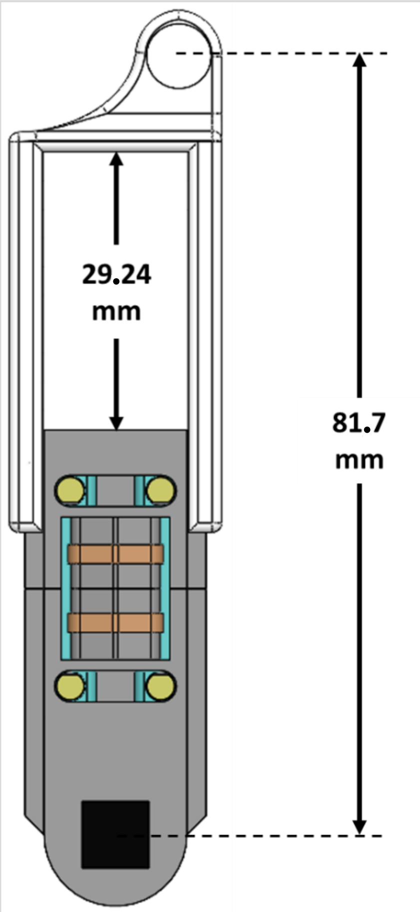


Figure 81 – Maximum Stable Height for this Group

Concerning the printing of the telescopic adjustment, figure 82 shows the printing position for the parts.

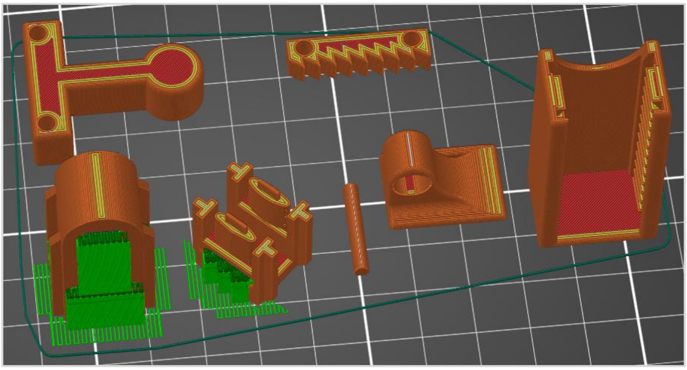


Figure 82 – Telescopic Adjustment Parts Printing Position

After printing and testing the mechanism, it showed that the connection with the *Pins* was not strong enough due to their dimensions (diameter = 2.9 mm and length = 19 mm). On the tests, the *Pins* bent, and, in others, they even broke when the buttons were pressed. The distance travelled to the middle plane (equidistant to both Toothed Elements) was found uneven when pressing the buttons which sometimes caused it to unlock on just one side. Also, due to the bends on the *Pin*, the mechanism was stuck in some tests. (Figure 83)

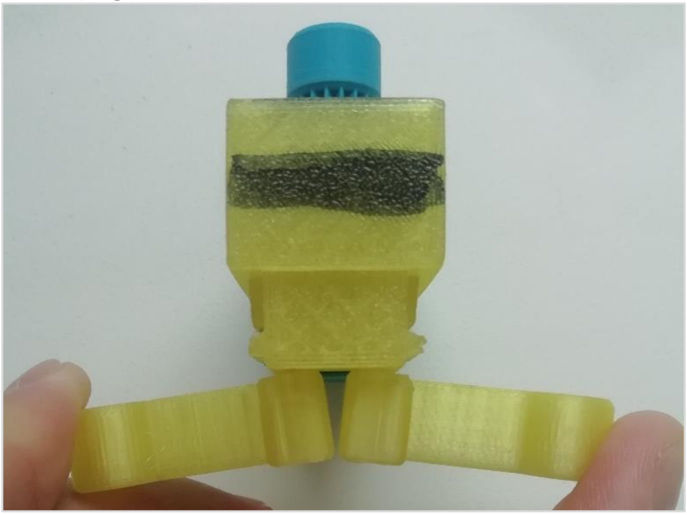


Figure 83 – Pin Warp and Non-Symmetric Adjustment

Since the called intermediate model didn't present the results expected, a different approach was made.

In this final model, the objective was to also implement a fast mechanism with the help of elastic bands but with stronger characteristics. The solution that was designed consisted of a similar concept to the intermediate one but changing from two *Toothed Elements* to just one and with a different housing both for the element and the *Elastic Bands*. (Figure 84)

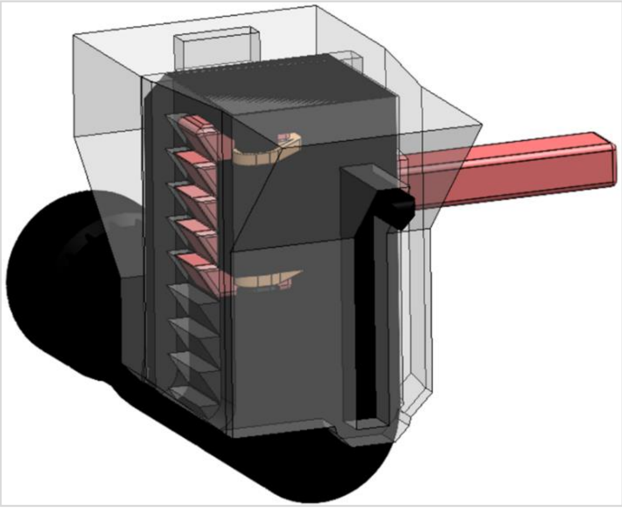


Figure 84 – Assembly of the Final Version of the Shoulder-Mandible Element

Differently from the intermediate version, the *Inner Part* of this one is split in three. This allows the assembly of two *Elastic Bands* forming a balanced distribution on the *Toothed Element*. The three parts are supposed to be glued and if one *Elastic Band* breaks, the whole group needs to be replaced like on the previous model. Another concern on this version is to create a stronger but smaller element to secure the *Elastic Bands*. As these elements are smaller there is more space for the three parts to receive guiding pins and the respective holes for a good connection (even the elastic band securing pins are also guiding pins between the three parts). (Figure 85 and 86)

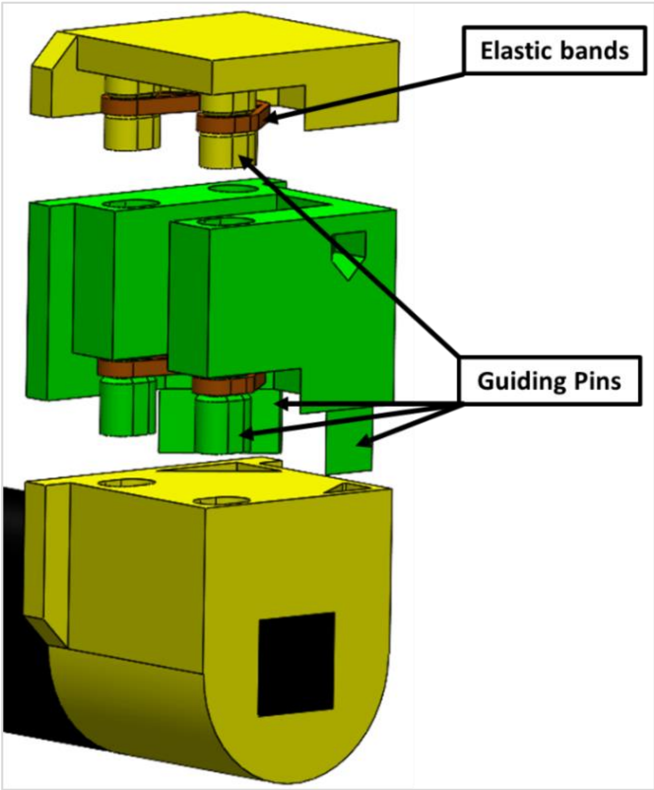


Figure 85 – Exploded View of the Inner Part

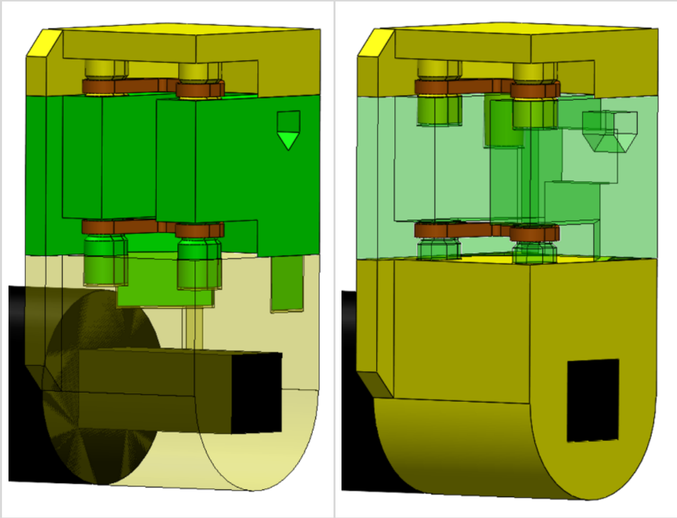


Figure 86 – Different Views of the Inner Part Assembly

As for the *Toothed Element*, it is inserted on a housing created by the three parts' walls. The middle part presents a hole where the extension of that element, that is used to be pulled to unlock the mechanism, is inserted. The tight fit of this hole in combination with the *Elastic Bands* positioning allows for the *Toothed Element* to have a balanced and straight sliding inside the housing. (Figure 87)

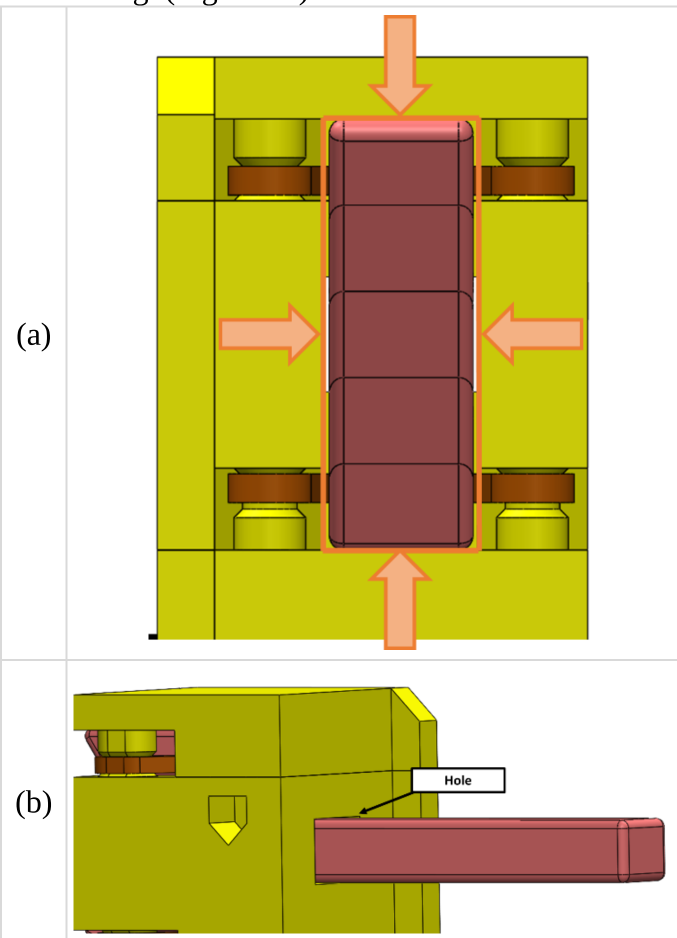


Figure 87 – Teeth Element Housing Movement Restrictions

Concerning the locked and unlocked position, as on the intermediate model, the natural position of this mechanism is locked, due to the *Elastic Band* tension.

It allows the upward movement by just pulling the *Outer Part*, locking immediately and automatically the position through rebound, and to return or reduce the height of the adjustment the extension of the *Toothed Element* needs to be pulled resulting in disengagement. (Figure 88)

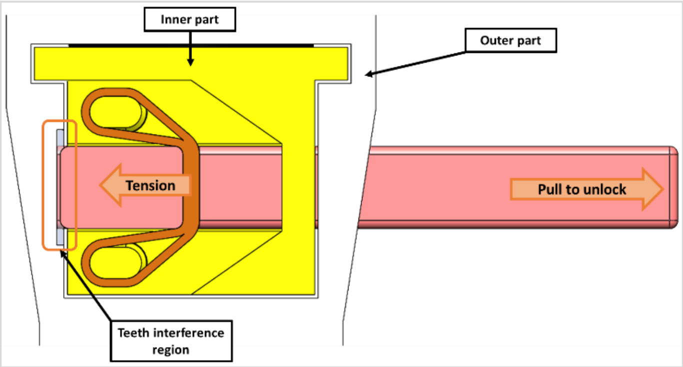


Figure 88 – Top Cut View of the Mechanism

The highest stable position, in this version, is marked with a post-assembly *Pin* that blocks the *Outer Part*, not allowing it to come out. It is inserted in such a way that it blocks it in its highest position, stopping its sliding movement. (Figure 89)

On the top of the *Outer Part*, and preparing to receive the *Mandible Support*, are two *Connecting Parts*. Those are glued during the assembly and meant to connect and lock the *Mandible Support*. (Figure 89)

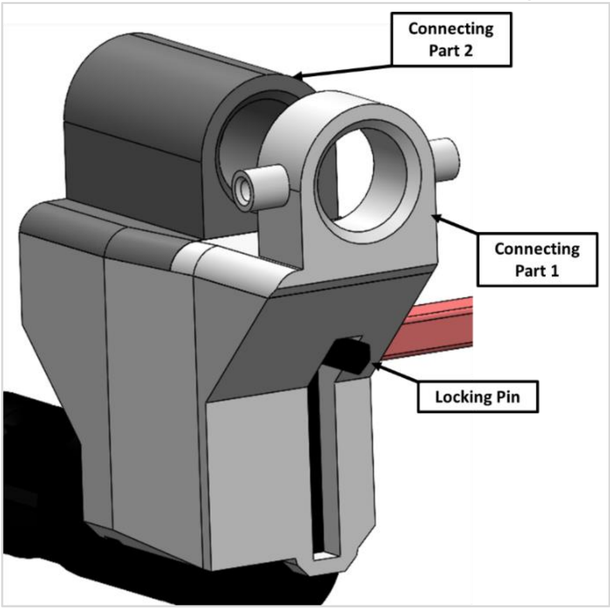


Figure 89 - Outer Part Description

As for dimensions, the group when in the closed position presents a height in relation to the rotation pin's gravity centre of around 41.5 mm. When extended the structure height is 57.57 mm. (Figure 90)

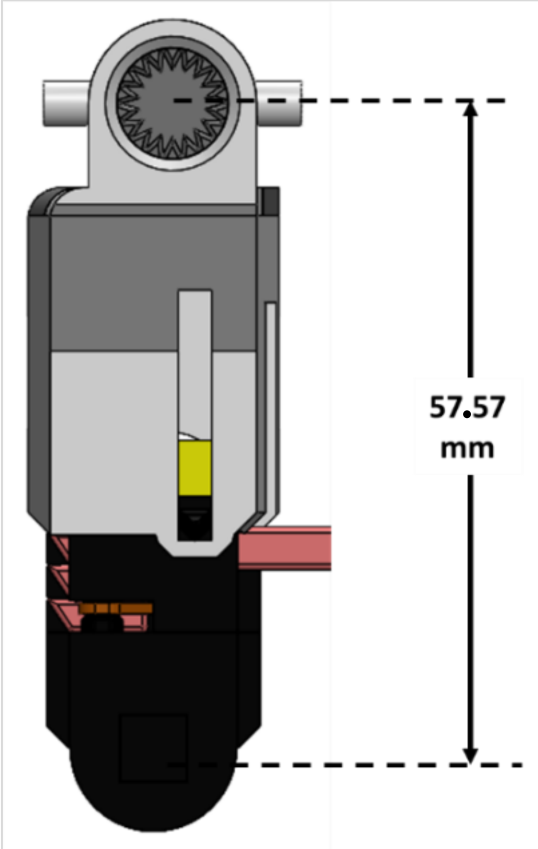


Figure 90 – Height of the Extended Outer Part of the Telescopic Adjustment

The printing positions for this group are presented in Figure 91.

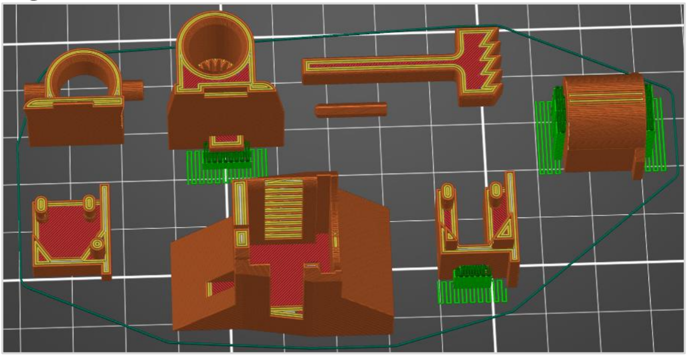


Figure 91 – Printing Position for the Shoulder-Mandible Elements

The connecting parts could be printed as one piece but the teeth inside the part number two, have extreme importance and should keep the tolerances.

As explained, the angle for any print to have quality shouldn't exceed the 45 degrees limit for wall printing. Since the teeth are printed inside a circular shape, that limit is exceeded when the part's position has the hole axis parallel to the printing bed. In this case, the most suitable printing position is with the hole axis perpendicular to the bed.

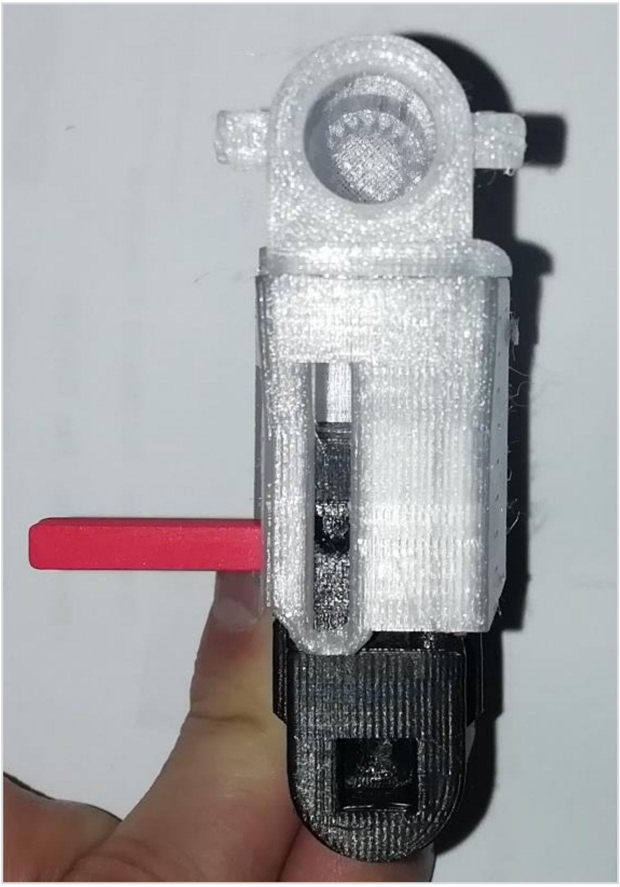
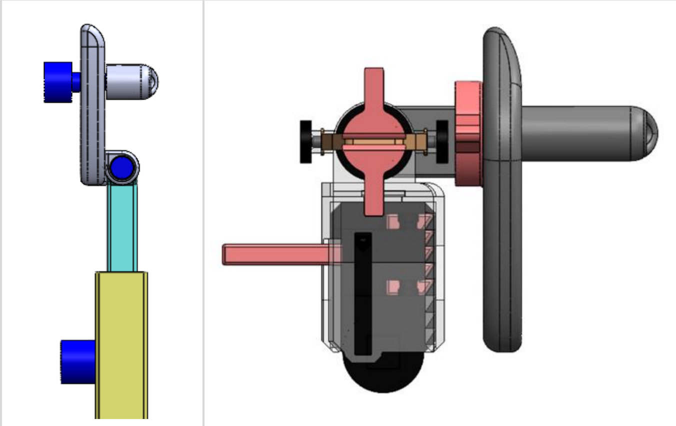


Figure 92 – Shoulder-Mandible Element

The *Mandible Support* from the Final Prototype keeps the angle adjustment mechanism but increases the degree of adjustment to 40 degrees. The way this piece was designed and implemented allows for this degree to be increased even more if necessary or intended.

The major difference compared to the previous model is on the side where the connection to the *Shoulder-Mandible Element* is made. As it is possible to see in Figure 93, the *Shoulder-Mandible Element* on the seventh model (Figure 93-a) is located on the right of the *Mandible Support* and the opposite happens on the final prototype. As mentioned in Appendix G – Model Seven, after printing and testing this connection, the rotation of the *Mandible Support* relative to the *Shoulder-Mandible Element* was reduced due to a shock between both. The new design (Figure 93-b and 94) shows that the problem is solved (before the tests) as there isn't any virtual barrier. The present solution allows a clear rotation of the *Mandible Support* in relation to the *Shoulder-Mandible Element* achieving around 177 degrees. (Figure 94)



(a)	(b)

Figure 93 – Front View of the Left Mandible Support Assembled on Model Seven (a) and on the Final Prototype (b)

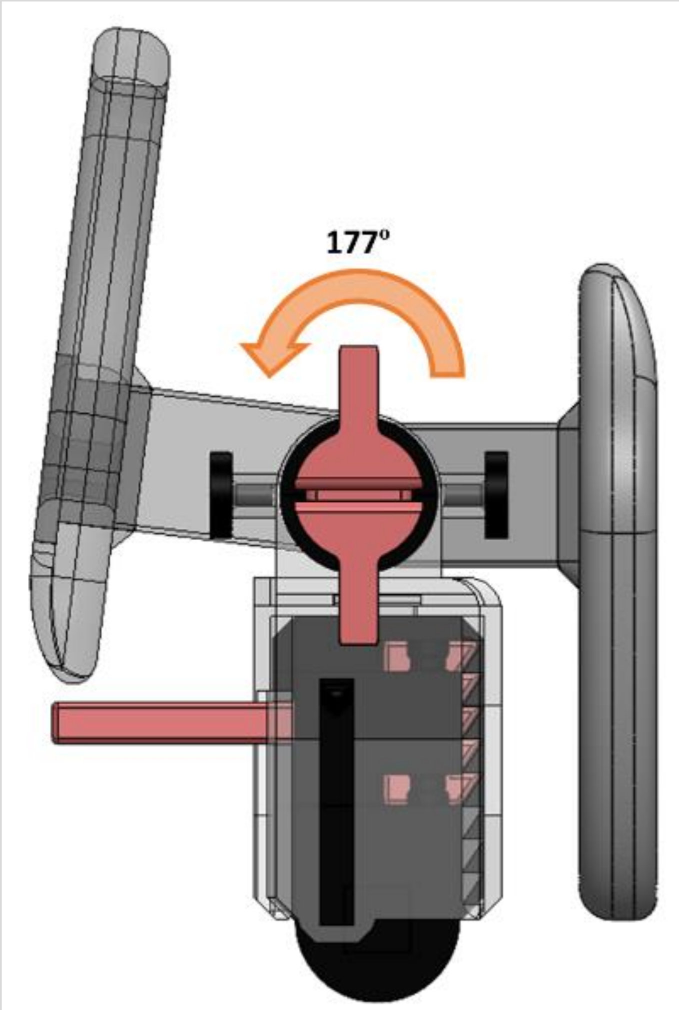


Figure 94 – Degree of Rotation Allowed on the Final Prototype Connection

To lock the rotation presented in Figure 94, a *Toothed Shaft* was added to the connection. This *Shaft* has two different diameter sized tooth patterns, one to rotate always with the *Mandible Support* engaged, and the other to lock the position desired. This result was achieved by sliding that shaft and engaging or disengaging it from the toothed locking region. (Figure 95)

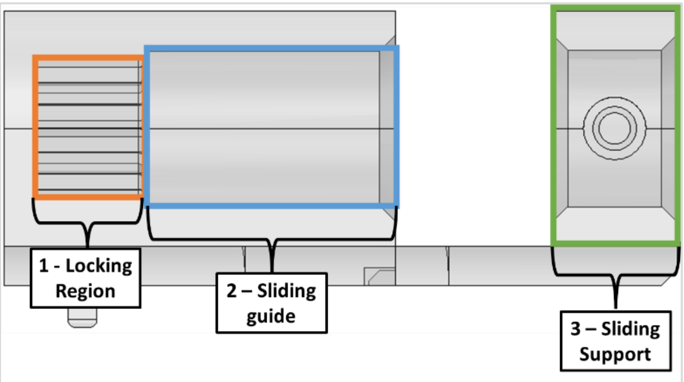


Figure 95 – Left View of the Connection Part

Figure 95 shows the three important areas that will allow to lock or unlock the rotation of the *Mandible Support*. The locking region (1 in Figure 95) is the region where the toothed pattern with a smaller diameter of the *Shaft* will slide in to lock or unlock the rotation of it and of the *Mandible Support*. The sliding guide region (2 in Figure 95) is the one of the connection parts. This will keep the smaller diameter toothed region of the *Shaft* always pointed and centred to re-engage on the locking region when disengaged. As for the Sliding Support (3 in Figure 95), it will allow for the *Shaft* to be centred on the hole by preventing any movement in other direction besides the sliding one. It also allows to secure the *Mandible Support* when connected to these parts.

Concerning the *Shaft*, Figure 96 describes all its particularities.

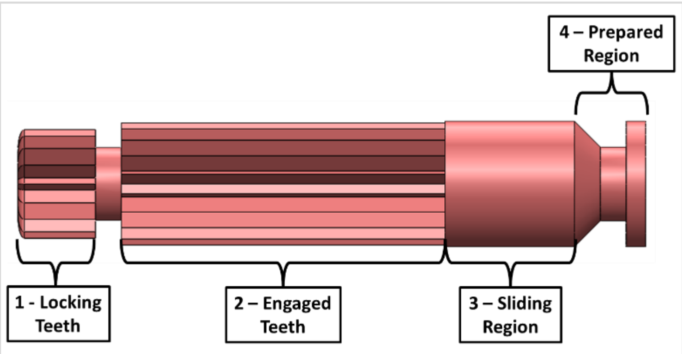


Figure 96 – Shaft Regions

The locking teeth (1 on Figure 96) are responsible for locking the rotation of the *Shaft* and the *Mandible Support* by engaging on the locking region of the *Connection Part*. This region matches the one mentioned as smaller diameter teeth of the *Shaft*. As for the engaged teeth (2 on Figure 96), they will always be engaged on the *Mandible Support* (Figure 97), even when the shaft is pulled to unlock. As this region is always engaged via teeth contact on the *Mandible Support*, when the *Shaft* is in the unlocked position, the entire group can be rotated and adjusted like in Figure 94.

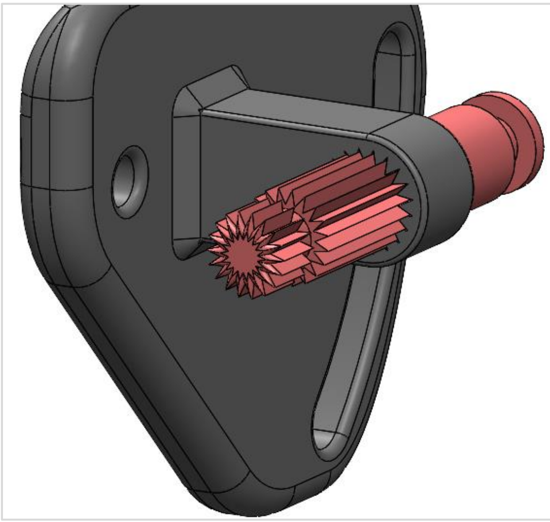


Figure 97 – Shaft and Mandible Support Engagement

The sliding region (3 in figure 96) offers support for when the shaft is in the locked position and is moved to the unlocked one. The *Shaft* with the prepared region (4 in figure 96) is ready for a combination of the mechanism with *Elastic Bands* for fast locking. (Figure 98)

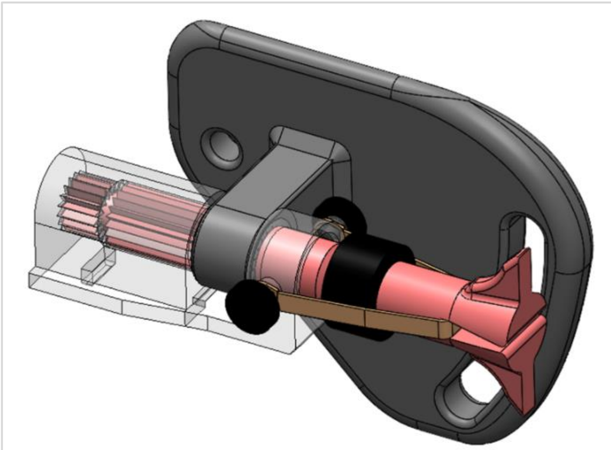


Figure 98 – Shoulder-Mandible and Mandible Support connection

The application of *Elastic Bands* on this lock follows the same principles as on the other developed mechanisms. By creating tension, the *Elastic Bands* keep the *Shaft* in the locked position and to unlock and change positions, an *Actuator* was designed for the user to pull the *Shaft*. After releasing it the position gets automatically locked. (Figure 99 and 100)

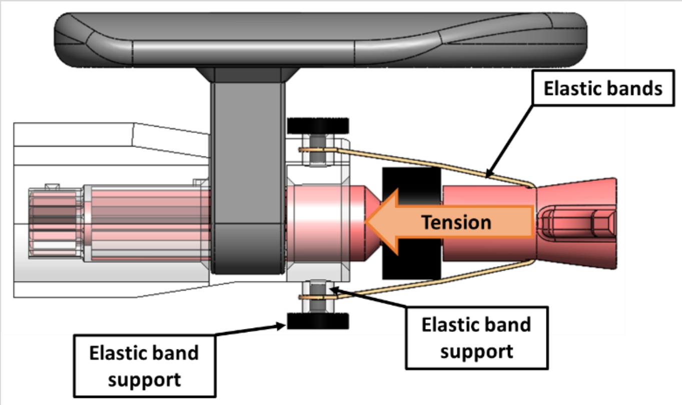


Figure 99 – Top view of the Shoulder-Mandible and Mandible Support connection

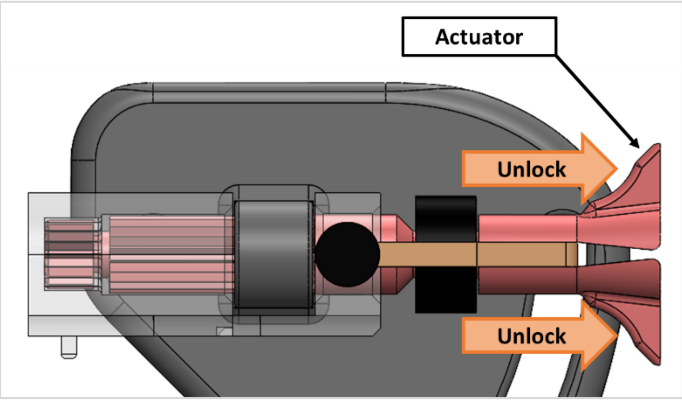


Figure 100 – Manual actuator detailed view

If the *Actuator* was all one piece with the *Shaft*, every rotation for adjustment would also rotate the *Actuator*, which would cause the *Elastic Band* to roll consequently affecting the purpose of the mechanism. For this reason, the *Shaft* and the *Actuator* were physically separated, and a *Union Ring* was used to keep both connected. This *Union Ring* allows for the *Shaft* to rotate independently from the *Actuator* and yet to be pulled by it. This way, the *Elastic Band* remains always in the same position independent of any adjustment and keeps the tension on the Shaft for the position to be locked. (Figure 101)

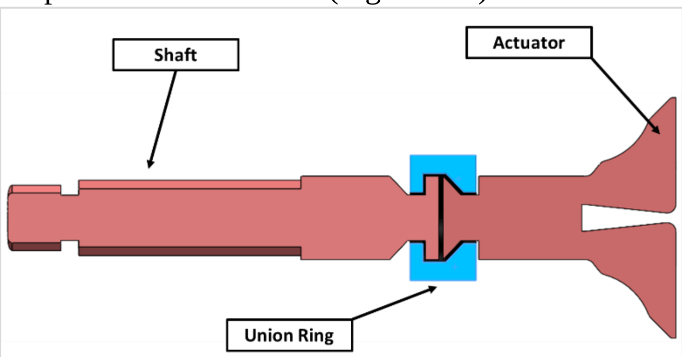


Figure 101 – Cut View of the Shaft, Actuator and Union Ring Assembled

For assembling this group, the *Union Ring* is printed in two parts and then glued. The inside of the *Union Ring* presents two shapes, a square one – on the *Shaft* (preceded by a tapered region) and a triangular one – on the *Actuator*. Both the *Actuator*, the *Union Ring's* half and the *Shaft* had in consideration the printing position and were designed with 45 degrees for a possible printing without supports. (Figure 102)

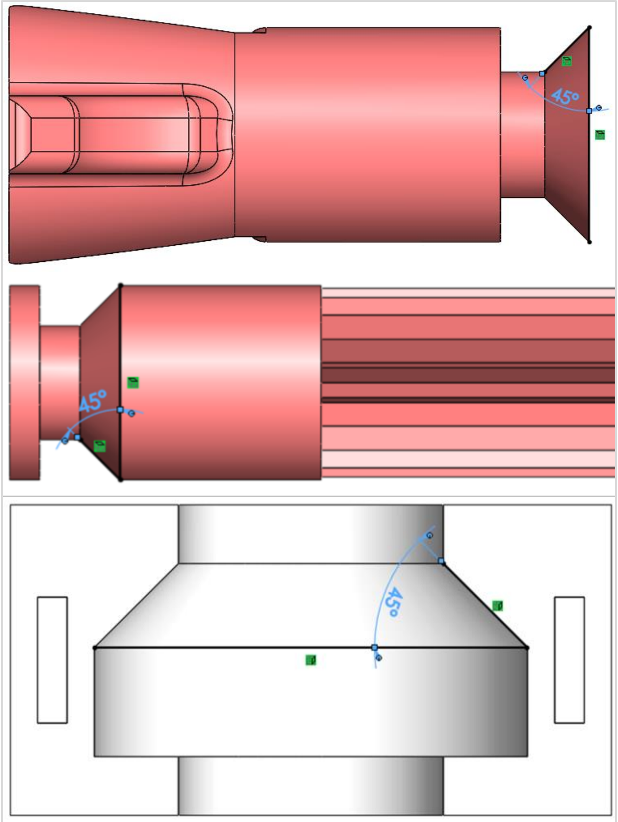


Figure 102 – Design Details Having in Consideration Printing Positioning

As for the *Mandible Support* group, it is composed of six parts. Two of them constitute the *Mandible Support* and the remaining four belong to the Angle *Adjustment Element*. As the *Toothed Pattern* of the *Mandible Support* needs printing rigour, that portion was separated from the main part of the *Mandible Support* to be able to be printed in a favourable position. The *Mandible Support* presents a square hole where the *Toothed Part* will be inserted and assembled. (Figure 103)

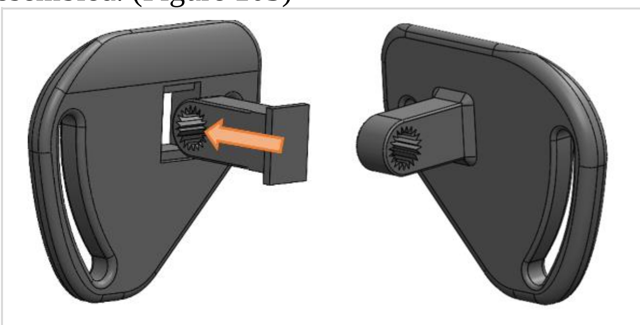


Figure 103 – Mandible Support

With respect to the *Angle Adjustment Element*, its assembly on the *Mandible Support* is the same as in the previous model. The different shape presented, allows for the *Angle Adjustment Element* to rotate to 40 degrees and still presents a margin to increase. The main difference in this model (besides its' shape) is the momentum achieved on the *Bolt* that locks the position. In this case, the head of the *Bolt* has now a teeth pattern and then a *Circular Element* with an extension is geared on it. This extension creates a greater momentum promoting an easier and stronger lock. When assembling, the *Bolt* should be tightened first and then, according to its position (0 or 40 degrees), assemble the extension part in the most favourable direction.

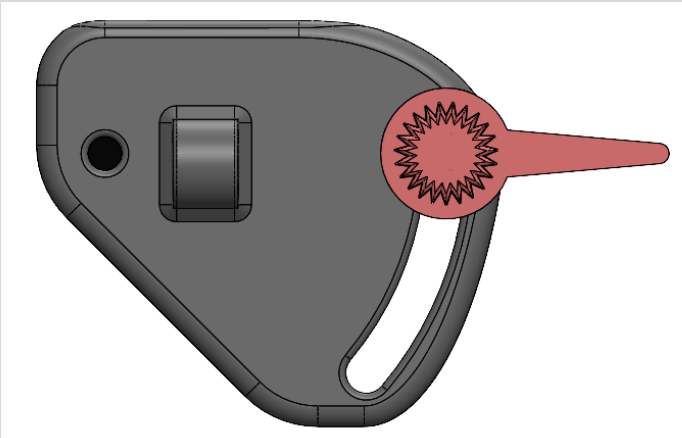


Figure 104 – Mandible Support Fully Assembled

About the printing of these parts and taking into consideration what have already been described in Figures 102 and 103, figure 105 shows the printing positioning for all the parts.

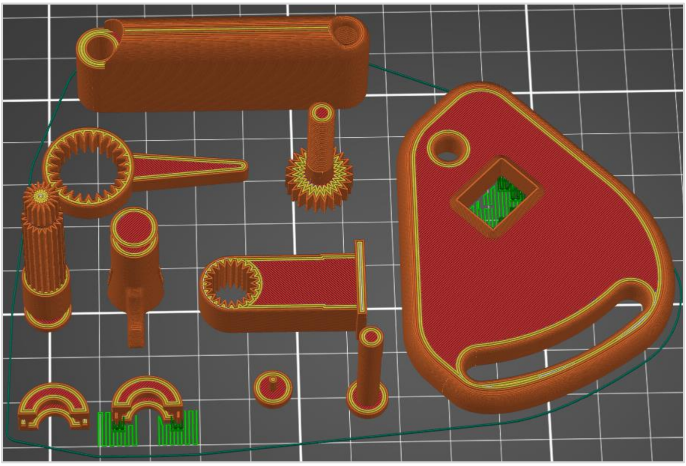


Figure 105 – Printing Position for the Mandible Support Parts

0 degrees position 40 degrees position

Figure 106 – Printed Assembly with 0 and 40 Degrees Position

The dimensions of the *Shoulder-Mandible Element* are not accurate as Knowing (2017) doesn't present exact dimensions for the relations needed to build this project, so approximate ones were used. A proper study with the dimensions according to reference points from this structure should be done, and the dimensions adjusted. In this case, only the height of the *Shoulder-Mandible Element* and the *Mandible Support* is not as exact as intended and both designs can be easily adjusted to the study results.

Chin Strap and Chin Attachment

For the *Chin Strap*, an adjustment element was needed. To fulfil that, a *Chin Attachment* (Figure 107) was created. This element presents a hole in the middle where the chin should settle and two square holes on each end where the *Chin Strap* passes through.

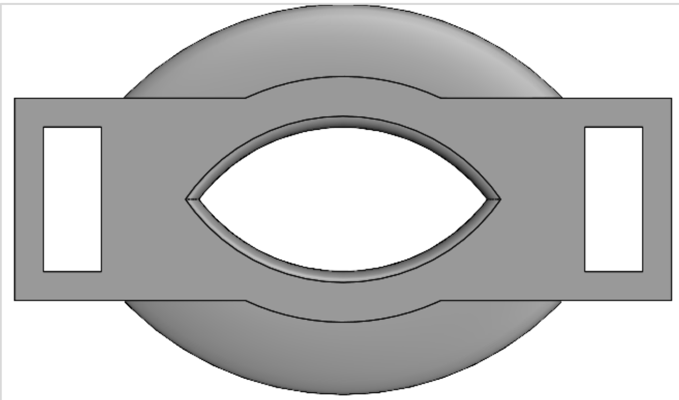


Figure 107 – Chin Attachment

For the real model, the *Chin Straps* were made with Velcro Material and for the *Chin Attachment*, as it needs to be comfortable when in contact with the patient, was printed in flexible material and glued some foam on the region where it contacts with the patients' skin. The way that the adjustment mechanism works in this case, is presented in figure 108.

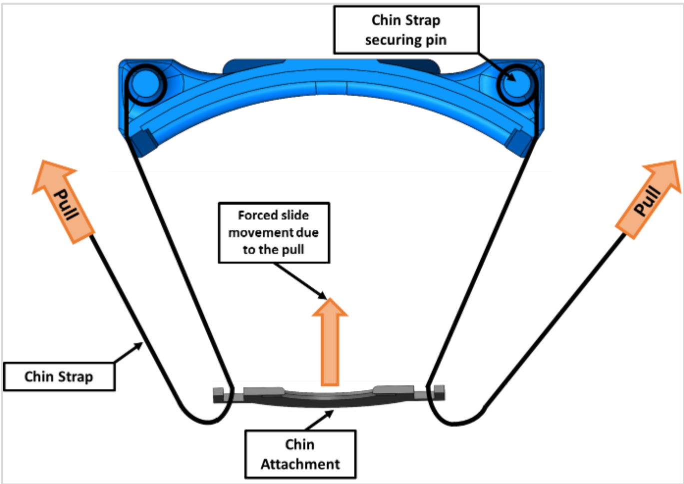


Figure 108– Cut Top View of the Back Portion and the Chin Attachment

By pulling the *Chin Strap* to a direction far from the Back Portion, the *Chin Attachment* slides to a position closer to the Back Portion. At some point, the *Chin Attachment* will apply pressure on the patient's head against the Back Portion which, through the *Balloons*, will be monitored and when achieving a certain limit value of fastening pressure, an alert will be given on the external device for the staff to know that that position is ideal and should be kept/locked (by joining the two Velcro sides on each side of the collar).

(a)

(b)

Figure 109 – Movement to Adjust the Chin Strap (a) and Adjustment Lock with Velcro (b)

Overall look of the cervical collar

The application of the cervical collar corresponded to all the theoretical assumptions made during the entire design and considerably limited the movements of the patient.

The following Figures 110 to 112 show the collar with all the electronic systems integrated.

Figure 110 – PCB and Battery Integrated on the Collar

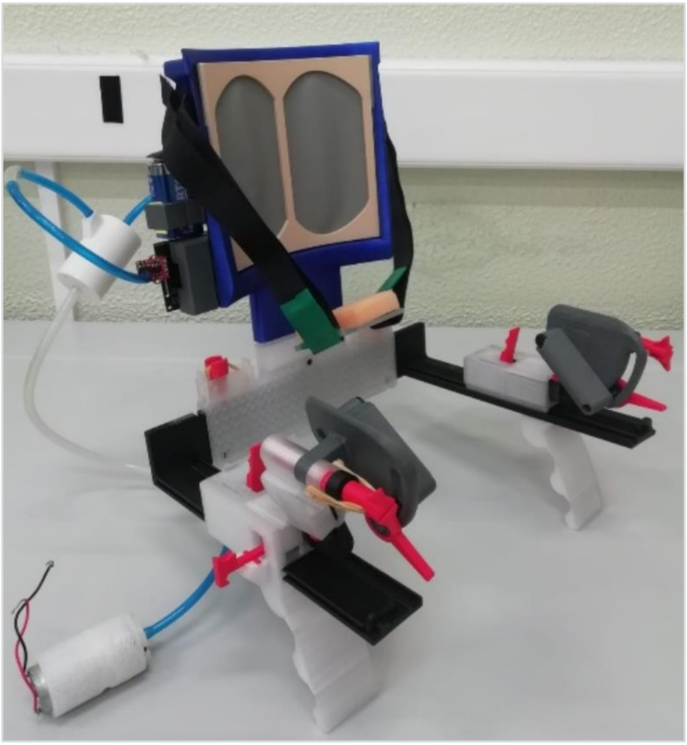


Figure 111 – Side View of the Final Prototype with all the Systems Connected

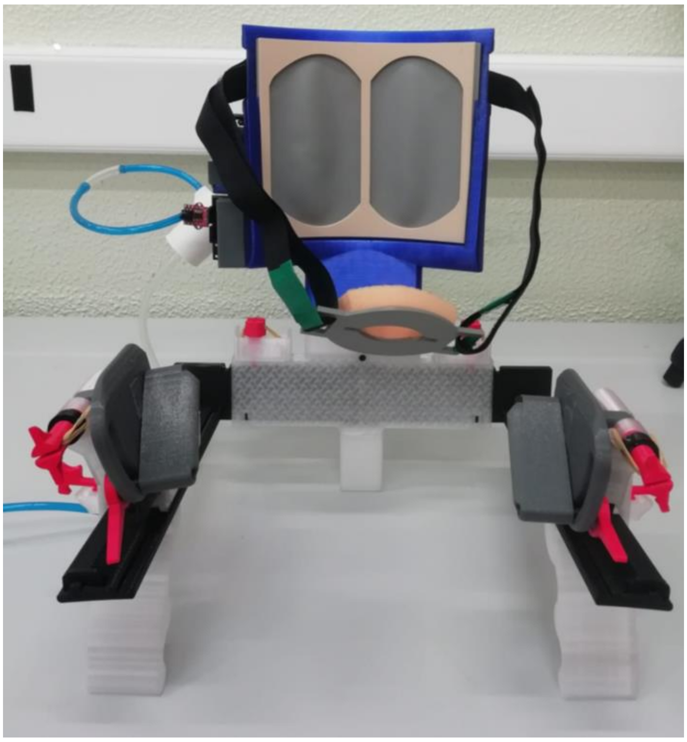


Figure 112 – Front View of the Final Prototype with all the Systems Connected

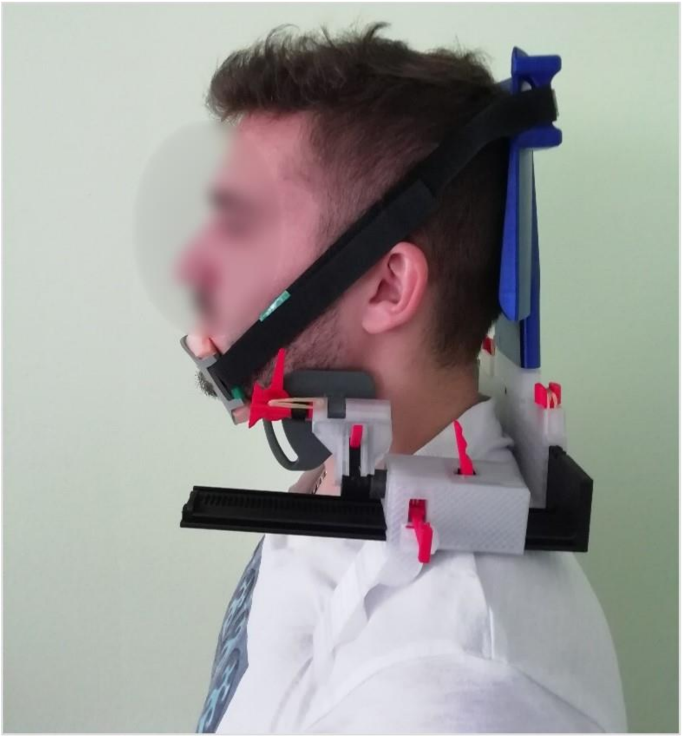


Figure 114 - Right View of the Cervical Collar Applied

Figures 113 and 114 show two different views of the cervical collar applied. In these pictures, the *Balloons* are not present as well as the electronics are not applied.

Figure 113 - Front View of the Cervical Collar Applied

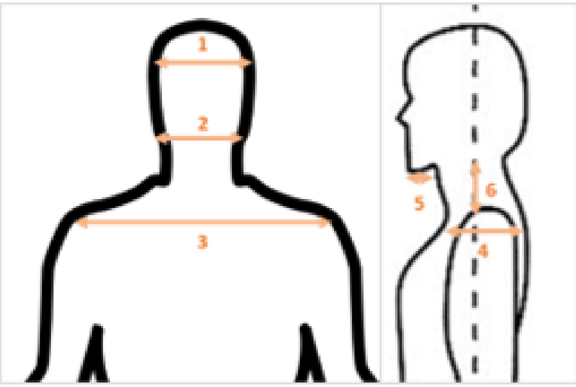
Novel Pre-Hospital Cervical Collar with Pressure Sensor

2020/2021

Test Report

Volunteer data

Test Number: **Height:** **Age:** **Gender:**



Volunteer Measurements [mm]	
1	
2	
3	
4	
5	
6	

To fill by the Test Performer

Parameter	1	2	3	4	5
Restriction of the flexion movement.					
Restriction of the extension movement.					
Restriction of left and right rotation.					
Restriction of right and lateral flexion.					

Note: 1 – Very Poor Performance; 2 – Poor Performance; 3 – Satisfactory Performance; 4 – Good Performance; 5 – Very Good Performance

- *Time taken for collar application:*

To fill by the Volunteer

Parameter	1	2	3	4	5
Felt discomfort when being immobilised					
The device presents all the necessary features for the context of immobilisation.					
The structure is appropriate for my size.					
The collar applies pressure on the neck.					

Appendix I

Novel Pre-Hospital Cervical Collar with Pressure Sensor

2020/2021

Parameter	1	2	3	4	5
The Mandible Supports are comfortable.					
The Chin Attachment is comfortable.					
The back of the head is comfortably supported.					
The Shoulder Support conditioned my breathing performance.					
The adjustment on the chest is painful.					
The structure is safe.					

Note: 1 – Very Poor Performance; 2 – Poor Performance; 3 – Satisfactory Performance; 4 – Good Performance; 5 – Very Good Performance, depending on the parameter, the qualitative evaluation can also have the value of: 1- No; 2 – Unsure/No; 3 – Unsure; 4 – Unsure/Yes; 5- Yes

Suggestions for device Improvement:

Appendix I

Annexes

Protocol for Approaching and Stabilise an Emergency Patient with Suspected SCI

ATUAÇÃO

- Pensar e agir sempre em função de AVALIAÇÃO PRIMÁRIA:
  - A Permeabilizar a via aérea com controlo da coluna cervical
  - B Ventilação e Oxigenação
  - C Assegurar a circulação com controlo da hemorragia
  - D Disfunção neurológica
  - E Exposição com controlo da temperatura
- Garantir desde o primeiro momento ao abordar a vítima a estabilização, alinhamento e imobilização da coluna cervical atitude que nunca deve ser abandonada. A utilização de um colar cervical torna-se fundamental. Estas vítimas nunca devem ser mobilizadas sem que estejam totalmente imobilizadas (ex. colete de extração, plano duro com imobilizadores laterais de cabeça), exceto se houver perigo de vida no local onde se encontram (ex. desabamento, explosão, fogo) ou se houver necessidade de iniciar manobras de suporte de vida;
- Administrar oxigénio:
  - Garantir oximetria ≥ 95% (se grávida ≥ 97% ; se DPOC entre 88-92 %);
  - 10 L/min;
- Se a vítima apresentar compromisso ventilatorio (frequência respiratória inferior a 8 ou superior a 35) iniciar ventilação assistida, com insuflador manual, 10 a 12 ciclos por minuto (para melhorar a quantidade de ar disponível para as trocas gasosas);
- Identificar e controlar hemorragias;
- Avaliar, registar e vigiar sinais vitais;
- Identificar sinais de choque;
- Não dar nada a beber;
- Recolher o máximo de informação sobre o mecanismo do trauma e a vítima, recorrendo à nomenclatura CHAMU.
- Efetuar a observação sistematizada de modo a detetar eventuais lesões associadas;
- Manter a temperatura corporal da vítima;
- Passagem de dados ao CODU;
- Considerar eventual pedido de apoio diferenciado (CODU);
- Transporte calmo e suave, com vítima imobilizada em plano rígido com imobilizadores laterais de cabeça (e/o maca de vácuo), evitando a trepidação.

> ⚠ Atenção: Vítimas com lesões cervicais podem ter compromisso respiratório (apneia).

Adapted from Valente *et al.*, 2012a, p.30.

Annex 1

Protocol for Approaching and Stabilise an Emergency Patient with Suspected Paediatric SCI

ATUAÇÃO NO TVM

Procedimentos idênticos aos apresentados para os adultos, no entanto existem alguns princípios a reter:

- Usar colar cervical e imobilizadores laterais de cabeça;
- Usar apenas o velcro frontal (a utilização do velcro sobre o mento pode provocar pressão sobre as partes moles e condicionar obstrução da via aérea);
- É necessário o acolchoamento de toda a região posterior desde a cintura escapular até aos pés, para evitar a flexão;
- Transportar de preferência em maca de vácuo (com plano duro por baixo) ou em alternativa em plano rígido com imobilizadores laterais de cabeça;
- Considerar pedido de apoio diferenciado (CODU).

Adapted from Valente *et al*., 2012a, p.46.

Annex 2

Safety Protocol When Approaching a Burn Victim

ATUAÇÃO

O primeiro passo na atuação é o afastamento do agente que provoca a queimadura ou em alternativa da vítima relativamente ao agente.

- No caso de fogo, a vítima deve ser deitada de modo a diminuir a inalação de fumos. As chamas devem ser rapidamente extintas com um cobertor, com água (se disponível) ou soro;
- Nas queimaduras químicas, a medida inicial consiste em remover a roupa contaminada, limpar a pele com compressas secas e irrigar com grandes quantidades de água ou soro. Limpar com compressas secas antes de iniciar a lavagem como soro ou água. A limpeza inicial com compressas é importante se o agente for em pó (ex. cal) ou insolúvel em água (ex. fenol). A lavagem deve durar, se possível, pelo menos 30 minutos e prosseguir mesmo durante o transporte até o hospital;
- A queimadura com ácido fluorídrico constitui exceção: a lavagem deve durar 5 a 10 minutos e a vítima rapidamente evacuada para o hospital para tratamento específico;
- De um modo geral, a neutralização química (utilização de um ácido para neutralizar uma base ou vice-versa) provoca uma reação em que se produz calor pelo que não deve ser realizada. A atitude correta é diluir o químico, mesmo quando este reage com água;
- Nas queimaduras elétricas, é necessário desligar a corrente elétrica e só depois observar a vítima. Nos acidentes com corrente de alta tensão, não se deve aproximar da vítima sem indicação do pessoal especializado no assunto (ex. companhia da eletricidade, caminhos de ferro) dado o risco de se provocar um arco voltaico, isto é a progressão da corrente elétrica pela atmosfera através de um campo magnético que existe em volta dos cabos ou terminais de alta tensão.

Adapted from Valente *et al.*, 2012a, p.74.

Annex 3

Protocol when Approaching a Burn Victim (After Safety Protocol)

Controladas que estão as condições de segurança iniciar a abordagem segundo o Exame da Vítima.

- Intervir sempre em função de AVALIAÇÃO PRIMÁRIA:
  - A Permeabilizar a via aérea com controlo da coluna cervical
  - B Ventilação e Oxigenação
  - C Assegurar a circulação com controlo da hemorragia
  - D Disfunção neurológica
  - E Exposição com controlo da temperatura
- Abordar a vítima, imobilizando a cabeça desta em posição neutra na suspeita de coexistir um TCE e/ou TVM; Deve ser colocado colar cervical em todos os queimados envolvidos em explosões ou acidentes com desaceleração e/ou projeção;
- Assegurar a permeabilidade da Via Aérea: As vítimas com queimaduras das vias aéreas ou com traumatismo da face, pescoço, ou tórax devem ser identificadas imediatamente, uma vez que podem necessitar de manobras de ventilação assistida. A inalação de vapor e gases quentes provoca edema da via aérea superior, que pode evoluir rapidamente para obstrução. Rouquidão progressiva é um sinal de obstrução iminente, pelo que deve redobrar a atenção e estar pronto a iniciar manobras de suporte básico de vida, quando depara com esta situação;
- Suspeitar que existe queimadura da via aérea quando:
  - História de queimadura em espaço fechado;
  - História de inalação de vapores;
  - História de perda de conhecimento, eventualmente provocada por má oxigenação do cérebro;
  - Queimadura da face;
  - Queimadura dos pelos nasais;
  - Queimadura da língua, lábios e cavidade oral;
  - Respiração ruidosa, rouquidão ou tosse;
  - Expetoração que apresente cinzas ou carvão;

ATUAÇÃO (CONTINUAÇÃO)

- Administrar oxigénio:
  - Garantir oximetria ≥ 95% (se grávida ≥ 97% ; se DPOC entre 88-92%);
  - 10 L/min;
- Se a vítima apresentar compromisso ventilatorio (frequência respiratória inferior a 8 ou superior a 35) iniciar ventilação assistida, com insuflador manual, 10 a 12 ciclos por minuto (para melhorar a quantidade de ar disponível para as trocas gasosas);
- Avaliar e registar sinais vitais;
- Despistar sinais de choque;
- Recolher o máximo de informação sobre o mecanismo do trauma e sobre a vítima recorrendo à nomenclatura CHAMU;
- Efetuar a observação sistematizada de modo a detetar eventuais lesões associadas;
- Não dar nada a beber;
- Manter a temperatura corporal; Durante a exposição, observação sistematizada e transporte da vítima devemos precaver o risco de hipotermia;
- Passagem de dados ao CODU;
- Considerar pedido de apoio diferenciado (CODU);
- Perante uma vítima queimada e após o parar o processo de queimadura este deve ser transportado sobre um lençol de queimados ou esterilizado e coberto com outro lençol semelhante;
- Nas queimaduras não deve remover a roupa que se encontra aderente, de forma a não agravar as lesões;
- Nas queimaduras elétricas deve sempre pesquisar a porta de entrada, a porta de saída e estar desperto para as lesões ocultas no trajeto entre as duas portas;
- Após a irrigação, para parar o processo de queimadura, as áreas queimadas devem ser cobertas com compressas humedecidas em Soro Fisiológico se a área corporal queimada for inferior a 10%. Se a área corporal queimada for superior a 10% cobrir queimaduras com compressas secas ou lençol esterilizado.
- É de extrema importância utilizar material esterilizado e cuidados rigorosos de modo a evitar a infecção uma vez que o risco é elevado pois a pele constitui uma importante barreira protetora aos microrganismos;
- Irrigar as áreas queimadas com grande quantidade de Soro Fisiológico ou água de forma a aliviar a dor e evitar o agravamento da queimadura em profundidade (no caso de queimaduras de 2º ou 3º grau com menos de 10% de área corporal, acima disto existe o risco de provocar hipotermia, algo não desejável). O arrefecimento precoce reduz a progressão da queimadura em profundidade e diminui a dor. Faz-se através de lavagem abundante com soro fisiológico ou água. É necessário cautela para evitar a hipotermia que se pode instalar rapidamente. O gelo pode agravar a lesão cutânea pelo que não deve ser utilizado;
- Nas queimaduras químicas, o tempo de lavagem é variável. Nas queimaduras por bases fortes, a lavagem pode prolongar-se por horas. No caso das queimaduras oculares, o tempo mínimo de lavagem recomendado é de 30 minutos.

Adapted from Valente *et al.*, 2012a, pp.74-75.

Annex 4

Secondary Evaluation Protocol

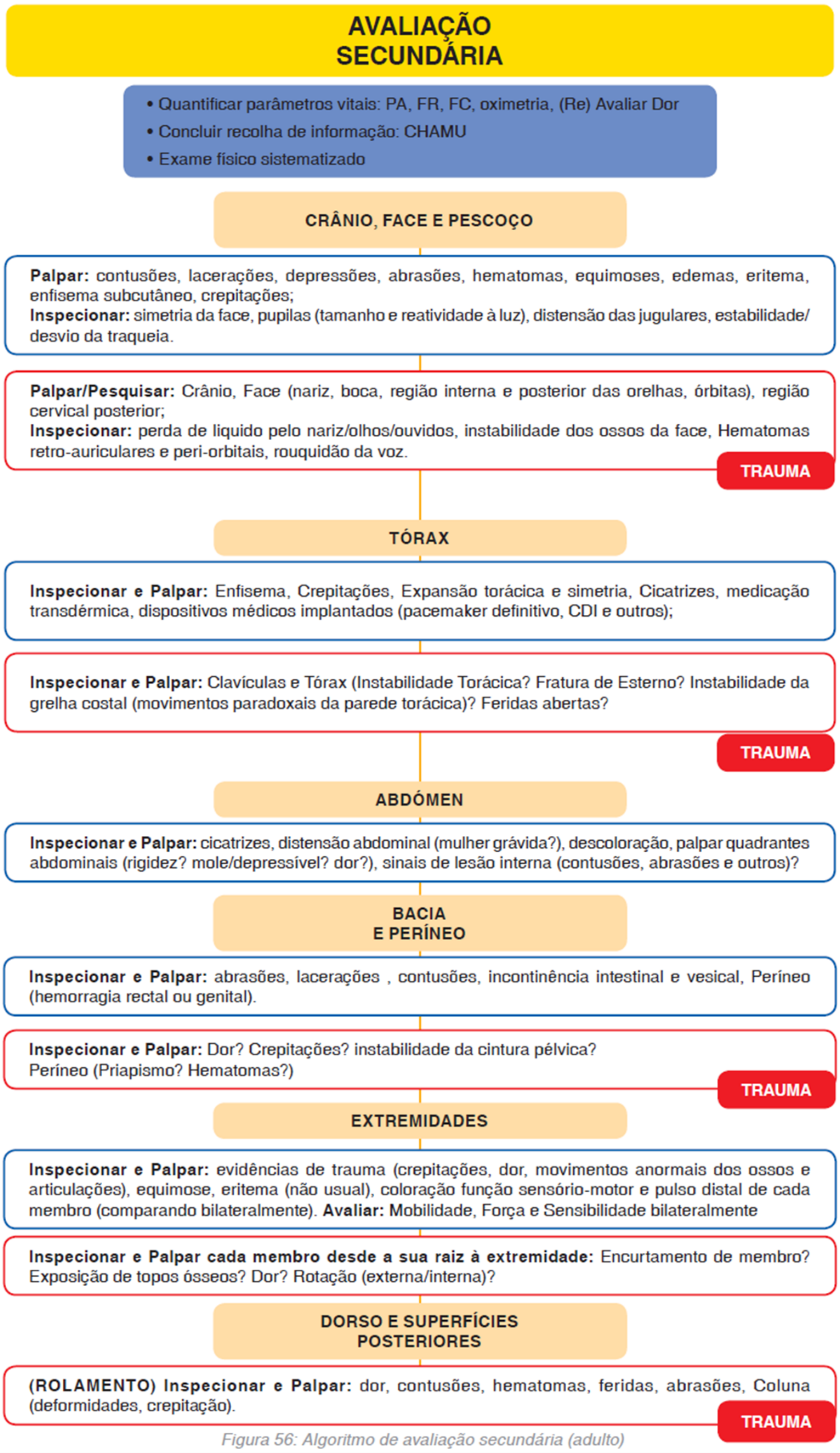
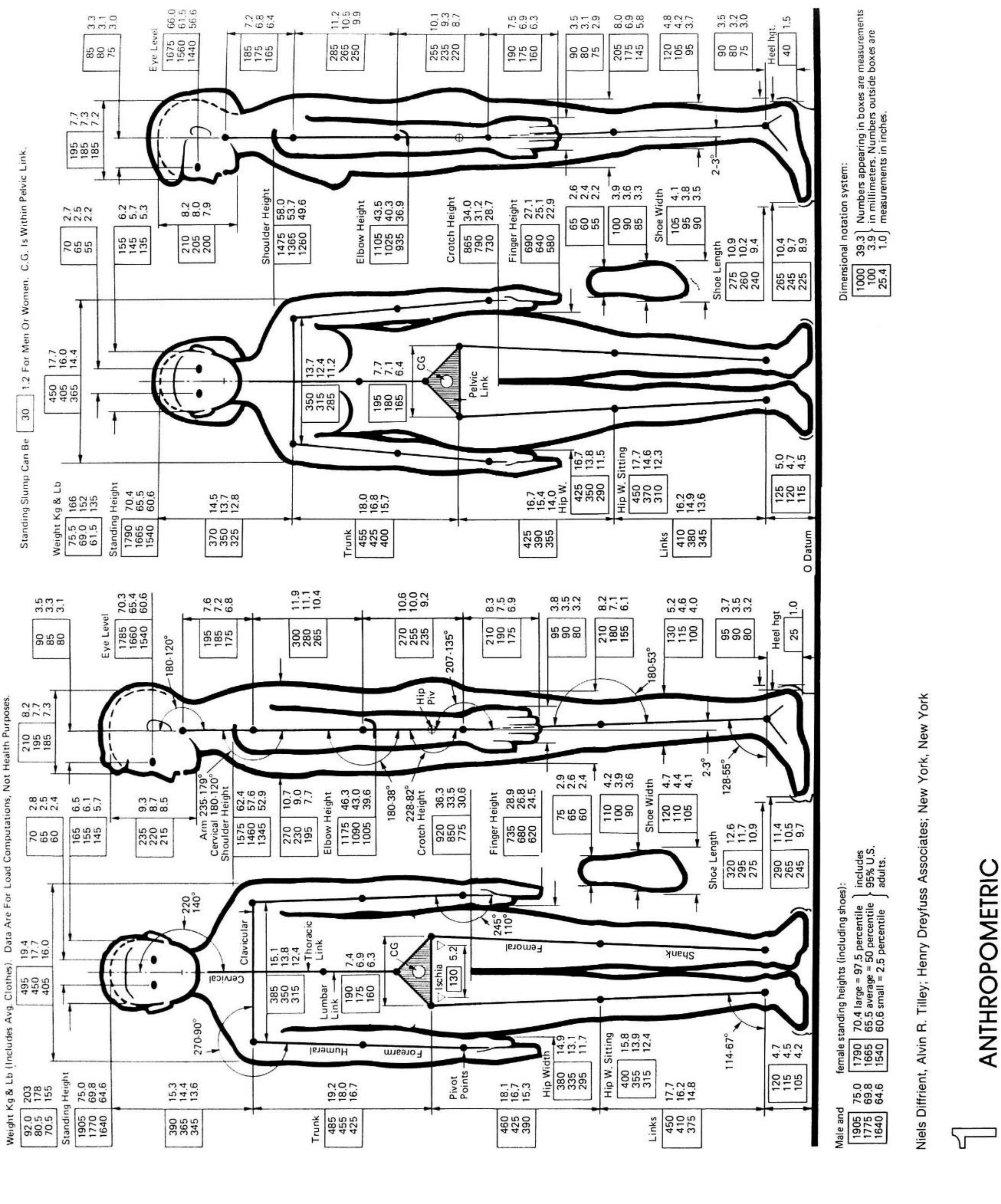


Figura 56: Algoritmo de avaliação secundária (adulto)

Adapted from Valente *et al.*, 2012b, p.72.

Annex 5

Anthropometric Dimensions of the Human Body on a Certain Population



Adapted from *Knowing-Making the Architectural Inhabitant* (2017)

Annex 6