Ministry of Education
University POLITEHNICA of Bucharest
Doctoral School of Industrial Engineering and Robotics

# PhD THESIS
# SUMMARY

*PhD Student,*
MURZAC N. Roman

*Scientific coordinator,*
Professor Cristian-Vasile DOICIN, PhD. Eng. Ec.

– BUCHAREST –

– 2021 –

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## RESEARCH ON THE DEVELOPMENT OF SMART ORTHOSES FOR POSTURE CORRECTION

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*PhD Student,*
**MURZAC N. Roman**

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# List of abbreviations

| *No.* | *Abbreviation* | *Meaning* |
|---|---|---|
| 01 | ABS | *Acrylonitrile Butadiene Styrene* |
| 02 | AHP | *Analytic Hierarchy Process* |
| 03 | ASCII | *American Standard Code for Information Interchange* |
| 04 | BOM | *Bill of Materials* |
| 05 | CAD | *Computer Aided Design* |
| 06 | CD | *Research and Development* |
| 07 | CDPD | *Convention on the Rights of Persons with Disabilities* |
| 08 | CE | *European Conformity* |
| 09 | CEN | *European Committee for Standardization* |
| 10 | CIF | *International Classification of Functioning, Disability and Health* |
| 11 | CT | *Computed Tomography* |
| 12 | DICOM | *Digital Imaging and Communications in Medicine* |
| 13 | DPN | *New Product Development* |
| 14 | EN | *European Standards* |
| 15 | FA | *Additive Manufacturing* |
| 16 | FDM | *Fused Deposition Modelling* |
| 17 | FEM | *Finite Element Method* |
| 18 | GMDN | *Global Medical Device Nomenclature* |
| 19 | HIPS | *High Impact Polystyrene* |
| 20 | IDE | *Integrated Development Environment* |
| 21 | ISCO | *International Standard Classification of Occupations* |
| 22 | ISO | *International Organization for Standardization* |
| 23 | MRI | *Magnetic resonance imaging* |
| 24 | OBJ | *Object File* |
| 25 | OCP | *Posture Correction Orthoses* |
| 26 | OMS | *World Health Organization* |
| 27 | OSIM | *State Office for Inventions and Trademarks* |
| 28 | PET | *Polyethylene Terephthalate* |
| 29 | PETG | *Polyethylene Terephthalate with Glycol* |
| 30 | PIB | *Gross Domestic Product* |
| 31 | PLA | *Polylactic acid* |
| 32 | PP | *Polypropylene* |
| 33 | PT | *Technological process* |
| 34 | RMN | *Nuclear magnetic resonance* |
| 35 | SLA | *Stereolithography* |
| 36 | SNOMED | *Systematically Organized Computer Collection of Medical Terms* |
| 37 | SR | *Romanian Standard* |
| 38 | STL | *Standard Tessellation Language* |
| 39 | TA | *Additive Technologies* |
| 40 | UE | *European Union* |
| 41 | USB | *Universal Serial Bus* |
| 42 | VCC | *Voltage Common Collector* |
| 43 | VDI | *Standard* |

# Introduction

The doctoral thesis is the result of five years of sustained activity to design and manufacture a product that will help several categories of people, from professionals who stay in the office all day, to people with medical problems to the spine, inherited or acquired with age. To ensure the security of a wide market, a market study was carried out to identify the potential market size for such a product.

In 2019 the employment rate in the European Union (EU) was 73.1%, which is the highest average recorded in the EU [J11]. In Romania, this rate was 70.9%, which is very close to the average EU value [J11].

In Romania, the number of active employees in September 2020 was 5,574,172 persons [M20]. From the data presented above that, only in Romania, over one million people work in the office and in the European Union over 40 million people work in the office.

The percentage of the population over the age of 60 was 8% in 1950 and 10% in 2000 and is estimated to reach 21% by 2050. The aging of the population has led, in recent decades, to an increase in the percentage of neuromotor disabilities and deficiencies, among the global population. The total or partial loss of mobility affects not only the ability to walk, but also the ability to perform personal daily activities, an important factor in reducing the quality of life [L01].

Based on the data presented on the number of people working in the office, as well as the problems related to the aging population, the doctoral thesis proposes a methodology for developing new products in general and a smart orthosis to correct the posture, in particular. The product is intended to prevent the occurrence of occupational diseases specific to staff working in the office, as well as to improve the specific diseases of the spine in the elderly. Also, the doctoral thesis deals with the stages described in the methodology of developing new products, starting from the analysis of the specific needs of the treated problem and ending with the testing and validation of the prototype. The paper contributes at all stages of development, from establishing specifications for the developed product, taking into account customer requirements obtained after their interview, to generating the product architecture based on independent systems in terms of production processes and performing economic analysis for establishing the cost-effectiveness of orthoses production, from detailed design to establishing manufacturing processes for each component and manufacturing with the help of additive technologies a prototype orthoses for posture correction.

Some components have been prototyped in several constructive variants. After validating each individual component, a prototype, the Alpha prototype, was assembled and tested. After testing, both local, on certain critical and general subassemblies, on the entire product and its functionality was demonstrated, the last necessary changes were made, and the Alpha prototype was validated.

# Definitions

**Conception, innovation, invention, and product**

It was considered important, before analyzing and applying the development methodologies, to define the main concepts used in the paper.

According to the author, Conception is a creative activity that, starting from a set of expressed requirements, aims to define a material or immaterial product.

The product is a good result from the production process.

**Design**

According to the author, product design is the creative activity through which a solution defined by the design and dimensions of some products are obtained, as a result of some functional requirements.

**Technological process**

A process is defined as a set of interrelated or interacting activities that transform inputs into outputs [A07].

According to the author, considering all this, the technological process is the set of activities that contribute to reaching a certain stage of the transformation of the raw material into a finished product.

**Manufacturing process**

The term manufacturing or manufacturing process defines the physical or chemical change of materials and / or components into new products, through a series of well-defined processes. Materials or substances are raw materials that are the result of other activities of the manufacturing process or are products of agricultural, forestry, fishing, mining or extractive industries [O07].

In the Encyclopaedia Britannica, the manufacturing process is defined as "any process that makes products from raw materials, using manual labor or machines, usually performed systematically with the division of labor" [B07].

Next, in the thesis will be used the term “manufacturing” process with the meaning of all technological processes that contribute to the transformation of raw material into a finished product.

**Product testing**

The term product testing refers to any process by which the performance, degree of safety, quality and conformity of the product with the imposed standards are measured. The main part that defines a product in terms of comparative testing is the part where the professionals involved perform tests independent of those of the manufacturers of the given products, suppliers, and traders of these products [B08].

## Justification of the theme

The author focused on research on the development of an intelligent orthosis to correct posture because in this area, there are a few needs for which no research has been conducted. Also, additive manufacturing is the right solution for personalized products, such as orthoses.

The objective is to support patients to enhance mobility. Orthoses can stabilize, immobilize, and discharge the affected body or limbs or provide physiologically correct guidance. Poor posture at work and misconduct weights can be prevented, mitigated, or corrected. In case of permanent damage, the orthoses can maintain their functions and can prevent or reduce pain.

Considering the above it is necessary to develop orthoses or orthopedic systems to meet the needs and demands for such equipment worldwide. Within this thesis, will develop a prototype of an orthosis for correction of posture that could be used both by those working in the office, and by people with spine problems.

## Structure and content of the doctoral thesis

The doctoral thesis is structured in 11 chapters and 8 annexes and contains 241 figures and 54 tables. The structure of the paper is defined following the stages of applied theoretical-experimental scientific research: analysis of theoretical, experimental, and applied research; modeling and algorithmization of physical processes; design and development of subsystems; integration and implementation of subsystems; experimental validation studies.

The first chapter presents general elements related to the current state of the demand for assistive products and the future forecasts of this demand. In the second chapter, an analysis was made of the structure of the spine, of the biomechanics of the spine to be able to design an orthosis that can assist the spine. The third chapter presents the steps taken to establish the methodology for developing new products. In the fourth chapter, the general objective of the doctoral thesis was established, which consists in the development of an Orthosis for Posture Correction. In the fifth chapter, 21 distinct stages of the new product development process were identified. The structure of the optimal methodology for developing a new product was determined. In the sixth chapter, customer requirements were assessed, and subsequently these requirements were transformed into specifications. In the seventh chapter, starting from the study of biomechanics that allows the use of mathematical calculus in the study of complex phenomena, the mechanical model for the spine was developed. The eighth chapter presents general elements related to the establishment of the general function of the product and the primary functions. In the ninth chapter the detailed design was carried out starting from the general function. In the tenth chapter, the customized components were manufactured, and the standardized ones were purchased. In the last chapter, the assembly stages of the product were presented. Tests were performed on the prototype to validate the principle of its operation and to measure the performance of the product.

# Chapter 1

# Current state of development of assistive products

## 1.1. Regulations

According to data from the World Health Organization (WHO) [W05], regional average life expectancy has steadily increased in recent years and the average life expectancy gaps both between genders and between countries are narrowing. The main goal of the WHO for the third decade is to increase overall life expectancy by reducing differences in life expectancy [W02].

## 1.2. Legislation

### *1.2.1. International legislation*

There is a **European Social Charter** in the European Union which guarantees the right of persons with disabilities to the effective exercise of autonomy, social inclusion, and active participation in community life through the employment of member states, regardless of their age, nature, and source of disability [ C02].

### *1.2.2. Romanian legislation*

In Romania, **Law 448/2006** - "on the protection and promotion of the rights of persons with disabilities" regulates the rights and obligations of persons with disabilities assigned for the purpose of their integration and social inclusion [L03].

**Law 8/2016** - “on the establishment of mechanisms provided by the Convention on the Rights of Persons with Disabilities provides for the designation and establishment of the Council for monitoring the implementation of the Convention, the mechanism for coordinating measures for implementing the Convention, and contact points for implementing the Convention” [L04].

**Law 176/2000** - "on medical devices, applies to medical devices and their accessories". Medical devices may be placed on the market, put into service, or used only if they are certified and registered in accordance with this law, so as not to compromise the safety and health of patients, users and others [M12].

## 1.3. Statistics

### *1.3.1. Regarding people with disabilities*

According to data from the Global Burden of Disease analysis, it is estimated that 15.3% of the global population has a “moderate or severe disability,” while 2.9% or about 190 million have a “severe disability” [W03].

### *1.3.2. Regarding professionals working in the office*

In the period 2005 - 2019, the employment rate of people aged between 20 and 64 increased from 66.8% to 73.1% in the European Union, and in Romania to 70.9% [E08]. The evolution of the employment rate of the population is presented in Figure 1.1.

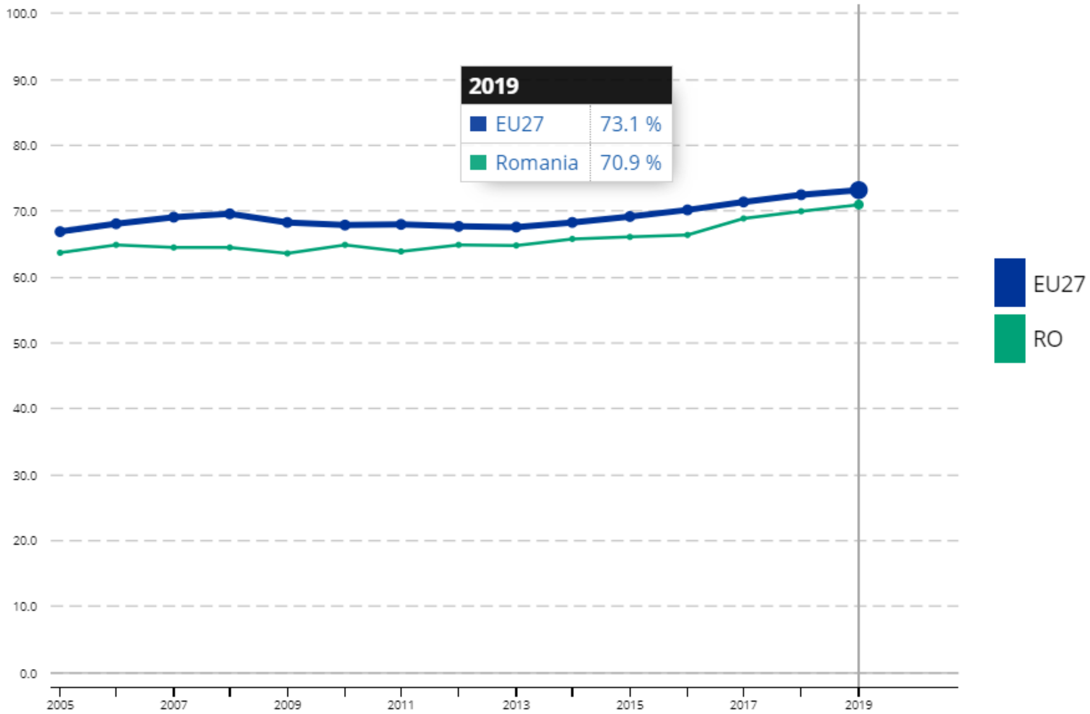



**Fig. 1.1.** Employment in the EU and Romania [E08]

According to the International Standard Classification of Occupations (ISCO), in terms of occupations, professionals accounted for the largest group in the EU-27 in 2019, with 19.5% of all employees. They were followed by technicians and associate professionals (16.9%) and service and sales workers (16.3%). On the other hand, the lower two categories were represented by agricultural workers (3.3%) and workers in the armed forces (0.6%) [E08]. Of those presented in Figure 1.2, the categories with the highest percentages are the categories that mainly work in the office. Thus, about 45% of all employees spend at least 40 hours a week in the office.


**Fig. 1.2.** Employed persons by occupation [E08]

## 1.4. Standards

### 1.4.1. Regarding people with disabilities

The most well-known classification of Assistive Technologies (TA) is the international classification ISO 9999, this is a three-level system that groups TA in classes (mobility, communication, recreation), then in subclasses (in the "mobility" class: spinal orthoses, orthoses abdominal), possibly "divisions" (in the subclass "spinal orthoses": sacroiliac orthoses). Each entry in ISO 9999 has a numeric code: for example, "thoraco-lumbo-sacral orthoses" has the code 06.03.09, where the first two digits represent Class 06 "mobility", the next two subclass 06.03 "spinal orthoses", and the last two represents the specific division. The ISO 9999 classes, subclasses and divisions are presented in the Table 1.1.

**Table 1.1.** Divisions (level 3) for the subclass 03 [I10]

| Class | Subclass | Division | Description |
|---|---|---|---|
| 06 | 03 | 03 | Sacro-iliac orthoses |
| 06 | 03 | 06 | Lumbo-sacral orthosis |
| 06 | 03 | 09 | Thoraco-lumbo-sacral orthosis |
| 06 | 03 | 12 | Cervical orthoses |
| 06 | 03 | 15 | Thoraco-cervical orthosis |
| 06 | 03 | 18 | Cervical-thoracic-lumbo-sacral orthosis |

### 1.4.2. Other ISO standards

Another important standard in the field of assistive equipment is ISO 13485, which presents requirements for a quality management system for the design and manufacture of medical devices [I09]. To this is added the standard EN 12182, the standard which has as its objective "Assistance products for people with disabilities. General requirements and test methods" [E05].

## 1.5. Market analysis

The market size is analysed both in terms of volume and in terms of value, various customer segments and purchasing patterns, competition, and economic environment in terms of regulation of the given market [T01].

### 1.5.1. Market volume

In accordance with Law no. 448/2006 on the protection and promotion of the rights of persons with disabilities, the following types of disabilities are defined: physical, visual, auditory, deaf blindness, somatic, mental, mental associated rare diseases [L03]. Thus, Figure 1.3 shows the number of people with disabilities broken down by type of disability.

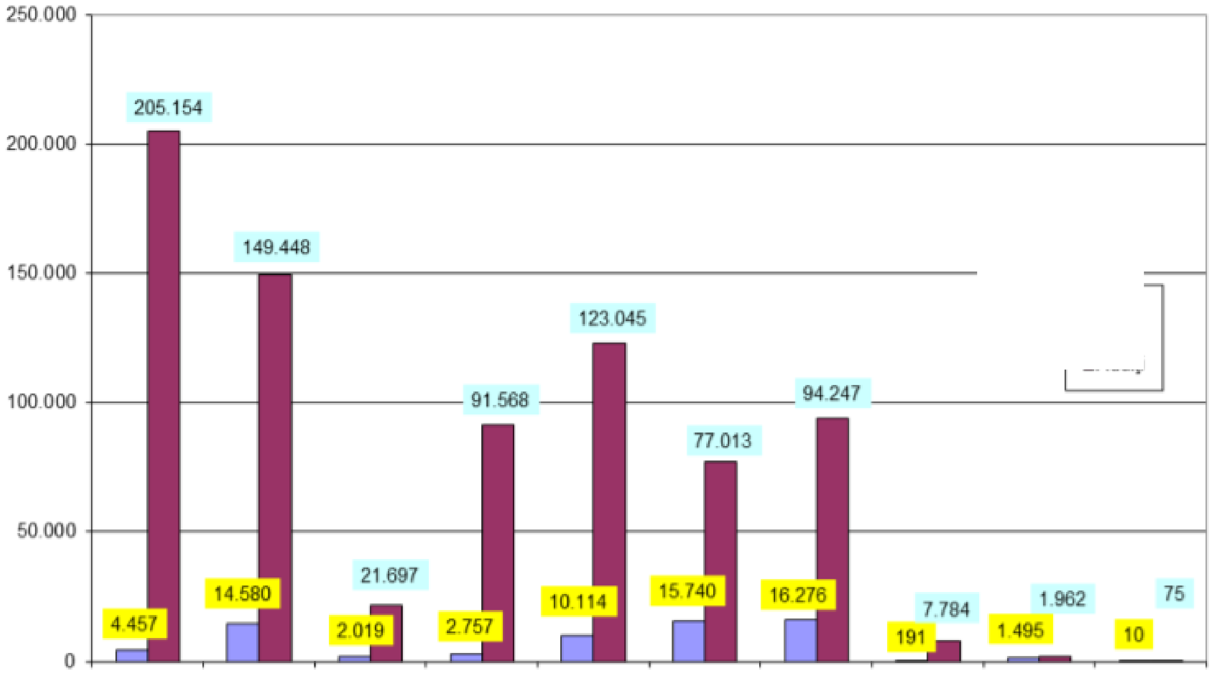



**Fig. 1.3.** Number of people with disabilities, by type of disability [B09]

### *1.5.2. Market value*

The percentage of the national GDP allocated to health in Romania is between 5% and 6%. In 2016, public health expenditures accounted for 5% of national GDP, Romania being the country with the lowest GDP allocations for health in the European Union [E06].

According to the graph in Figure 1.4, Romania ranks last in the European Union in terms of investment in this sector. The share of health services in national GDP is 5.0%, a very small percentage compared to developed EU member states [C07].

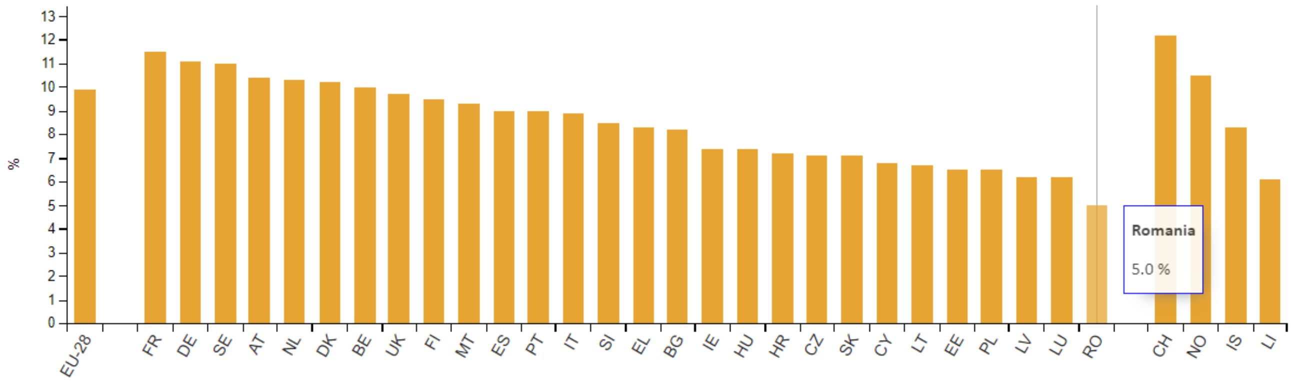



**Fig. 1.4.** Health spending in the European Union [E06]

### *1.5.3. Competition*

The number of public social assistance institutions for adults with disabilities is 448 of which: 388 residential and 60 non-residential [B09]. Almost two thirds (59.28%) of public residential institutions for adults with disabilities are care and assistance centers (29.64%), with 6,510 beneficiaries, and sheltered housing (29.64%), with 914 beneficiaries, they represent 41.04% of the total number of 18,090 people in residential institutions [B09].

### 1.5.4. Market segmentation

The map of the number of people with disabilities by counties is presented in Figure 1.5.

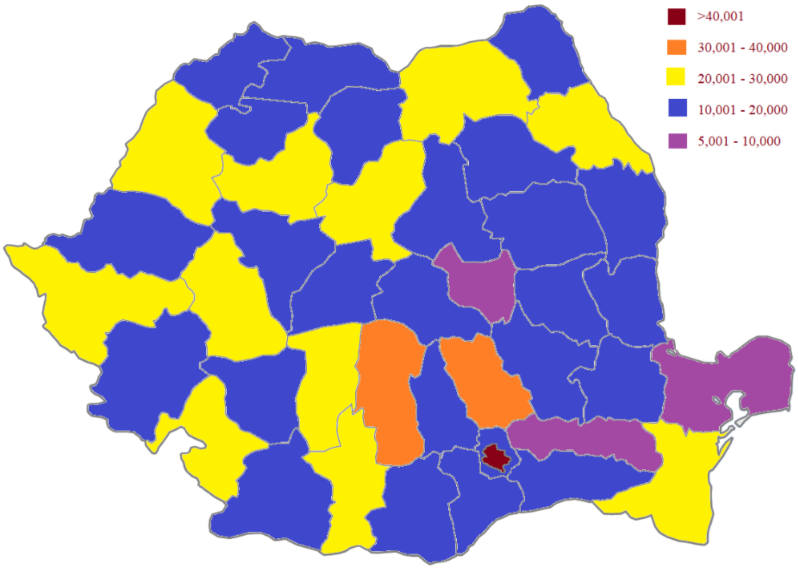



**Fig. 1.5.** Number of people with disabilities by counties

The following criteria were considered for market segmentation:

- Geographical:
  - Region - South-Muntenia and Bucharest-Ilfov;
  - County - Bucharest, Ilfov, Prahova, Dâmbovița, Argeș and Giurgiu;
  - Environment - rural and urban.
- Demographics:
  - Type of disability - physical;
  - Age area - adults;
  - Gender - male and female.

Following the analysis of the statistical data from the Statistical Bulletin, the targeted market segment was identified, presented in Figure 1.6. Thus, the type of disability was identified - physical, age - adults, both genders, and the geographical area is South-Muntenia and Bucharest-Ilfov [M14].

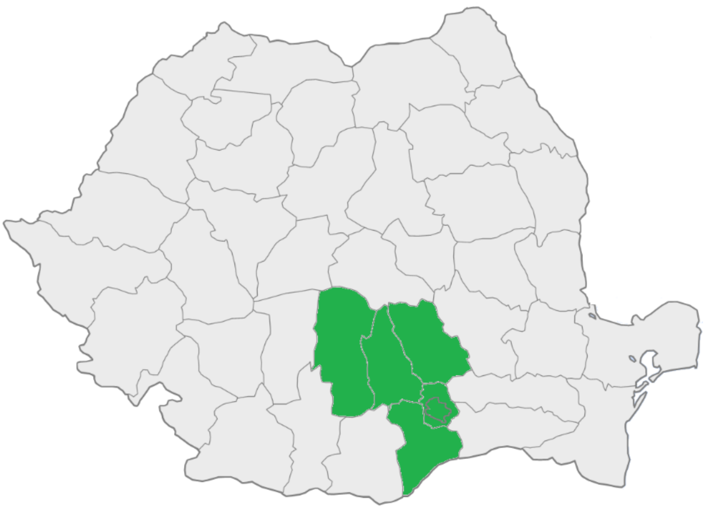


**Fig. 1.6.** Geographical area for the target market [M14]

## 1.6. Assistive technologies

Assistive technologies (TA) can be defined as "any equipment or product used to increase, maintain or improve the functional capacity of persons with disabilities, whether purchased commercially, modified or customized" [O04].

### *1.6.1. Types of assistive technologies*

Just as people may have different types of disabilities, different categories of devices and support services are available to help overcome these deficiencies [P05].

### *1.6.2. Assistive technologies for mobility*

Two categories of mobility are defined: manual mobility which includes manual wheelchairs, poles, walking supports, bicycles and tricycles, transport seats and body transfer devices and mechanized mobility which includes motorized wheelchairs, scooters, mopeds, mechanized devices, wheelchair interfaces, robotic orthoses [C09].

## 1.7. Categories of assistive products

### *1.7.1. Mobility devices*

Mobility devices are among the simplest technologies and assistive devices. The main purpose of mobility devices is to facilitate or increase the user's personal mobility - this refers to their ability to change or maintain their body position and move from one place to another [O04].

### *1.7.2. Orthosis*

The orthosis is defined as a device applied over the human body that is designed and mounted on it to: control biomechanical alignment, correct skeletal deformities, protect an injured area, assist the rehabilitation process, reduce pain, increase mobility.

The prefabricated orthosis involves a prefabricated and subsequently customized device to meet the specific needs of the customer. They are prescribed for short-term use. Also, all prefabricated orthoses are modified and must be customized to suit each individual client and to ensure that the treatment objectives are achieved and that the best functional result is achieved [A09].

The custom orthosis involves a specialized device, manufactured following the shape and individual dimensions of the user. It cannot be used by another person because it is designed and manufactured to meet only the specific needs of a user [A09].

### 1.7.3. Robots

Robots have enormous potential to be the mainstay of healthcare by improving health and well-being, compensating for lack of care, helping caregivers and supporting health care workers [R03]. They achieve this change through operating principles that can produce movements of parts of the user's body - locomotion or objects in the environment - manipulation [R04].

### 1.7.4. Exoskeleton

Exoskeletons are designed for certain parts of the body, they can be designed for one hand, one leg or even the whole body. Thus, the separation of classes shows that exoskeletons can be built for the most common parts of the body. The whole-body class refers to exoskeletons made to help all limbs or the whole body. The upper body class refers to exoskeletons made for the upper limbs, which involve the chest, head, back and shoulders. Lower body class refers to exoskeletons made for the lower limbs: thighs, legs, and hips. Moreover, there are classes for specific limbs and joints, these include exoskeletons designed for the joints of the knees, ankles, hands, arms and legs. In addition, there is a special class for any other exoskeleton that is not included in the previous classes [T08].

## 1.8. Additive manufacturing in medicine

Additive manufacturing (AF) involves creating 3D objects from a digital model. A 3D printer uses software that "cuts" the model into thin layers and uses that information to deposit the material, layer by layer, where necessary to create the object. Because it is an additive process, the use of materials is minimized and complex shapes that would be difficult or impossible to achieve with conventional manufacturing methods have become easy to manufacture [F02].

The medical industry can use 3D printing to create a wide range of body parts and medical devices, such as dental implants, hearing aids, prostheses, knee and hip implants and surgical instruments. The industry is ready to make a few landmark improvements that are revolutionizing the healthcare industry [F02].

Additive manufacturing for medical applications is expanding rapidly and is expected to revolutionize healthcare. 3D printing for medical uses, both current and potential, can be organized into several broad categories, including: fabrication of tissues and organs; creation of custom prostheses, implants and anatomical models; and pharmaceutical research on dosage forms, drug delivery and discovery. The application of additive manufacturing in medicine offers many benefits, including: personalization of medical products, medicines and equipment; cost efficiency; increased productivity; democratization of design and manufacturing; improved collaboration [V01].

### 1.8.1. History of additive manufacturing

Charles Hull is the inventor of the first FA technology, which he called "stereolithography" in 1986. Stereolithography uses a STL file format to interpret data from a CAD file, allowing this data to be communicated electronically to the printer. 3D. In 1988, 3D Systems produced the first commercially available 3D printer, the SLA-250. Charles Hull's research, like that of other researchers, has revolutionized production and is ready to do the same in many other fields - including medicine [V01].

### 1.8.2. Medical applications of additive manufacturing

3D printing has been applied in medicine since the early 2000s, when the technology was first used for the manufacture of dental implants and custom prostheses. Since then, 3D printing for medical applications has evolved considerably. Recent published reviews describe the use of 3D printing to produce bones, ears, exoskeletons, jaw bones, cell cultures, stem cells, blood vessels, vascular networks, tissues and organs [V01].

### 1.8.3. Benefits of using AM technologies in medicine

One of the biggest advantages that 3D printers offer in medical applications is the freedom to produce customized medical products and equipment. Implants and customized surgical instruments can have a positive impact on the time required for surgery, the patient's recovery time and the success of the operation [V01].

Another important advantage of 3D printing is its ability to produce products with low production costs. The cost of 3D printing is becoming increasingly competitive for the small series production process. This is especially advantageous for companies with low production volume or producing very complex products or requiring frequent changes [E07].

## 1.9. Conclusions

The analysis of the current state of development of assistive products highlighted the demand for assistive products needed for both people with disabilities and people working in the office. The analysis shows that in Romania alone there are over 200,000 people with a physical disability, and the number of people working in the office is over 2,000,000. The market value at national level is over 60 billion lei. These data confirm the existence of a demand in this area. The target market for the developed product was also identified. The target market is made up of specialists working in the office and people with spinal health problems. The fields of development of assistive robots and additive manufacturing technologies that will allow the development of customized assistive products, at an affordable price and with a delivery time close to the delivery time of large series products, were analysed.

# Chapter 2
# Descriptive elements regarding the spine

The doctoral thesis focuses on the development of an intelligent orthosis for posture correction, which is why it was considered necessary to present some biomechanical elements of the spine.

The spine consists of 7 cervical vertebrae, 12 thoracic vertebrae, 5 lumbar vertebrae, 5 sacral vertebrae and 4-5 coccygeal vertebrae that weld, giving rise to 2 bones: the sacrum and the coccyx. The length of the spine is on average 73 cm in men and 63 cm in women, thus representing 40% of the total length of the body. The maximum width of the spine is at the base of the sacrum, where it measures 11 cm. The maximum sagittal diameter is at the level of the last lumbar vertebrae where it reaches 7 cm [N02]. Figure 2.1 shows the shape and composition of the spine.

## 2.1. Structure of the spine

The spine is divided into four regions, each of which is normally made up of a fixed number of vertebrae. The vertebrae in each region have morpho functional characteristics related to the fulfilment of the two important functions of the human spine: the function of supporting the weight of the head, trunk and upper limbs and the function of ensuring sufficient mobility [N02].

Depending on the area in which they are located, the vertebrae can be:

- Cervical vertebrae, corresponding to the neck. They are 7 in number and are marked from C1 to C7. Together they form the cervical area.
- Thoracic or dorsal vertebrae corresponding to the thorax. They are 12 in number and are numbered from T1 to T12. Together they form the thoracic area.
- Lumbar vertebrae, numbering 5 and noted from L1 to L5. Together they form the lumbar area.
- Sacro-coccygeal vertebrae, in number of 5, respectively 4-5 bone pieces and correspond to the pelvis. They are welded giving rise to two bones: the sacred, respectively coccygeal. Being bones welded together, they are also called false vertebrae [N02].

The spine articulates superiorly, through the first cervical vertebra, with the skull, and inferiorly through the sacrum with the coxal bones.

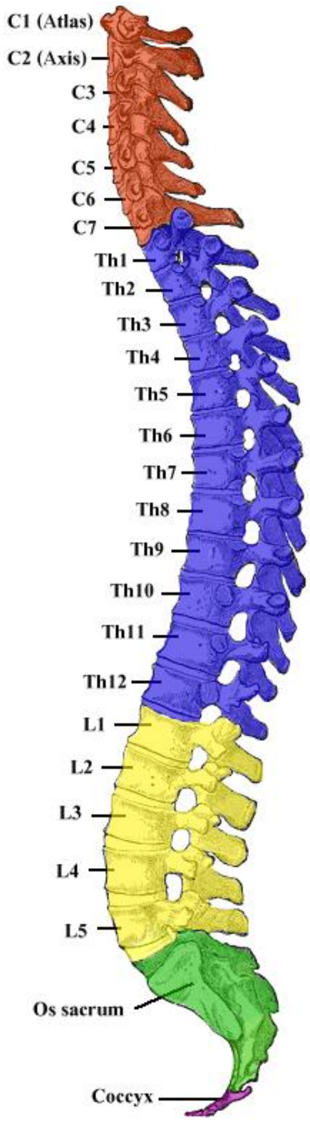



**Fig. 2.1.** Spine [G03]

## 2.2. Normal curves and deviations of the spine

The spine consists of 3 normal curves, they give the spine increased elasticity and strength, the normal curves of the spine are shown in Figure 2.2 (a - cervical area, b - thoracic area, c - lumbar area) [B05]:

- "thoracic kyphosis, posterior convex" (figure 2.2-2);
- "cervical lordosis, anteriorly convex" (figure 2.2-3);
- "thoracic scoliosis, convex on the side of the dominant hand" (figure 2.2-4).

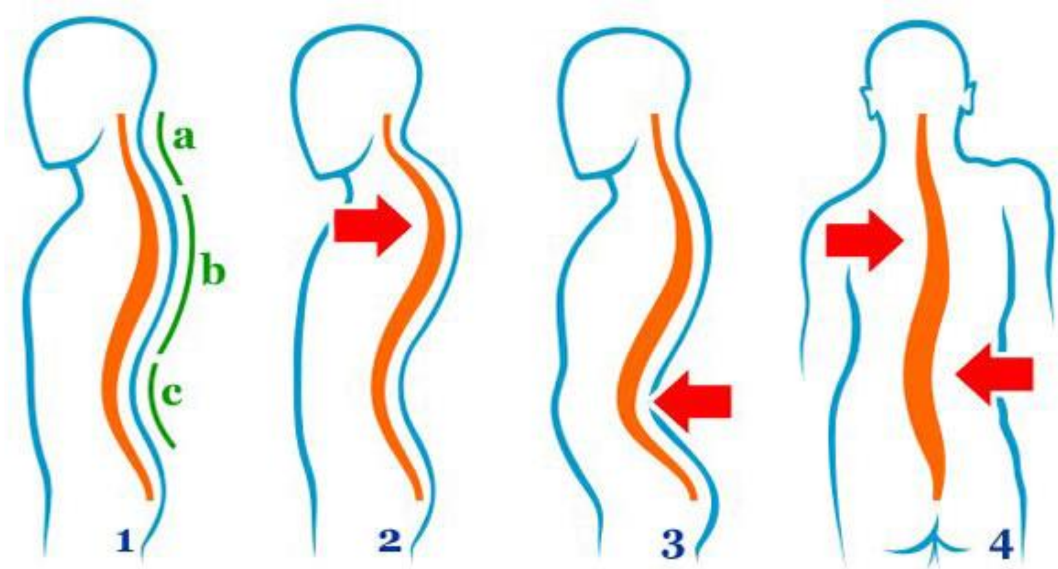



**Fig. 2.2.** Normal curves and deviations of the spine [N02]

## 2.3. Spinal biomechanics

In this subchapter are presented notions about the biomechanics of the spine, important notions for the development of the product treated in this paper.

The simple movements that the human body can perform are the translational movement and the rotational movement. All other movements of the human body, such as pivoting, plane-parallel movements and roto translational motion are obtained by combining simple movements, considered in plane or space.

The movement of the human body or kinematic elements always refers to a reference system. The reference system means a non-deformable landmark to which all the positions of a given material system relate. Reference systems are fixed or mobile, so the motion relative to a fixed reference system is called absolute motion and the motion relative to a mobile reference system is called relative motion. In biomechanics, the mobile reference system usually originates in the center of gravity of the human body, moving at the same time as the movement of the body. This reference system is called the relative or cardinal reference system [B12].

## 2.4. Types of posture

To be able to define the user's positions during the use of the developed product, an analysis of the anatomically and / or medically described types of attire was needed. The most common types of attire are shown in Figure 2.3 [NO2].

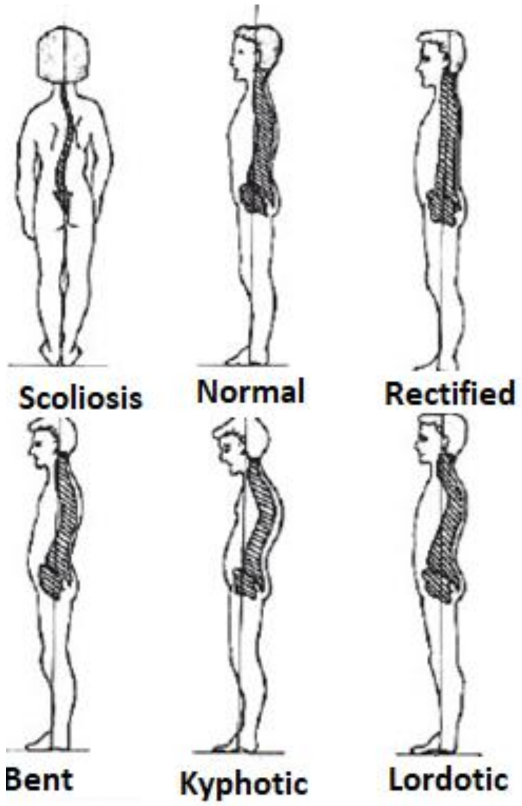



**Fig. 2.3.** Types of posture [B03]

## 2.5. Existing solutions for spine problems

External research involves identifying existing solutions for the needs identified by the development team. An important source of information is defined by existing patents in the field. 42 patents have been identified for similar products.

## 2.6. Conclusions

Following the analysis of the structure of the spine, the areas of interest (thoracic and lumbar) were identified for a product intended to act on it. From the analysis of the normal curves and the deviations of the spine, the health problems that can appear at the level of the spine were identified. Analysing the most common types of attire, we identified the correct posture and the positions to be corrected using an orthosis to correct the posture. Existing solutions to spinal problems have also been studied.

# Chapter 3

# Current state of existing methodologies of product development

The literature describes many situations in which the development of companies has been dependent on their ability to innovate quickly and efficiently [K08].

The objectives of the product development process deviate from the general objectives of the company, which generates the first restrictive element, because those responsible for the introduction of new products must state a wording that harmonizes the interests of the company, both in the short term and in the future long term. The second element that influences the goal setting process comes from the uniqueness of the process activities and its results. Due to this, the statement of objectives must be detailed until each compartment and, afterwards, any person who is part of the process comes to master the tasks to be performed, the deadline by which they must complete their activity and the reason for this activity [K08].

## 3.1. Product development methodologies

Innovation and development of new products are essential for most companies to support their revenue growth and even to stay in the market [K05].

The development of new products includes a considerable number of topics and demands in a company, these can be: (1) "strategy formulation"; (2) "allocation of resources"; (3) "collaboration between the teams involved"; (4) “systematic planning” and (5) “monitoring and control of the development process” [K04].

The introduction of new products on the market consists in their launch or marketing. New products are placed on the market upon successful completion of the new product development project (DPN) [K05]. The studied methodologies are presented below, along with the names of those who proposed them.

## 3.2. Conclusions regarding the studied methodologies

Within this chapter were studied 26 methodologies for product development proposed by authors from various fields of activity. Methodologies were studied both within the university, proposed by professors working in the field of product development, and methodologies developed by companies working in various fields in the industry.

Although the studied methodologies vary in form and content from author to author, a clear structure can still be observed that is outlined around some indispensable stages in most of the studied methodologies. The differences in form and content derive from the specifics of the companies where the methodologies were developed or depending on the universities from which the professors who proposed these methodologies come.

# Chapter 4
# Objectives and researc directions

Based on the conclusions drawn from Part I of the thesis, the current state of research in the field on the problems that arise in the spine have been established the objectives and directions of research to be pursued in the doctoral thesis. Thus, in Part II of the thesis, Own contributions on the development of an orthosis for posture correction, the fulfillment of the objectives established in this chapter will be pursued, considering the proposed research directions.

## 4.1. Purpose and objectives of the research

The main objective of the advanced research-development activity within the doctoral thesis is to develop a methodology and a prototype manufactured using additive technologies for an intelligent orthosis to correct posture.

The specific objectives are detached from the main objective:

- Selective documentary research on the history, evolution and current trends in the development of orthoses for the spine;
- Critical documentary research on existing product development methodologies and elaboration of an own, original structure of product development methodology;
- Carrying out a market analysis, including identifying the needs of people with physical disabilities and establishing specifications for a product that meets the identified needs;
- Carrying out experimental studies with intelligent orthosis to correct posture in order to validate functionality, achieve process performance, and customize it for different users.

## 4.2. Methodology and the stages of research

The research-development methodology is elaborated as a reference base for the achievement of the main objective of the doctoral thesis, as well as of some further developments. The relevant methodological benchmarks for solving the proposed objectives were considered the following:

1. Study of regulations, legislation and standards in the field of assistive products;
2. Descriptive elements regarding the spine;
3. The current stage regarding the existing methodologies of product development;
4. Elaboration of a methodology for the development of new products;
5. Analysis of user requirements and establishing the specifications of a smart orthoses;
6. 3D modeling of the user's body;
7. Functional analysis and conceptual design of an intelligent orthoses;
8. Detailed design of an intelligent orthoses;
9. Manufacture of smart orthosis components;
10. Testing the prototype of the smart orthoses.

# Chapter 5
# Development of a methodology for developing new products

Starting from the conclusions of the study carried out in Chapter 3, it is intended to develop an optimal, original structure of product development methodology within the doctoral thesis. The analysed methodologies will be decomposed at the level of component stages and the Multicriteria Analysis will be used to establish the importance of each stage. The stages with the highest frequency of occurrence will be combined and any auxiliary stages will be added.

## 5.1. Analysis of the studied methodologies

The methodologies proposed by twenty-six authors were studied: university professors, specialists in the field of new product development, commercial companies, and prestigious universities in the United States of America. All authors whose methodologies were studied in the doctoral thesis are summarized alphabetically in Table 5.1, they are presented in different colours in the table mentioned as follows: university professors - yellow, specialists in the development of new products - green, commercial companies - blue and universities - red.

**Table 5.1.** List of authors

| No. | Author | | No. | Author |
|---|---|---|---|---|
| 1 | Robert Cooper and Scott Edgett | | 14 | Douglas Mader |
| 2 | Nigel Cross | | 15 | Martec International |
| 3 | M. Crowford and A. Di Benedetto | | 16 | M. Millson and D. Wilemon |
| 4 | Steven Eppinger | | 17 | John Myers |
| 5 | Olivia Grey | | 18 | Silvia Olaru |
| 6 | General Motors | | 19 | Gerhard Pahl and Berthold Beitz |
| 7 | Hines & Lee | | 20 | M. Rouse and A. Kioski |
| 8 | Stefan Husig, Stefan Kohn and Jarno Poskela | | 21 | Tool and Manufacturing Engineers Handbook |
| 9 | Anil Khurana and Stephen Rosenthal | | 22 | Toyota |
| 10 | Peter Koen | | 23 | Karl Ulrich |
| 11 | Mika Juhani Koivuniemi | | 24 | Karl Ulrich andSteven Eppinger |
| 12 | Philip Kotler | | 25 | University of Minnesota |
| 13 | C. Loch and S. Cavadias | | 26 | Steven Wheelwright and Kim Clark |

### 5.1.1. Centralization of stages

The frequency of use by the authors of the same number of stages was analysed, being studied: 2 methodologies with twelve stages, 3 methodologies with ten stages, 2 methodologies with nine stages, 4 methodologies with eight stages, 7 methodologies with seven stages, 4 methodologies with six stages, 3 methodologies with five stages, a methodology with four stages.

### 5.1.2. Determining the frequency of occurrence of stages

Following the study of the twenty-six methodologies proposed by different authors, 21 distinct stages were identified. The distinct stages encountered in each studied methodology were centralized in Table 5.2, and the frequency of their presence methodologies is represented in Figure 5.1. We identified: 7 stages that appear in 46% - 53% of the total stages (stages present in 12 - 14 methodologies out of a total of 26 methodologies), 5 stages in the range 34% - 42% (stages present in 9 - 11 methodologies), 6 stages in the range of 23% - 30% (stages present in 6 - 8 methodologies) and 3 stages in the range of 11% - 19% (stages present in 3 - 5 methodologies).

**Table 5.2.** Frequency of the presence of the stage

| No. | Name of stage | Frequency |
|---|---|---|
| 1 | Identifying opportunities | 14 |
| 2 | Opportunity analysis | 6 |
| 3 | Generating ideas | 13 |
| 4 | Selection of ideas | 12 |
| 5 | Development planning | 7 |
| 6 | Establishing needs | 4 |
| 7 | Establishing specifications | 7 |
| 8 | Generating concepts | 13 |
| 9 | Concept selection | 8 |
| 10 | Economic analysis | 9 |
| 11 | Product architecture | 11 |
| 12 | Principle design | 14 |
| 13 | Detail design | 10 |
| 14 | Prototype generation | 7 |
| 15 | Concept testing | 5 |
| 16 | Market testing | 12 |
| 17 | Marketing strategy | 11 |
| 18 | Product manufacturing | 11 |
| 19 | Product testing | 6 |
| 20 | Commercialisation | 14 |
| 21 | Disposal | 3 |

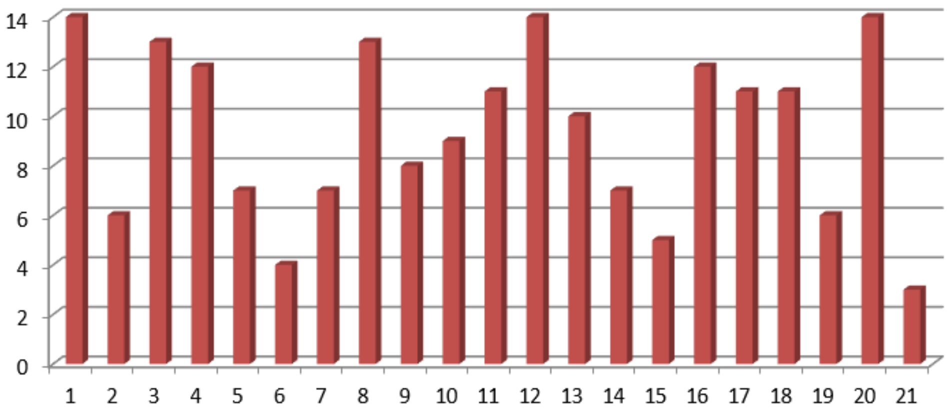



**Fig. 5.1.** Frequency of stages in the studied methodologies

### 5.1.3. Establishing the categories of stages

Following the study performed on the 26 methodologies, 21 distinct stages were identified. All these steps are important for the methodology of which they are part.

To define one's own methodology for developing a new product, it is necessary to include in this methodology the most important stages of those studied. Thus, the 21 identified stages were divided into 11 distinct categories, presented in Table 5.3.

**Table 5.3.** Stages divided into categories

| Category no. | Name of stage | Category no. | Name of stage |
|---|---|---|---|
| 1 | Identifying opportunities | 5 | Economic analysis |
| | Opportunity analysis | 6 | Detail design |
| | Establishing needs | 7 | Prototype generation |
| 2 | Generating ideas | | Concept testing |
| | Selection of ideas | 8 | Market testing |
| | Establishing specifications | | Marketing strategy |
| 3 | Generating concepts | 9 | Product manufacturing |
| | Concept selection | | Product testing |
| | Principle design | 10 | Commercialisation |
| 4 | Development planning | 11 | Disposal |
| | Product architecture | | |

## 5.2. Analytic hierarchy process

Analytic hierarchy process (AHP) describes any structured approach used to determine the general preferences between several alternative options, which options lead to the fulfilment of several different objectives [R05]. The method is used to perform a comparative assessment of the alternative steps.

### 5.2.1. Options

In the case of the current analysis, the options analysed represent the steps in the categories established according to Table 5.3. Thus, three categories of stages are identified that have 3 options and four categories that have 2 options each. Therefore, 7 distinct categories will be analysed.

### 5.2.2. Criteria and ranges of values

To determine, within each category, which stage is optimal, 5 criteria will be used, two qualitative: quality and performance and three quantitative: frequency, cost and time.

Of these, for three the aim will be to obtain maximum values (Frequency, Quality and Performance), and for the other two, minimum values (Cost and Time).

### 5.2.3. Performance matrix

The performance matrix includes all the alternatives for the analysed stages. Each row in this performance matrix describes an option and each column describes the performance of the stages according to each criterion. They were denoted by 1A, 1B, 1C, 2A, 2B, 2C, 3A, 3B, 3C, 4A, 4B, 7A, 7B, 8A, 8B, 9A, 9B, using a one-digit encoding and a letter, the number represents a set of stages, and the letter represents the alternatives of the stages in the same category.

### 5.2.4. Importance of the criteria

The importance of the decision criteria is the stage in which each decision criterion is assigned a value or a weight. Criterion C1 is considered the most important because it is based on the experience of the authors of the studied methodologies, receiving a share of 40%. Criterion C5 measures the degree of competitiveness, for this reason it is the second criterion of relative importance (25%). The other three criteria are estimated to be close in terms of their impact, obtaining 10% (C3 and C4) and 15% (C2).

### 5.2.5. Establishing scores

The determination of the scores for each analysed stage was made based on the estimated values. The establishment of the scores was done by transforming the measurement scale, so that because each criterion had different limits, they were transposed on a unitary scale, from 0 to 100.

### 5.2.6. Normalization of the performance matrix

Normalization is the process by which the values of the criteria expressed by different units of measurement are transposed on a common scale, which allows a comparison between them.

The calculations are performed for each group of steps / alternatives corresponding to a category. The normalization calculation was applied for each group of analysed steps, from each category separately.

### 5.2.7. Hierarchy of options

For the ranking of options, the weight and score for each stage are multiplied to obtain a weighted value. The stages are ranked by summing the weights related to the criteria scores for each stage. Table 5.4 shows the final weights of the stages for each category analysed.

Thus, for stage 1B, the normalized value for criterion C1 is 0.43, for criterion C2 it is 0.60, for criteria C3 and C4 it is 0, and for criterion C5 it is 0.50.

The weight for criterion C1 is 0.40, for criterion C2 it is 0.15, for criteria C3 and C4 it is 0.10, and for criterion C5 it is 0.25.

**Table 5.4.** Hierarchy of options for categories

| Alternative / Stage | | Criteria | | | | | Total |
|---|---|---|---|---|---|---|---|
| | | C1 | C2 | C3 | C4 | C5 | |
| **Importance** | | 0,40 | 0,15 | 0,10 | 0,10 | 0,25 | |
| 1A | Identifying opportunities | 0,400 | 0,030 | 0,025 | 0,050 | 0,0825 | 0,5875 |
| 1B | Opportunity analysis | 0,172 | 0,090 | 0 | 0 | 0,125 | 0,387 |
| 1C | Establishing customer needs | 0,116 | 0,150 | 0,025 | 0,066 | 0,250 | **0,607** |
| 2A | Generating ideas | 0,400 | 0,090 | 0 | 0 | 0,1675 | 0,6575 |
| 2B | Selection of ideas | 0,368 | 0,090 | 0 | 0 | 0,0825 | 0,5405 |
| 2C | Establishing specifications | 0,216 | 0,150 | 0,050 | 0,032 | 0,250 | **0,698** |
| 3A | Generating concepts | 0,372 | 0,030 | 0,025 | 0,034 | 0,0825 | 0,5435 |
| 3B | Concept selection | 0,228 | 0,150 | 0,050 | 0,066 | 0,125 | 0,619 |
| 3C | Principle design | 0,400 | 0,090 | 0 | 0 | 0,250 | **0,740** |
| 4A | Development planning | 0,252 | 0,060 | 0,033 | 0 | 0,1675 | 0,5125 |
| 4B | Product architecture | 0,400 | 0,150 | 0 | 0 | 0,250 | **0,800** |
| 7A | Prototype generation | 0,400 | 0,150 | 0 | 0,050 | 0,250 | **0,850** |
| 7B | Prototype testing | 0,288 | 0,090 | 0,075 | 0,083 | 0,0825 | 0,6185 |
| 8A | Market testing | 0,400 | 0,060 | 0 | 0 | 0,1675 | 0,6275 |
| 8B | Marketing strategy | 0,368 | 0,150 | 0,050 | 0,067 | 0,250 | **0,885** |
| 9A | Product manufacturing | 0,316 | 0,150 | 0 | 0 | 0,250 | **0,716** |
| 9B | Product testing | 0,172 | 0,090 | 0,075 | 0,083 | 0,0825 | 0,5025 |

### 5.2.8. Resulted structure

Following the application of the Analytic hierarchy process, only one stage was chosen from each category. Table 5.5 presents the structure of the methodology established by the study performed [D08]. The definition of the structure of the product development methodology within the doctoral thesis started from the analysis of the existing methodologies, elaborated by specialists in their fields of activity.

**Table 5.5.** Selected stages of the new methodology

| No. | Name of stage |
|---|---|
| 1 | Establishing customer needs |
| 2 | Establishing product specifications |
| 3 | Principle design |
| 4 | Product architecture |
| 5 | Economic analysis |
| 6 | Detail design |
| 7 | Prototype generation |
| 8 | Establishing the marketing strategy |
| 9 | Product manufacturing |
| 10 | Commercialization |
| 11 | Disposal |

Thus, the experience of 26 authors in extracting the most important steps for the product development methodology was summarized. By applying the Multicriteria Analysis, the indispensable stages of a competitive product development methodology were established, based on five well-founded criteria from the point of view of the field of application of the methodology.

The structure of the methodology obtained in the end is a logical one, in which the stages are coherently linked and the information follows a logical path, from the initial stage to the final one.

# Chapter 6
# Analysis of user requirements and establishment of smart orthoses specifications

The development of a new product begins with identifying an opportunity. An opportunity is an idea about a new product, a raw description of a product, a newly identified need, or an association of a problem with a possible solution, in its infancy.

A consistent contribution to the crystallization of the new idea is brought by customers, who can express their proposals in the form of requirements regarding the product whose development has just begun.

Delimiting the client's requirements involves three steps [W07]: (1) interviewing clients; (2) the interpretation of the requirements expressed and (3) the transformation of those requirements into product specifications.

## 6.1. Process of setting user requirements

The process of identifying needs involves the following steps [S02]: Defining the purpose (establishing the mission); Data collection (interviews, target groups); Interpretation of data (interpretation of needs); organization of needs (hierarchy); Determining the importance (examining the relative importance) and reconsidering the process (continuous improvement).

## 6.2. Identifying opportunities

The doctoral approach started from the idea of solving, with the tools provided by the author's engineering training, a problem in the medical field. The idea did not appear suddenly, over time the author was attentive to various problems that needed solutions (the need to go independently, the need to coordinate the upper limbs, the need to have a correct posture, the need to maintain lifting / sitting balance), but the most attractive was chosen to be developed through the doctoral cycle.

It is desired that the product Orthosis for posture correction be portable - to allow it to be worn under clothes, to be light - its total mass to allow daily movements without inconvenience to the user, to be programmable and electrically operated, allowing continuous correction of the spine to brings in normal / natural position. In addition to the posture correction regime, the orthosis will have a regime of relaxation of the spine and prevention of spinal disorders. Along the way, it is possible to enrich the list of features as the stages of the development process go.

## 6.3. Data collection

To identify customer requirements, they will be interviewed. An interview guide was developed with the help of which data were collected from 25 interviewees.

The requirements interpreted were centralized, and each requirement was assigned a coefficient of relative importance from 1 to 5. The coefficient of relative importance for each requirement was determined by how much it contributes to the overall satisfaction of the need. Table 6.1 summarizes customer requirements and their relative importance.

**Table 6.1.** Relative importance of requirements

| Customer requirements | Relative importance |
|---|---|
| The product is used during daily activities | 4 |
| The product performs therapeutic movements | 5 |
| The product ensures posture correction | 5 |
| The product allows periodic sterilization | 4 |
| The use of the product ensures the comfort of the user | 5 |
| The product is easy to maintain | 3 |
| The product is operated in complete safety | 5 |
| The product is accompanied by a technical book | 4 |
| The product protects the user from injury | 5 |
| The product has dimensions proportional to those of the user | 4 |
| The product allows its effortless handling by the user | 3 |
| The product is multifunctional | 1 |
| The product is adjustable and allows its customization | 5 |
| The product allows dynamic correction | 2 |
| The product allows the skin to breathe | 4 |

### 6.4. Competing products

The relationship between the new product and the competitors is essential for determining commercial success. The objective specifications are the language used by the team to discuss and agree on the precise positioning of its product in relation to existing products, both its own and that of the competition. Information on existing products must be obtained to substantiate positioning decisions. Information on all competing products.

### 6.5. Establishing the list of characteristic values

In this stage, the available information is synthesized to establish the effective values of the quantities that will characterize the developed product. For each analysed size, two types of objectives are set: an ideal objective and a limit objective. The ideal size goal is the value that gives the product the best performance. The size limit is the lowest performance at which the product is commercially viable.

The correlation of the clients' requirements with the sizes of the developed product is done through a size-requirements matrix. This allows the identification of those sizes that meet a certain customer requirement. Thus, depending on the relative importance of the requirement, those sizes will be selected that satisfy as many needs as possible with a relative importance as high as possible. The size-requirements matrix is presented in Table 6.2.

**Table 6.2.** Matrix characteristics-requirements

| Characteristics / Requirements | | Dimensions | Size | Treated problem | Type | Locking system | Action system | Wear duration | Warning | Weight | Power supply | Colour | Composition | Area of action | Technical instruction | Adju8stable | Incommode | Therapeutic move | Stiffening | Price |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
| 1 | The product is used during daily activities | | | * | | | | * | | | | | | | | | | | | |
| 2 | The product performs therapeutic movements | | | | | | | | | | | | | * | | | | * | | |
| 3 | The product ensures posture correction | | | * | * | | | | | | | | | * | | | | | | |
| 4 | The product allows sterilization | | | | | | | | | | | | * | | | | | | | |
| 5 | The use of the product ensures the comfort of the user | | | | | | | * | | * | | | | | | * | | | | |
| 6 | The product is easy to maintain | | | | | | * | | | | * | | | | | | | | | |
| 7 | The product is operated in complete safety | | | | | * | | | * | | | | | | | | * | | | |
| 8 | The product is accompanied by a technical book | | | | | | | | | | | | | | * | | | | | |
| 9 | The product protects the user from injury | | | | | | | | | | | | | | | | * | | * | |
| 10 | The product has dimensions proportional to those of use. | * | | | | | | | | | | | | | | | | | | |
| 11 | The product allows its effortless handling | | * | | | | | | | * | | | | | * | | | | | |
| 12 | The product is multifunctional | | | | * | | | | | | | | | * | | | | | | |
| 13 | The product is adjustable and allows its customization | | | | | | | | | | | * | | | | * | | | | * |
| 14 | The product allows dynamic correction | | | | | | * | | | | | | | | | | | * | * | |
| 15 | The product allows the skin to breathe | | | | | | | | | | | | * | | | | | | | |

## 6.6. Determining the relative importance of values

To identify important sizes, they are ranked, in correlation with the relative importance of the requirements. For the Orthosis product, the most important sizes are the problem treated, the closure system, the wear time, the mass of the product, the area of action, the adjustment, and the selling price and these will be further considered. Also important are overall dimensions, mode of warning during operation, stiffening or anchor point. The least important sizes are colour and supply voltage.

## 6.7. Identifying objective values

To establish the ideal target and limit values of the specifications, an ideal target is chosen for each size, which represents the best result and an acceptable limit target, which represents the value that allows the product to be commercially viable. Immediately after identifying the customer requirements, the objective specifications are established, and after selecting the concept, the finalized specifications will be developed. The target values of the specifications are presented in Table 6.3.

Objective specifications are ideal values for the developed product, but they are established before knowing the restrictions that the product technology will impose.

For example, for Dimensions, the ideal values for the lens specifications are between 50 and 130 cm, but limit values between 70 and 110 cm are also allowed.

**Table 6.3.** Objective specifications

| Char. No. | Require. No. | Character. | Relative importance | Unit of measure | Limit value | Ideal value |
|---|---|---|---|---|---|---|
| 1 | 10 | Size | 4 | cm | 70 - 110 | 50 - 130 |
| 2 | 11 | Numbers | 3 | nr | > 4 | > 6 |
| 3 | 1, 3 | The problem addressed | 5 | - | Posture correction | Posture correction; Scoliosis |
| 4 | 3, 12 | Type | 3 | - | Semi-rigid | Flexible |
| 5 | 7 | Locking system | 5 | - | Velcro | Magnetic |
| 6 | 6, 14 | Action system | 3 | - | Mechanic | Electric |
| 7 | 1, 5 | Wear duration | 5 | h/zi | > 10 | 24 |
| 8 | 7 | Warning | 4 | - | Sonorous | Sonorous, visual |
| 9 | 5, 11 | Table | 5 | g | < 4000 | < 1500 |
| 10 | 6 | Supply voltage | 2 | V | < 6 | < 4 |
| 11 | 13 | Colour | 1 | - | Monocolour | Multicolour |
| 12 | 4, 15 | Composition | 5 | - | Polyester | Cotton |
| 13 | 2, 3, 12 | Area of action | 5 | - | Lumbar | Thoracic, Lumbar |
| 14 | 8, 11 | Technical books | 3 | Yes/No | Yes | Yes |
| 15 | 5, 13 | Adjustable | 5 | Yes/No | Yes | Yes |
| 16 | 7, 9 | Uncomfortable | 5 | Yes/No | No | No |
| 17 | 2, 14 | Therapeutic movements | 3 | - | No | Yes |
| 18 | 9, 14 | Stiffening | 4 | - | Yes | Yes |
| 19 | 13 | Price | 5 | RON | < 500 | < 350 |

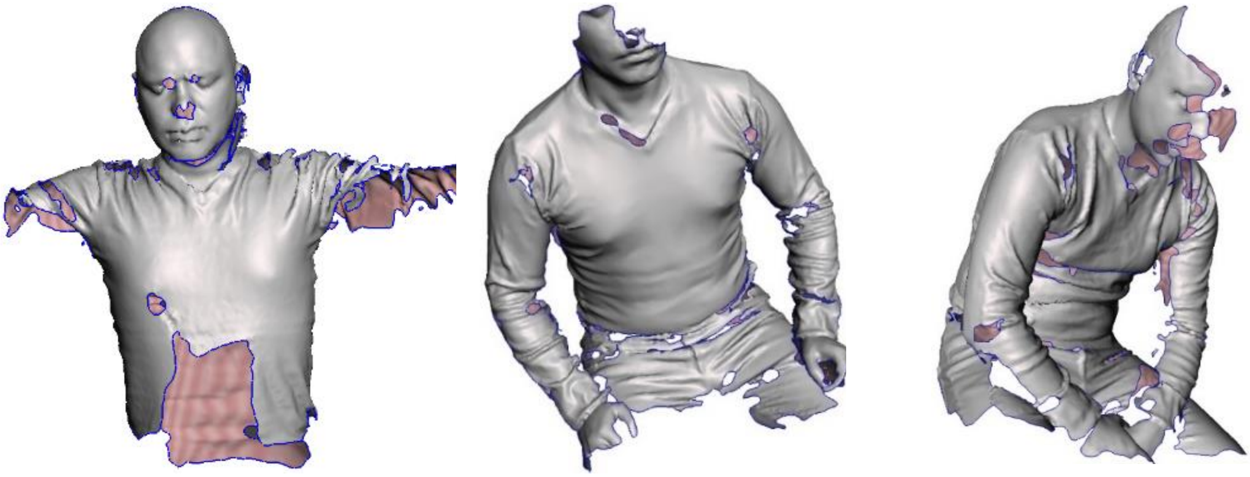
# Chapter 7
# 3D modelling of the user's body

## 7.1. Development of a 3D model of the user's body

The starting point to be able to fulfil the main objective of the doctoral thesis is to create a 3D geometric model of the user's body, in a CAD format.

### *7.1.1. Data processing algorithm*

To obtain the 3D model of the user's body, the author underwent a 3D scanning operation, which was performed with a portable scanner with a resolution of 0.100 mm and an accuracy of 0.050 mm. The scanning process was divided into 3 distinct stages: Position of the correct posture, the result can be seen in Figure 7.1.a; The position of the deviated posture, which involved scanning in the office position, the result is shown in Figure 7.1.b; The position of the deviated position, which involved scanning in the same position as in the second stage, only that after sitting for an hour in the sitting position, the result is shown in Figure 7.1.c.



**a)** **b)** **c)**

| | | |
|---|---|---|
| 83.77661 | -16.27576 | 367.09027 |
| 85.50806 | -16.27576 | 371.09027 |
| 85.21509 | -20.27576 | 367.09027 |
| -208.10144 | -71.50952 | 615.09027 |
| -208.10144 | -73.47046 | 619.09027 |
| -212.10144 | -71.93872 | 619.09027 |
| 86.48779 | -20.27576 | 371.09027 |
| -204.10144 | -73.23669 | 615.09027 |
| -204.10144 | -74.98096 | 619.09027 |
| 80.60291 | -12.27576 | 363.09027 |
| 82.33862 | -12.27576 | 367.09027 |
| 82.06384 | -16.27576 | 363.09027 |
| -200.10144 | -74.45837 | 615.09027 |
| -200.10144 | -71.49084 | 611.09027 |
| -200.10144 | -76.08008 | 619.09027 |
| -244.87482 | -48.27576 | 603.09027 |
| -245.96680 | -44.27576 | 603.09027 |
| -244.10144 | -44.27576 | 600.82086 |

**d)**

| | | |
|---|---|---|
| 256.07104 | -97.56651 | 525.34924 |
| 256.06158 | -95.60402 | 526.30585 |
| 254.06157 | -97.60622 | 524.99213 |
| -200.64284 | 119.90132 | 383.25928 |
| -201.57652 | 119.75319 | 381.84628 |
| -200.66853 | 120.06075 | 382.44125 |
| -202.19753 | 119.56483 | 380.75409 |
| -200.77748 | 120.73445 | 380.51199 |
| 40.09734 | -13.55321 | 363.25723 |
| 40.07027 | -15.60063 | 361.99515 |
| 38.08894 | -13.56792 | 362.57077 |
| 40.03883 | -17.65910 | 360.75467 |
| 38.03865 | -17.65965 | 360.12122 |
| 38.05898 | -15.62169 | 361.32172 |
| -195.73039 | 122.52364 | 383.25162 |
| -197.64082 | 121.34395 | 383.07257 |
| -197.82701 | 122.08711 | 381.20142 |
| -219.91376 | -149.70369 | 307.26398 |

**e)**

| | | |
|---|---|---|
| -237.49698 | -95.70428 | 395.55432 |
| -236.97565 | -99.70428 | 395.55432 |
| -239.05319 | -95.70428 | 399.55432 |
| -94.24780 | 132.29572 | 430.21356 |
| -90.24780 | 131.51062 | 431.55432 |
| -94.24780 | 128.71942 | 435.55432 |
| -238.75354 | 182.75916 | 355.55432 |
| -238.24780 | 182.93243 | 354.27362 |
| -238.24780 | 182.36047 | 355.55432 |
| 61.75220 | -308.07663 | 455.55432 |
| 65.75220 | -307.65485 | 455.55432 |
| 65.75220 | -306.01840 | 459.55432 |
| 61.75220 | -306.52652 | 459.55432 |
| -238.93015 | 182.63818 | 356.23663 |
| -239.27954 | 181.45752 | 359.55432 |
| -238.24780 | 180.57776 | 359.55432 |
| -239.61099 | 179.21967 | 363.55432 |
| -239.39893 | 180.42261 | 361.75507 |

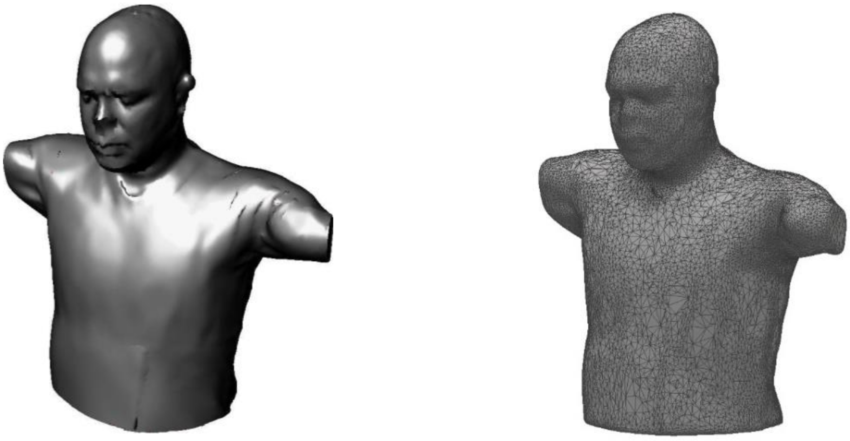
**f)**

**a)** and **d)** the image of the reference model and the coordinates of the points
**b)** and **e)** the image of the model with the correct posture and the coordinates of the points
**c)** and **f)** the image of the model with the deviated posture and the coordinates of the points
**Fig. 7.1.** User scan positions

### 7.1.2. Making CAD model of the user's body

3D modelling of the user's body required the identification of software applications capable of building the 3D model of the human body starting from DICOM type files, based on the segmentation technique. The software application chosen for DICOM image processing is Meshmixer, designed for working with faceted network structures and which allows the analysis and editing of images obtained through CT scans, MRI, nuclear medicine, and microscopy.

After the model has been edited using Meshmixer software, it is exported in STL format, and the result is shown in Figure 7.2.a, in the form of a closed polygonal network, which will allow further processing and additive manufacturing of the model. The model obtained at the previous stage was exported in solid format. The process of transforming the surface type model into a solid model resulted in the file shown in Figure 7.2.b.



**a)** Reference model **b)** The obtained solid model

**Fig. 7.2.** The obtained models

### 7.1.3. Making physical model

Each component was manufactured individually, with the general values initially established. Once all the components were printed, they were physically assembled to verify the correct design of the models in electronic format and then glued together to generate the final assembly of the trunk. Figure 7.3 shows the result of the entire process of developing the physical model for the user's body.

**Fig. 7.3.** The final assembly of the body

## 7.2. Development of a mathematical model of the spine

To perform the orthosis, it is necessary to know the current position of some current characteristic points of the spine, following that the orthosis acts automatically in the sense of correcting the current posture until it brings the spine in a normal position. The x and y coordinates of the points will be read in the joints between two rigid segments and will be inscribed in an orthogonal system, in a median (sagittal) plane, passing through the vertebrae. Starting from the description of the spine in medical terms, a geometric model of it was defined. Such a model approximates well enough the curvature of a healthy spine in a working position sitting (at the desk) or walking.

The input data of the mathematical calculation model are: the coordinates of the initial positions of the joints: $S_1$ $(x_1, y_1)$, $S_2$ $(x_2, y_2)$, $S_3$ $(x_3, y_3)$, $S_4$ $(x_4, y_4)$ and $S_i$ $(x_i, y_i)$; the coordinates of the final positions of the joints: $S_1'$ $(x_1', y_1')$, $S_2'$ $(x_2', y_2')$, $S_3'$ $(x_3', y_3')$, $S_4'$ $(x_4', y_4')$ and $S_i'$ $(x_i', y_i')$; the values of the angles between the rigid segments: $\alpha_1$, $\alpha_2$, $\alpha_3$ și $\alpha_i$; length of rigid segments: $l_1$, $l_2$, $l_3$ și $l_i$. The output data of the mathematical calculation model are the angular values of rotation for each of the rigid segments: $u_1$, $u_2$, $u_3$ și $u_i$.

### 7.2.1. *Assumptions*

The known data for the geometric model are the coordinates of the starting point $S_1$ $(x_1, y_1)$, the orientation angles between the rigid segments ($\alpha_1$, $\alpha_2$, $\alpha_3$ și $\alpha_i$) and the lengths of the rigid segments ($l_1$, $l_2$, $l_3$ și $l_i$). The chosen approach refers to a mathematical model based on straight segments: the relations necessary to calculate the coordinates of the target points are of the first degree. Thus, a linear system of equations is reached that is easy and fast to solve.

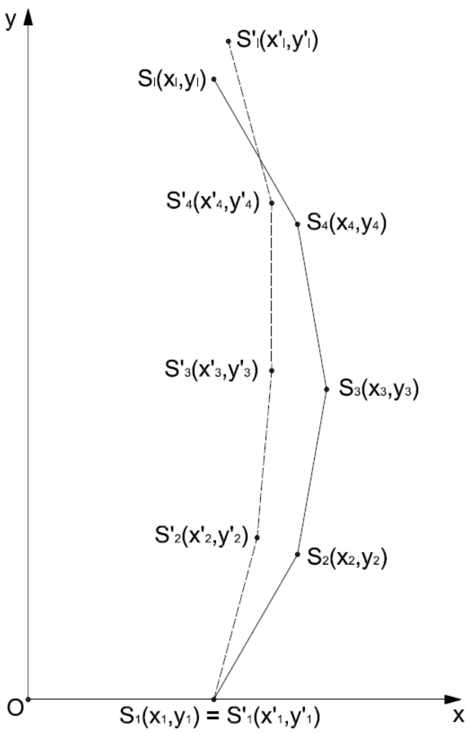



**Fig. 7.4.** Positions of characteristic points

### 7.2.2. Determination of the angle of rotation $u_1$

**Stage 1 –** ***Initialize the coordinates of the starting point***

① $\mathbf{S_1}$:

$(x_1, y_1)$ – they remain fixed.

**Stage 2 –** ***Determination of the initial coordinates of the joints***

② $\mathbf{S_2}$:

$$\begin{pmatrix} x_2 \\ y_2 \end{pmatrix} = l_1 \begin{pmatrix} \cos\alpha_1 & -\sin\alpha_1 \\ \sin\alpha_1 & \cos\alpha_1 \end{pmatrix} \begin{pmatrix} 0 \\ 1 \end{pmatrix} + \begin{pmatrix} x_1 \\ y_1 \end{pmatrix} \tag{7.1}$$

③ $\mathbf{S_3}$:

$$\begin{pmatrix} x_3 \\ y_3 \end{pmatrix} = \frac{l_1}{l_2} \begin{pmatrix} \cos\alpha_2 & -\sin\alpha_2 \\ \sin\alpha_2 & \cos\alpha_2 \end{pmatrix} \begin{pmatrix} x_1 & -x_2 \\ y_1 & -y_2 \end{pmatrix} + \begin{pmatrix} x_2 \\ y_2 \end{pmatrix} \tag{7.2}$$

$\mathbf{S_i}$:

$$\begin{pmatrix} x_i \\ y_i \end{pmatrix} = \frac{l_{i-2}}{l_{i-1}} \begin{pmatrix} \cos\alpha_{i-1} & -\sin\alpha_{i-1} \\ \sin\alpha_{i-1} & \cos\alpha_{i-1} \end{pmatrix} \begin{pmatrix} x_{i-2} & -x_{i-1} \\ y_{i-2} & -y_{i-1} \end{pmatrix} + \begin{pmatrix} x_{i-1} \\ y_{i-1} \end{pmatrix} \tag{7.3}$$

**Stage 3 –** ***Calculation of the angle of rotation***

⑤ $\mathbf{u_1}$:

$$\begin{pmatrix} x'_2 \\ y'_2 \end{pmatrix} = \begin{pmatrix} \cos u_1 & -\sin u_1 \\ \sin u_1 & \cos u_1 \end{pmatrix} \begin{pmatrix} x_2 - x_1 \\ y_2 - y_1 \end{pmatrix} + \begin{pmatrix} x_1 \\ y_1 \end{pmatrix} \leftrightarrow \begin{pmatrix} x'_2 - x_1 \\ y'_2 - y_1 \end{pmatrix} = \begin{pmatrix} \cos u_1 & -\sin u_1 \\ \sin u_1 & \cos u_1 \end{pmatrix} \begin{pmatrix} x_2 - x_1 \\ y_2 - y_1 \end{pmatrix} \rightarrow$$

$$cosu_1 = \frac{\begin{vmatrix} x'_2 - x_1 & -(y_2 - y_1) \\ y'_2 - y_1 & x_2 - x_1 \end{vmatrix}}{\begin{vmatrix} x_2 - x_1 & -(y_2 - y_1) \\ y_2 - y_1 & x_2 - x_1 \end{vmatrix}} \tag{7.4}$$

**Stage 4 –** ***Checking the coordinates of the joint in the final position***

⑥ $\mathbf{(x'_2, y'_2)}$:

$$\begin{pmatrix} x'_2 \\ y'_2 \end{pmatrix} = \begin{pmatrix} \cos u_1 & -\sin u_1 \\ \sin u_1 & \cos u_1 \end{pmatrix} \begin{pmatrix} x_2 - x_1 \\ y_2 - y_1 \end{pmatrix} + \begin{pmatrix} x_1 \\ y_1 \end{pmatrix} \tag{7.5}$$

### 4.3.3. Determination of the angle of rotation $u_i$

**Stage 5 –** ***Calculation of rotation angles***

⑦ $\mathbf{u_i}$:

$$\begin{pmatrix} x'_{i+1} \\ y'_{i+1} \end{pmatrix} = \begin{pmatrix} \cos u_i & -\sin u_i \\ \sin u_i & \cos u_i \end{pmatrix} \begin{pmatrix} x_{i+1} - x_i \\ y_{i+1} - y_i \end{pmatrix} + \begin{pmatrix} x_i \\ y_i \end{pmatrix} \leftrightarrow \begin{pmatrix} x'_{i+1} - x_i \\ y'_{i+1} - y_i \end{pmatrix} = \begin{pmatrix} \cos u_i & -\sin u_i \\ \sin u_i & \cos u_i \end{pmatrix} \begin{pmatrix} x_{i+1} - x_i \\ y_{i+1} - y_i \end{pmatrix}$$

$$\rightarrow cosu_i = \frac{\begin{vmatrix} x'_{i+1} - x_i & -(y_{i+1} - y_i) \\ y'_{i+1} - y_i & x_{i+1} - x_i \end{vmatrix}}{\begin{vmatrix} x_{i+1} - x_i & -(y_{i+1} - y_i) \\ y_{i+1} - y_i & x_{i+1} - x_i \end{vmatrix}} \tag{7.6}$$

**Stage 6 –** ***Checking the coordinates of the joints in the final position***

⑧ $\mathbf{(x'_{i+1}, y'_{i+1})}$:

$$\begin{pmatrix} x'_{i+1} \\ y'_{i+1} \end{pmatrix} = \begin{pmatrix} \cos u_i & -\sin u_i \\ \sin u_i & \cos u_i \end{pmatrix} \begin{pmatrix} x_j - x_i \\ y_j - y_i \end{pmatrix} + \begin{pmatrix} x_i \\ y_i \end{pmatrix} \tag{7.7}$$

# Chapter 8
# Functional analysis and conceptual design of an intelligent orthoses

Once the product specifications are established, concepts conforming to those specifications are generated. The success of this stage is favored by the generation of as many concepts as possible, in a process that will be as free and, as possible, unrestricted as possible.

## 8.1. Establishing the functions of an intelligent orthoses

The notion of function allows the definition of each of the services expected by the user in terms of finality and not of technical solutions. The function expresses what is expected of a product for a specific need, with a well-defined purpose [D14].

### *8.1.1. General function*

Starting from the identified need - that of having a correct posture, it was established that the general function of the developed product is to correct the posture.

### *8.1.2. Main functions*

Ordering involves the classification of functions, on several levels, according to the degree of detail of the analysis, in a logical structure that can identify the interdependencies between them [C14].

The main functions are shown in Table 8.1.

**Table 8.1.** List of main functions

| Function no. | Main function |
| --- | --- |
| $\phi_1$ | Adapt for various categories of people |
| $\phi_2$ | Fix the orthosis on the human body |
| $\phi_3$ | Schedule wear intervals |
| $\phi_4$ | Signal the operating status |
| $\phi_5$ | Set the treatment regimen |
| $\phi_6$ | Ensure fixed position |
| $\phi_7$ | View operation indicators |
| $\phi_8$ | Ensure the physical continuity of the components |
| $\phi_9$ | Combine the components together |
| $\phi_{10}$ | To ensure the aesthetics of the orthosis |

## 8.2. Identification of critical functions

To determine the critical functions, the hierarchy of the main functions was elaborated, this consists in the comparison of the main functions between them and the allocation of an importance coefficient. For each function, the values of the assigned coefficients were summed, and then the unit weight of each main function was calculated. Following the analytical process of ranking, the critical functions presented in Table 8.2 were established.

**Table 8.2.** List of critical functions

| Function no. | Critical function | Weight |
|---|---|---|
| $\phi_2$ | Fix the orthosis on the human body | 0,142 |
| $\phi_3$ | Schedule wear intervals | 0,125 |
| $\phi_5$ | Set the treatment regimen | 0,150 |
| $\phi_6$ | Ensure fixed position | 0,142 |
| $\phi_{10}$ | To ensure the aesthetics of the orthosis | 0,117 |

## 8.3. Generating conceptual solutions

42 patents have been analyzed, granted since the 1950s and until now.

The analysis revealed the following necessary characteristics:

- the device has an anatomical shape;
- the device ensures the comfort of the user;
- the device is ergonomic;
- the device allows the skin to breathe and evacuate perspiration;
- the device allows the replacement of damaged components.

The number of technically possible solutions is very large, considering the previously established objective specifications. Following the compilation of the archive of known and new conceptual solutions for the main functions of the orthosis, the product was divided into 6 main systems that materialize the main and secondary functions previously established, as follows: body, (3) The system for timing the wearing period, (4) The system for choosing the area of action, (5) The system for performing therapeutic movements and (6) The system for ensuring the fixed position. Possible conceptual solutions for each individual system were selected. Following this selection, 10 x 12 x 11 x 7 x 11 x 4 = 406560 solutions should be analyzed. Taking into account the objectively established specifications, some conceptual solutions were excluded.

**Concept no 6**

**Table 8.3.** The solution concept 6

| Size adjustment system | Body mounting system | System for timing the wear period | System for choosing the area of action | System for performing therapeutic movements | Fixing system |
|---|---|---|---|---|---|
| Adjustable straps | Velcro system | Digital timer | Electronic system | Mechanical spine | Belts |

The posture correction orthosis has a vest (1) made of cotton. The dimensions are adjusted progressively by means of the adjustable strap system (2). Thus, with the help of the adjustable strap system, the posture correction orthosis can be adjusted on the human body with the continuous adjustment step to ensure the most accurate adjustment possible. After the dimensional adjustment of the vest on the body, it is fixed by means of velcro systems (3) which are located on the waistcoat to fit the individual anatomy of each type of user. According to the prescriptions of the specialist, the user can set the daily wear interval with the help of the digital timer (4). With the help of the timer (4), the user can set an "alarm" for remembrance, both for the dressing time and for the end of the wearing period. Depending on the condition of the user, the area of action of the orthopedic vest (cervical, thoracic, lumbar, or sacro-coccygeal) can be chosen by means of the electronic system (5). The therapeutic effect of the orthopedic vest is given by the mechanical spine (6) which directly stimulates the peripheral and lymphatic circulatory systems, and indirectly, the muscular and neurological systems. The fixed position is ensured by means of a system of fixed straps (7), they "fit" the user's body in the orthopedic vest, so the spine is supported by them. The outline of concept 6 is presented in Figure 8.6.

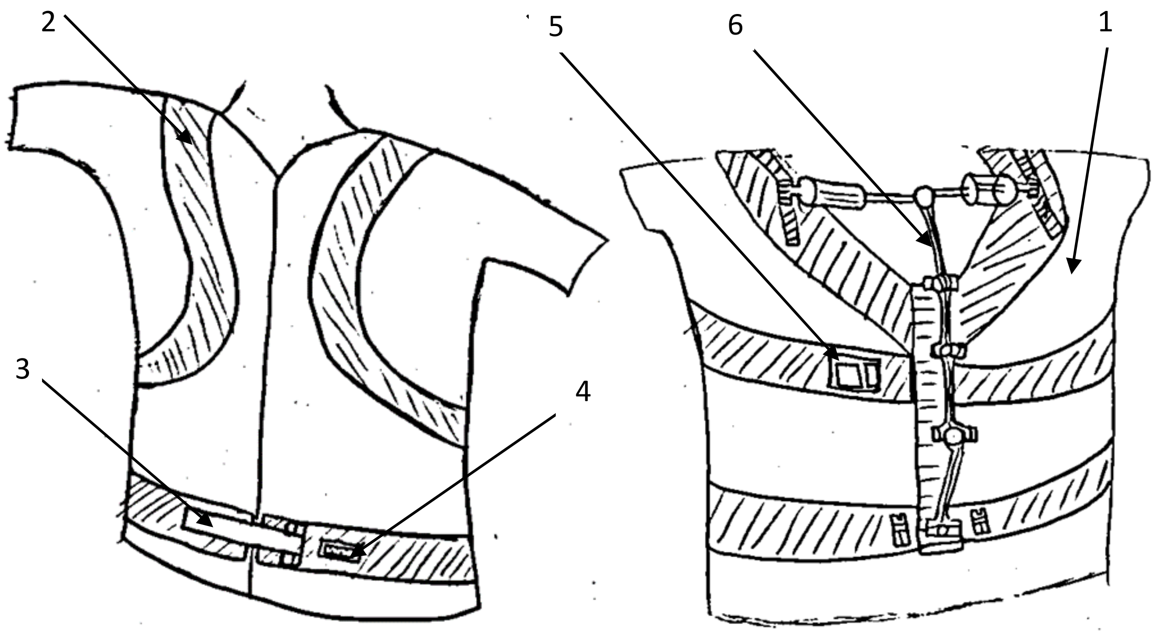



**Fig. 8.1.** Sketch of concept no. 6

## 8.4. Selecting the optimal concept

The selection of the concept is done in two stages: Sorting and Evaluating the concepts.

### *8.4.1. Sorting concepts*

In the concept sorting stage, the resulting concepts are analyzed at the concept generation stage. The concept generation stage resulted in six product concepts, which have the general function of correcting posture. For each sorting criterion, the degree of satisfaction of it by each concept was established by comparison with the reference concept.

### *8.4.2. Evaluation of concepts*

After sorting the concepts, 3 integral concepts were selected: C1, C2 and C6 of the product. Following the evaluation of the concepts, concept 6 obtained a total score of 4.35, 0.9 more than the next concept. Concept 6 is assigned rank 1, it will be further developed.

**Table 8.4.** Concept's evaluation matrix

| No. | Weight | Concept 1 | | Concept 2* | | Concept 6 | |
|---|---|---|---|---|---|---|---|
| **T1** | **20** | | | | | | |
| T1.1 | 10 | 4 | 0,40 | 3 | 0,30 | 3 | 0,30 |
| T1.2 | 10 | 4 | 0,40 | 3 | 0,30 | 4 | 0,40 |
| **T2** | **10** | | | | | | |
| T2.1 | 3 | 3 | 0,09 | 3 | 0,09 | 5 | 0,15 |
| T2.2 | 3 | 3 | 0,09 | 3 | 0,09 | 5 | 0,15 |
| T.2.3 | 4 | 4 | 0,12 | 3 | 0,09 | 4 | 0,12 |
| **T3** | **20** | | | | | | |
| T3.1 | 8 | 4 | 0,32 | 3 | 0,24 | 4 | 0,32 |
| T3.2 | 12 | 5 | 0,06 | 3 | 0,36 | 5 | 0,60 |
| **T4** | **5** | | | | | | |
| T4.1 | 3 | 2 | 0,06 | 3 | 0,09 | 3 | 0,09 |
| T4.2 | 2 | 3 | 0,06 | 3 | 0,06 | 3 | 0,06 |
| **T5** | **15** | | | | | | |
| T5.1 | 9 | 4 | 0,36 | 3 | 0,27 | 5 | 0,45 |
| T5.2 | 6 | 3 | 0,18 | 3 | 0,18 | 5 | 0,30 |
| **T6** | **10** | | | | | | |
| T6.1 | 5 | 5 | 0,25 | 3 | 0,15 | 5 | 0,25 |
| T6.2 | 3 | 4 | 0,12 | 3 | 0,09 | 4 | 0,12 |
| T6.3 | 2 | 4 | 0,08 | 3 | 0,06 | 5 | 0,10 |
| **T7** | **20** | | | | | | |
| T7.1 | 8 | 4 | 0,32 | 3 | 0,24 | 5 | 0,40 |
| T7.2 | 6 | 5 | 0,30 | 3 | 0,18 | 5 | 0,30 |
| T7.3 | 6 | 4 | 0,24 | 3 | 0,18 | 4 | 0,24 |
| **Total score** | | **3.45** | | **2.97** | | **4.35** | |
| **Rank** | | **2** | | **3** | | **1** | |

## 8.5. Orthoses architecture design and economic analysis

### 8.5.1. Product architecture

To materialize the functions defined in Figure 8.2, the product was divided into 3 systems: (1) the support system, (2) the data acquisition system and (3) the drive system.

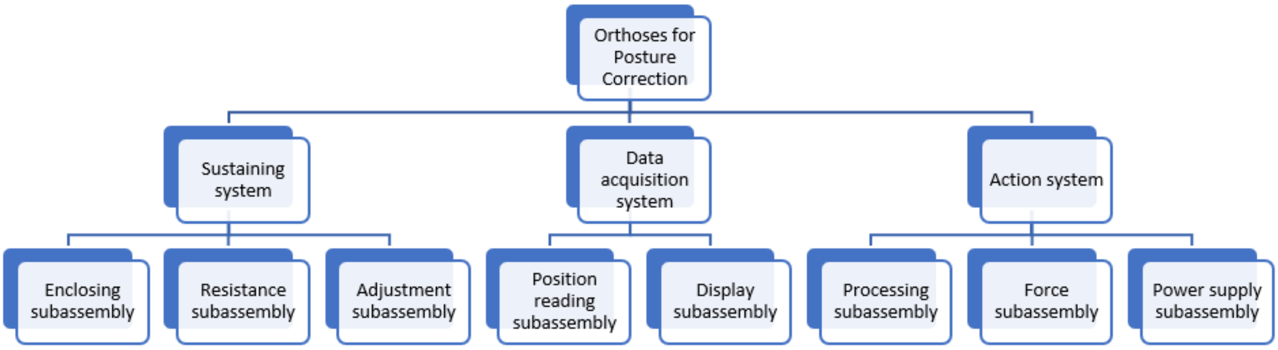



**Fig. 8.2.** Posture Correction Orthosis Product Architecture

### 8.5.2. Economic analysis

The economic analysis of the product variants involves the determination of the production cost for the analyzed product. The model of the total cost used is presented in Figure 8.3.

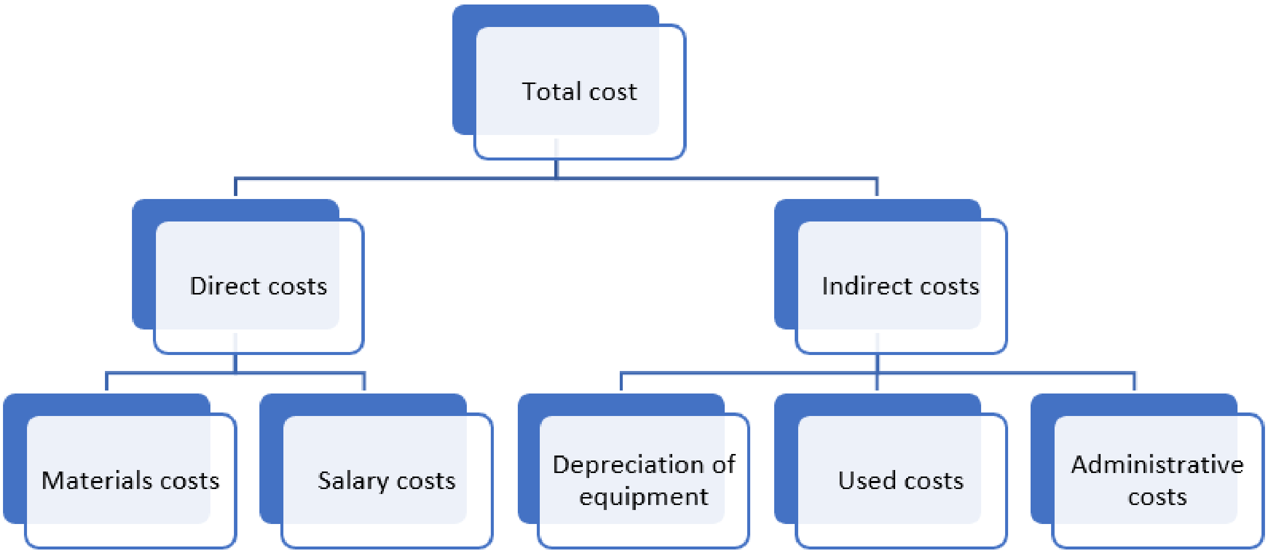



**Fig. 8.3.** Total cost model [U02]

The cost for components manufactured by additive technologies is presented together with the parts / parts purchased commercially in the List of components presented in table 8.5. The total cost of the Posture Correction Orthosis is 1285 RON / pc.

**Table 8.5.** List of materials and cost of prototype

| Subansamby | Component | Quantity | Unit of measure | Unit cost | Total cost | Remarks |
|---|---|---|---|---|---|---|
| Jacket | fabric | 6 | m | 35 | 210 | |
| | Thread | 2 | roll | 22.5 | 45 | |
| Resistance | Belt 1 | 2 | m | 3.46 | 6.92 | |
| | Belt 2 | 6 | m | 7.28 | 43.68 | |
| | Timing belt | 1 | m | 39 | 39 | |
| | Support plate | 1 | piece | 37.73 | 37.73 | Manufact |
| | Buckle | 2 | piece | 10 | 20 | |
| | Velcro tape | 2 | m | 12.5 | 25 | |
| Reading | Vertebral body | 8 | piece | 18.07 | 144.56 | Manufact |
| | Thoracic joint | 1 | piece | 8.26 | 8.26 | Manufact |
| | Lumbar joint | 1 | piece | 3.23 | 3.23 | Manufact |
| | Potentiometer | 8 | piece | 1.69 | 13.52 | |
| | Shaft | 8 | piece | 0.72 | 5.76 | Manufact |
| | Display | 1 | piece | 35 | 35 | Manufact |
| | Housing | 1 | piece | 2.14 | 2.14 | Manufact |
| Display Processing | Arduino Mega board | 1 | piece | 59 | 59 | |
| | Shield Arduino L298P | 1 | piece | 36 | 36 | |
| | Housing | 1 | piece | 3.72 | 3.72 | Manufact |
| | Pins | 1 | piece | 2 | 2 | |
| | Connection cable | 1 | piece | 4 | 4 | |
| Force | Engine | 2 | piece | 179 | 358 | |
| | Support | 2 | piece | 2.69 | 5.38 | Manufact |
| | Cogwheel | 2 | piece | 50 | 100 | |
| | Coupler | 2 | piece | 1.87 | 3.74 | Manufact |
| | M3 screw | 32 | piece | 0.5 | 16 | |
| | M3 nut | 26 | piece | 0.25 | 6.5 | |
| | Wire 1 | 40 | piece | 0.3 | 12 | |
| | Cable | 40 | piece | 0.5 | 20 | |
| Power supply | Battery | 2 | piece | 6 | 12 | |
| | Housing | 2 | piece | 2.03 | 4.06 | Manufact |
| | Connector | 2 | piece | 2 | 4 | |
| **Total Cost [RON]** | | | | | **1285** | |

# Chapter 9
# Detailed design of a smart orthoses

Starting from the Objective Specifications established in Chapter 5 and the concept selected in the same chapter, we moved on to the Detailed Design, according to the General Structure of the Posture Correction Orthosis presented in Figure 9.1.

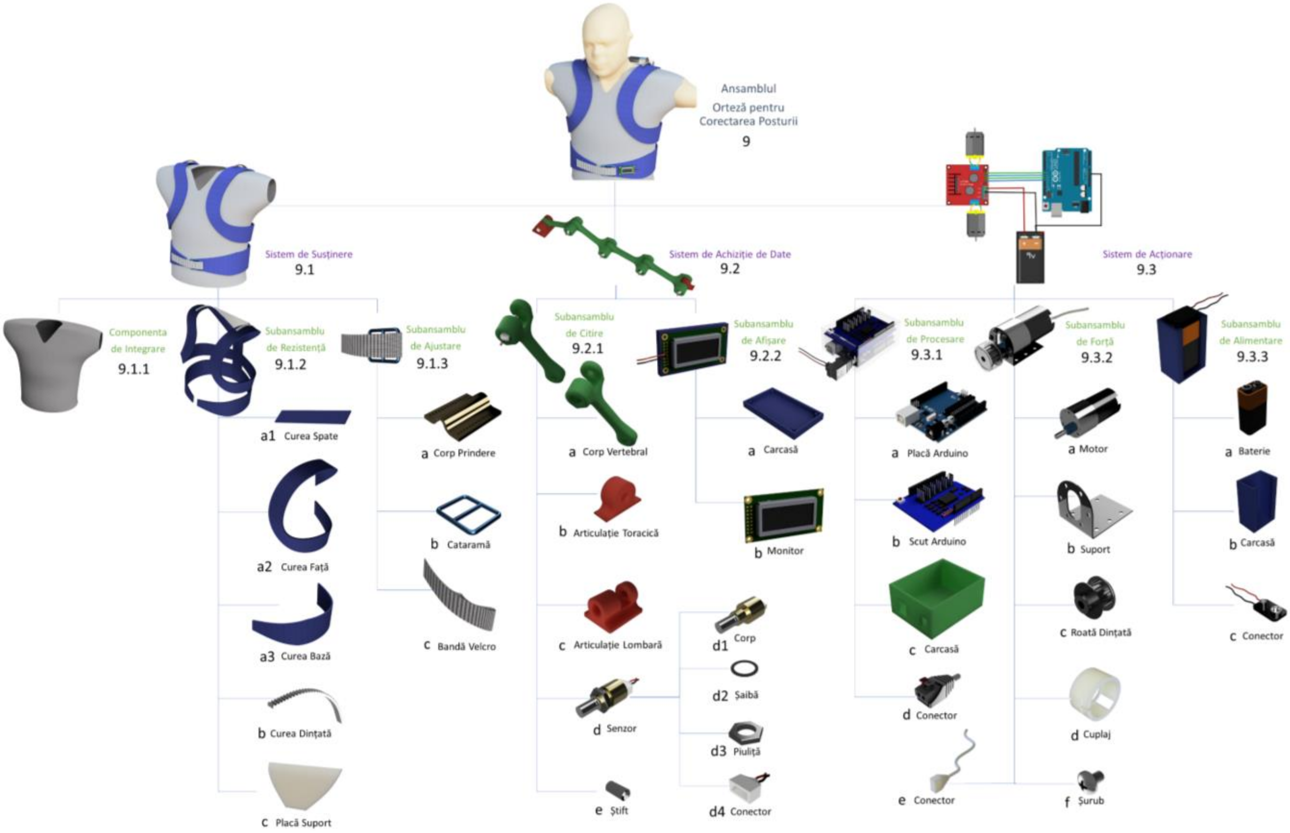
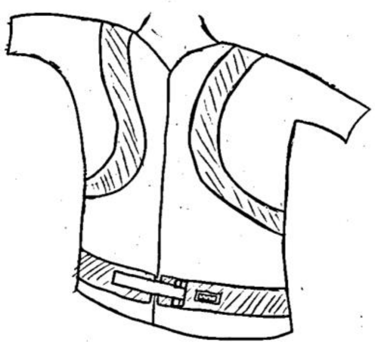



**Fig. 9.1.** Product disaggregation structure

## 9.1. Design of the support system

The system for supporting the components of the Posture Correction Orthosis is composed of 3 subassemblies, as shown in the figure below: (1) The subassembly for incorporating the components; (2) Resistance subassembly and (3) Adjustment subassembly.



**a)** Sketch

**b)** 3D model

**Fig. 9.2.** Support system

### 9.1.1. Design of the enclosing component subassembly

The element embedding system contains a single component, the Jacket. To create the "Jacket" part that will serve as a support for the rest of the orthosis components, the user's body model will be used.

### 9.1.2. Design of the resistance subassembly

The resistance subassembly consists of a belt system and a motor support plate. The strap system was tailored to the custom dimensions and shapes of the manikin used.

### 9.1.3. Design of the adjustment subassembly

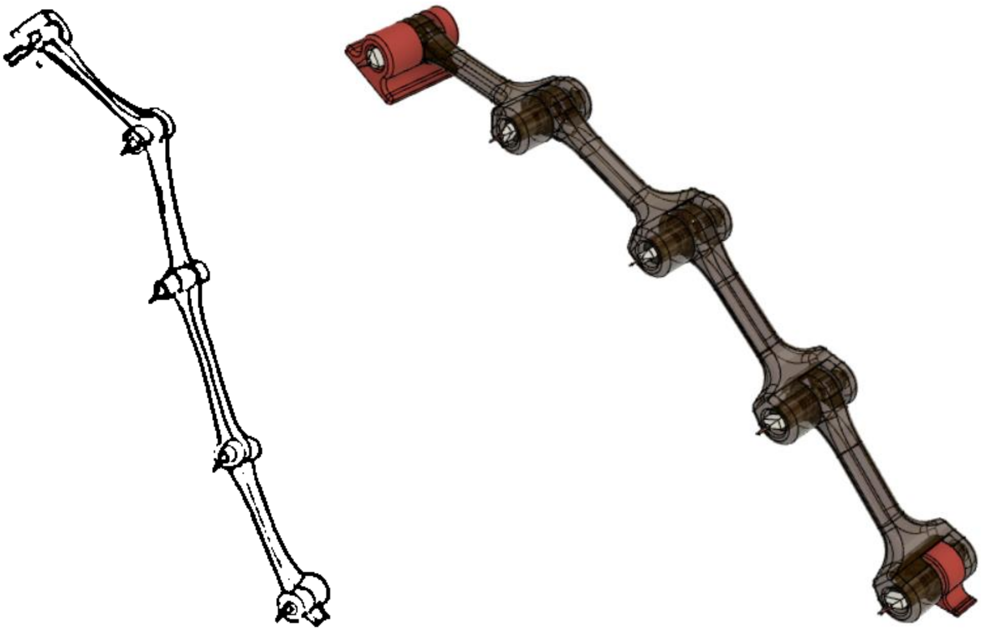
The adjustment subassembly has the role of adjusting and fixing the Resistance System on the user's body. It consists of: Body, Buckle and Velcro Strap. The adjustment system will be incorporated on the Vest, in 3 positions, to adjust it to the size of the wearer.

## 9.2. Design of the data acquisition system

The data acquisition system consists of two subassemblies: (1) the position reading subassembly and (2) the results display subassembly.

### 9.2.1. Design of the position reading subassembly

The position reading subassembly is composed of 5 main components: Mechanical Spinal Body, Thoracic Joint, Lumbar Joint, Sensor and Pin and is shown in Figure 9.3.



**a)** Sketch **b)** 3D model

**Fig. 9.3.** Data acquisition system

***Mechanical Vertebral Body (CVM)***

The Mechanical Vertebral Body materializes a structure like the vertebrae in the spine. At each end, the vertebral body has a seat for the sensor and a joint so that it can be assembled with another vertebral body or with one of the two end joints (thoracic or lumbar). The body is rigid and has a fixed length, in an alternative variant the length can be variable. The position reading subassembly contains, in the 3D modeled version, four vertebral bodies, which also form the resistance structure of the product, following at the same time the curvature of the user's spine. For a better approximation of the curves, it is possible to use several vertebral bodies, of smaller dimensions, depending on the concrete needs.

After all the design iterations and the choice of the material for the manufacture of the component, in Figure 9.4 is presented the sketch of the final variant of the Mechanical Vertebral Body.

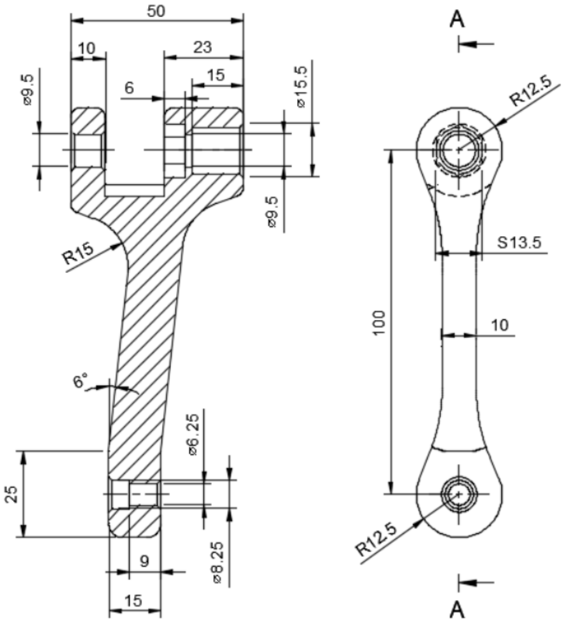



**Fig. 9.4.** Vertebral Body sketch, Version 4

### 9.2.2. *Design of the display subassembly*

The result display subassembly consists of 2 main components: The Support Housing and the Display.

## 9.3. Design of the drive system

The operating system of the Posture Correction Orthosis consists of 3 subassemblies as shown in figure 9.5: (1) The processing and control subassembly, (2) the power subassembly and (3) the power supply subassembly.

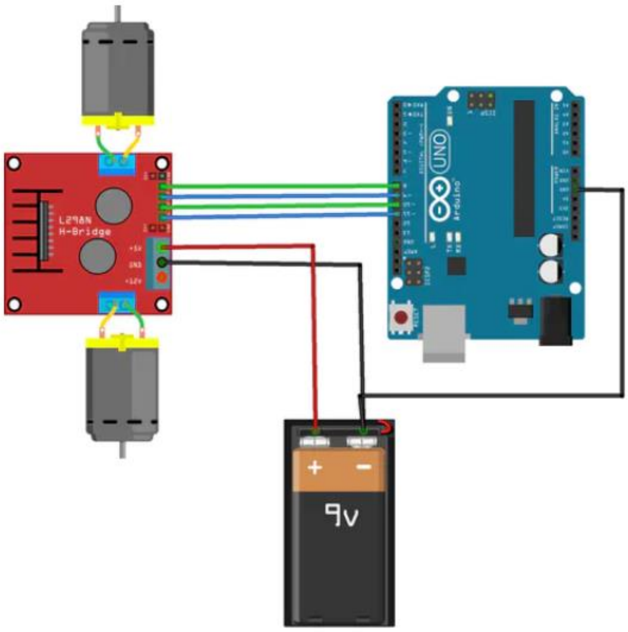



**Fig. 9.5.** Schematic drive system

### 9.3.1. Design of the processing and control subassembly

The processing and control subassembly consists of 3 main components: the Arduino development board, the Shield, and the Support Housing. To be integrated in the final model of the Posture Correction Orthosis, both the Arduino Board and the Shield were modeled.

### 9.3.2. Design of the force subassembly

To determine the force required to lift the human body to size the motors, the position of the spine is simplified and is considered similar to an inclined plane. For this plane to remain in balance, the condition that the sum of the moments in point A is equal to zero is sufficient. Thus, the moments acting at point B (the center of gravity of the human body) and the force required to act at point C, at the shoulders - where the motors will operate, so that the equilibrium condition is satisfied, will be found. The sizing model of the motors is in Figure 9.6.

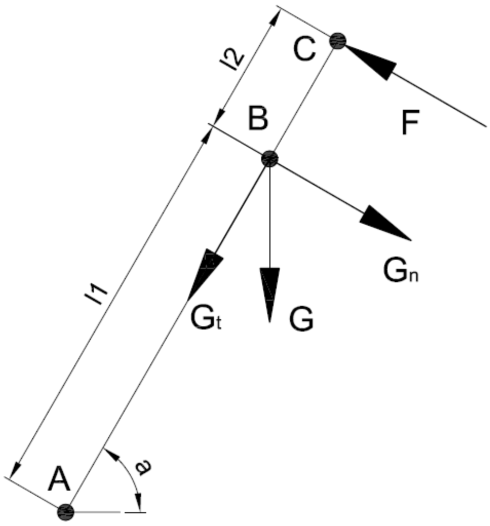



**Fig. 9.6.** Mechanical model of lifting force

Initial data: the total body mass is known (75 kg), corresponding to the 3D model of the body, so the mass of the upper body is considered 2/3 of the total body mass, m = 50 kg; weight force, G = 500 N; the position of the center of gravity, knowing the length of the body (l = 1700 mm), determine the center of gravity and the actuating point of the force F, $l_1$ = 300 mm; position of engine actuation point (design dimension), $l_2$ = 100 mm; body tilt angle, α = 30 °.

$\Sigma M_A = 0$ (9.1)

$F \bullet (l_1 + l_2) - G_n \bullet l_1 = 0$ (9.2)

$F \bullet (l_1 + l_2) = G_n \bullet l_1$ (9.3)

$F \bullet (l_1 + l_2) = G \bullet \cos\alpha \bullet l_1$ (9.4)

$F = \frac{G \bullet \cos\alpha \bullet l_1}{l_1 + l_2} \Rightarrow F = \frac{500 \bullet 0{,}866 \bullet 300}{300 + 100} = 325\ N$ (9.5)

F = 325 N = 33 kgf

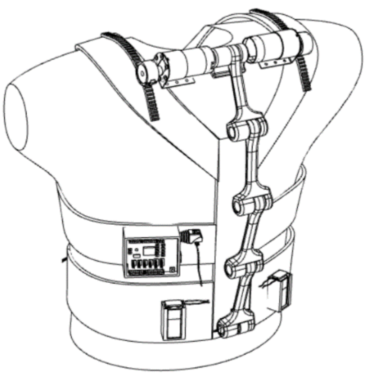
The motor chosen for the product is a high torque continuous gear motor that offers a torque of 32 Kg * cm.

### 9.3.3. Design of the power supply subassembly

The power subassembly consists of 3 main components: Alkaline Battery, Housing and Battery Connector.

## 9.4. Design of the Posture Correction Orthoses assembly

The final set of Orthoses for Posture Correction incorporates the functions previously established. Thus, in the figures below are presented, by comparison, the conceptual solution, and the detail design solution. Figure 9.7 shows the front view of the concept.



**a)** OCP – front view

**b)** OCP – back view

**Fig. 9.7.** OCP design

## 9.5. Optimizing the design process

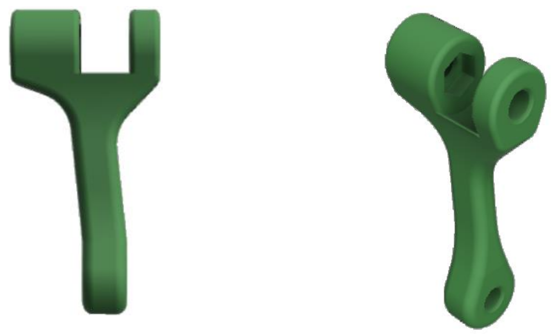
Design optimization implies the existence of a mathematical formulation of an objective function to be optimized, based on which the optimal project can be selected from several existing alternatives.

### 9.5.1. Parametric design

The parametric design was performed, as well as the detailed design, in the Fusion 360 software from Autodesk Inc. After designing the component, the parameters used to generate it were analyzed and presented in Figure 9.8.

Because the dimensions of the vertebral body bores depend on the dimensions of the components to be assembled, they were left as model parameters, they were not customized.

In the first instance, the dimensions that influence the geometry of the vertebral body were parameterized according to the user's height. Thus, relationships were defined between the dimensions of the model.



| Parameter | Name | Unit | Expression | Value |
|---|---|---|---|---|
| Favorites | | | | |
| User Parameters | | | | |
| User Para... | h | mm | 1500 mm | 1500.00 |
| User Para... | X | | h / 1700 m... | 0.882353 |
| Model Parameters | | | | |
| Corp_Vertebral_... | | | | |
| Sketch1 | | | | |
| D... | d1 | mm | 25 mm | 25.00 |
| Li... | d2 | mm | X * 100 mm | 88.235 |
| Extrude1 | | | | |
| Extrude2 | | | | |
| Extrude3 | | | | |
| Extrude4 | | | | |
| Sketch3 | | | | |
| Li... | d16 | mm | d2 / 10 | 8.824 |
| Li... | d17 | mm | 5 mm | 5.00 |
| A... | d18 | deg | 45 deg | 45.0 |
| Li... | d19 | mm | 15 mm | 15.00 |
| A... | d20 | deg | 45 deg | 45.0 |

a) Front view b) Isometric view c) Parameters for the height of 1.5 m

| Parameter | Name | Unit | Expression | Value |
|---|---|---|---|---|
| Favorites | | | | |
| User Parameters | | | | |
| User Para... | h | mm | 2000 mm | 2000.00 |
| User Para... | X | | h / 1700 m... | 1.17647 |
| Model Parameters | | | | |
| Corp_Vertebral_... | | | | |
| Sketch1 | | | | |
| D... | d1 | mm | 25 mm | 25.00 |
| Li... | d2 | mm | X * 100 mm | 117.647 |
| Extrude1 | | | | |
| Extrude2 | | | | |
| Extrude3 | | | | |
| Extrude4 | | | | |
| Sketch3 | | | | |
| Li... | d16 | mm | d2 / 10 | 11.765 |
| Li... | d17 | mm | 5 mm | 5.00 |
| A... | d18 | deg | 45 deg | 45.0 |
| Li... | d19 | mm | 15 mm | 15.00 |
| A... | d20 | deg | 45 deg | 45.0 |

g) Front view h) Isometric view i) Parameters for the height of 2.0 m

**Fig. 9.8.** Dependence of the dimensions of the model on the height of the user

### 9.5.2. Generative design

Generative design is an iterative design process, involving a program, which consists of generating a few options that meet certain imposed constraints.

Starting from the initially generated assembly, it is proposed to optimize the Vertebral Body through generative design. This involves going through a process that has as input the component material, the proposed objective, the restrictive geometry, and the result will be represented by variants that meet the required conditions. In this sense, the whole of the Mechanical Column is further analyzed.

**Fig. 9.10.** The initial assembly of the mechanical spine

For each of the variants obtained from the iterative design process, its overall integration can be simulated. This simulation can also serve as a decision factor in the process of selecting the optimal variant of geometry, manufacturing technology and material from which the given component is made. Figure 9.11 shows the simulation of the integration of an overall variant.

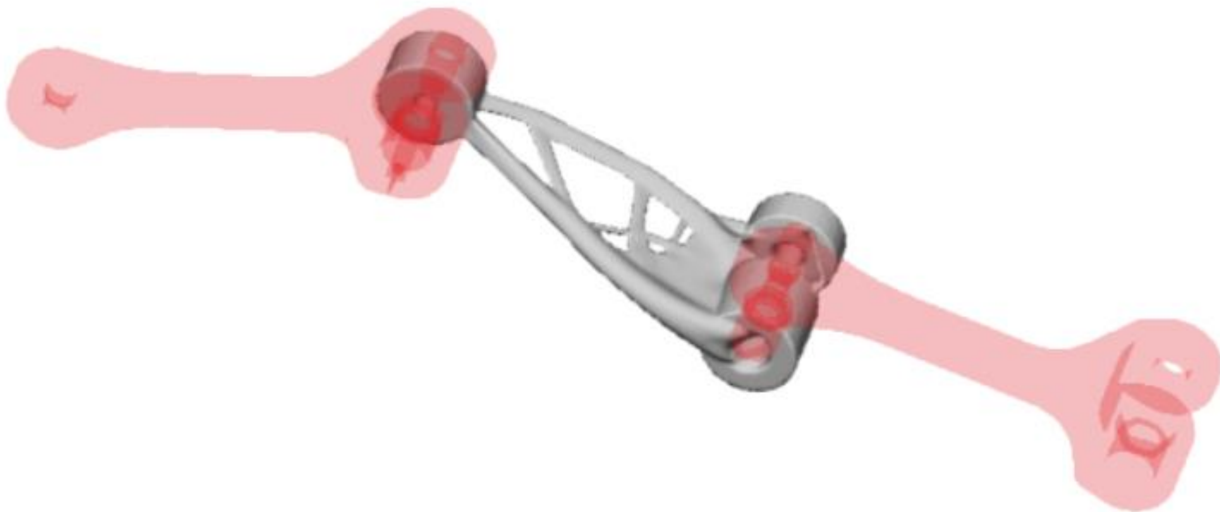


**Fig. 9.11.** Assembly preview

# Chapter 10
# Manufacture of smart orthoses components

The term “manufacturing” refers to a wide range of human activities, from handcrafted works to production using state-of-the-art technologies, but is used for industrial production, in which the raw material is transformed into finished goods.

## 10.1. Manufacture of the base product system

The clothing products are made successively, by processing the parts to obtain the product elements, followed by the coupling of the elements in subassemblies whose complexity and degree of processing increase until obtaining the finished product.

### *10.1.1. Used materials*

The basic textile materials used in the manufacture of clothing are the face of the product. These materials are: fabrics, T-shirts, non-woven textiles, natural furs and imitations of fur [D06]. The basic material used for the waistcoat is a composite of blue cotton (96%) and elastane (4%).

### *10.1.2. Manufacturing technology*

The choice of the optimal variant considers the time of its realization, the technical possibilities of realization, the characteristics of the raw material, the material consumptions and the quality requirements imposed on the finished product.

The closing elements of the clothing products can be differentiated constructively and technologically and can be of the type: with buttons or buttons, with zipper, with buckles, with gaiters, with stitches, etc. The supporting elements of the products on the body are the cords and the straps.

### *10.1.3. Finishing the jacket*

Finishing is the part of manufacturing technology that, when applied to manufactured products, allows to obtain appropriate shapes, aspects, and qualities. The main operations performed during the finishing process are: transport, pressing, lint cleaning, button sewing, labeling, quality control and packaging.

## 10.2. Manufacture of custom components

With the advent of additive manufacturing technologies (AF), it has become possible to customize products at an unprecedented pace. As the developed orthosis requires many elements customized according to the user, an AF technology was chosen for their realization.

### 10.2.1. Design for additive manufacturing

Additive manufacturing (FA) brings together a set of technologies that have one thing in common: the manufacture of a part is done by adding material, layer by layer, not by removing material. The need to design products so that they can be produced by FA technologies to the specifications desired by the user is a real, practical, and extremely current one. It is believed that using AF technologies any kind of geometric shape can be constructed [P07].

### 10.2.2. Data transfer to the 3D printer

STL is an abbreviation of the term "stereolithography" (or Standard Tesselation Language). This is a native file format for stereolithography software created by 3D Systems. The STL format is supported by many other software packages, it is widely used for rapid prototyping, 3D printing and computer aided manufacturing. However, STL files only describe the surface geometry of a three-dimensional object without any representation of the color, texture, or other common attributes of the CAD model [C03].

### 10.2.3. Process preparation

By planning, the 3D printing process is meant the set of measures for creating and assimilating components in manufacturing and optimizing those already manufactured. This subchapter presents the main stages of preparation for the additive manufacturing itself. It also presents the choice of 3D printers used and software for generating processing programs and describes the operations of simulating these processes.

### 10.2.4. Equipment and materials used

The Kreator 3D printer is a universal 3D printer, one of the most versatile 3D printers on the market, which can print a wide variety of materials: from PLA and ABS to composite wood, composite metal, and high-strength materials [K11].

**Table 10.1.** Features of used 3D printers [K11] [Z01]

| | | **3D Kreator** | **Zortrax M300 Plus** |
|---|---|---|---|
| *Parameter* | *u.m.* | *Value* | |
| Nozzle diameter | mm | 0,4 – 0,6 | 0,4 – 0,6 |
| Workspace | mm | 200 x 200 x 190 | 300 x 300 x 300 |
| Nozzle temperature | °C | 180 - 260 | 290 |
| Plate temperature | °C | 80 – 100 | 105 |
| Printing accuracy | µm | 60 | 90 – 290 |

The Kreator 3D printer operates with G-code files that can be generated with the help of several software available on the market. PLA components were manufactured during this time of the printer.

The large workspace of the Zortrax M300 Plus printer allows you to print large models in one piece, without breaking them down into separate parts to be assembled [Z01].

The Zortrax M300 Plus printer operates with ".zcodex" files. Z-HIPS and Z-PETG components were manufactured during this time of the printer.

Polylactic acid (PLA) is a thermoplastic aliphatic polyester derived from renewable resources. In 2010, PLA was the second most consumed bioplastic in the world, although it is not a commodity polymer. Its widespread application has been hampered by numerous physical and processing deficiencies. PLA is a food material and is used for the manufacture of condensed filaments for 3D printers [N01].

**Table 10.2.** Properties of materials used [Z01] [N01]

| **Characteristics** | *u.m.* | **PLA** | **Z-HIPS** | **Z-PETG** | *Standard* |
|---|---|---|---|---|---|
| | | *Value* | | | |
| Tensile strength | MPa | 47,95 | 16,90 | 40,18 | ISO 572: 1998 |
| Breaking strength | MPa | 46,53 | 13,02 | 37,27 | ISO 572: 1998 |
| Traction elongation | % | 3,80 | 1,87 | 5,83 | ISO 572: 1998 |
| Elongation at break | % | 4,32 | 7,75 | 6,39 | ISO 572: 1998 |
| Bending strength | MPa | 56,80 | 29,30 | 55,30 | ISO 178:2011 |
| Flexion module | GPa | 1,47 | 1,18 | 1,39 | ISO 178:2011 |
| Impact | kJ/$\mathbf{m}^2$ | 3,14 | 4,82 | 3,27 | ISO 180:2004 |
| Transition temperature | °C | 57,06 | 98,68 | 77,65 | ISO 11357-3:2014 |
| Viscosity | g/min | 1,448 | 0,714 | 2,002 | ISO 1133:2006 |
| Density | g/$\mathbf{cm}^3$ | 1,292 | 1,136 | 1,295 | ISO 1183-3:2003 |
| Hardness | D | 79,8 | 73,2 | 71,4 | ISO 572: 1998 |

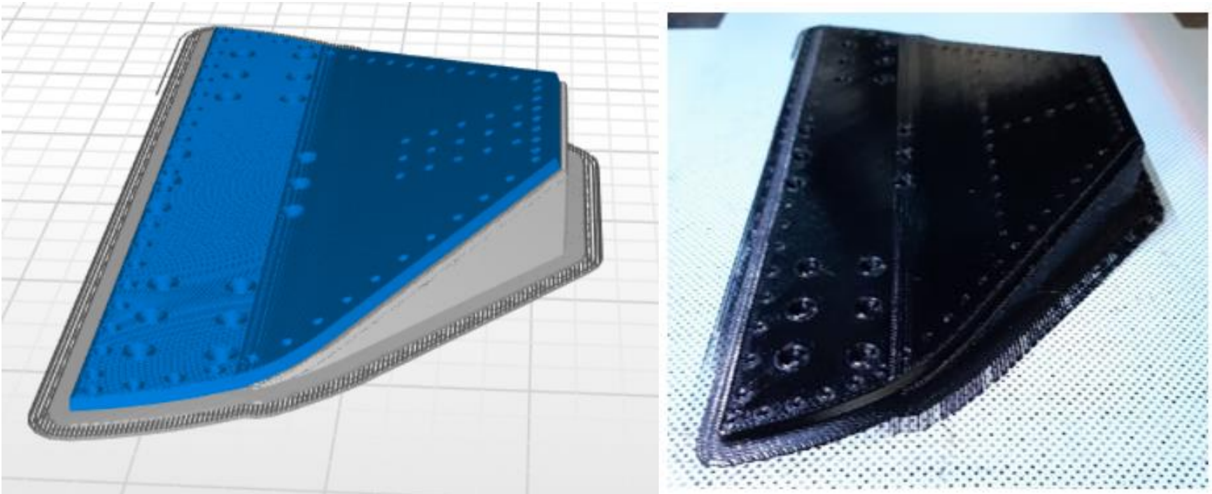
### *10.2.5. Components manufacturing*

The manufacture of components by FA was performed using the equipment previously presented in the Product Development Laboratory of the Faculty of Industrial Engineering and Robotics, POLITEHNICA University of Bucharest. For their manufacture were used three different materials, available in the laboratory. For each component manufactured, according to their technical requirements, the equipment and material were selected.

The support plate was manufactured on the Zortrax M300Plus printer, and the material used in the additive manufacturing process was Z-PETG, in order to provide the component with the necessary strength. Table 10.3 shows the parameters used to manufacture the component, as well as the time and material consumption. Figure 10.1 shows the stages of the manufacturing process.

**Table 10.3.** AM parameters used for the Support

| Crt. | Parameter | Value | | Crt. | Parameter | Value |
|---|---|---|---|---|---|---|
| 1 | 3D printer | M300Plus | | 9 | Print speed [mm / s] | 30 |
| 2 | Material | Z-PETG | | 10 | Support structure angle [°] | 30 |
| 3 | Layer thickness [mm] | 0,14 | | 11 | Support structure type | Liniar |
| 4 | Wall thickness [mm] | 0,8 | | 12 | Support density [%] | 10 |
| 5 | Filling density [%] | 90 | | 13 | Platform adhesion type | Raft |
| 6 | Filling structure | Grid | | 14 | Print time [min] | 717 |
| 7 | Head temperature [°C] | 237 | | 15 | Material length [m] | 33,05 |
| 8 | Mass temperature [°C] | 30 | | 16 | Material table [g] | 100 |



**a)** Simulated model **b)** Physical component

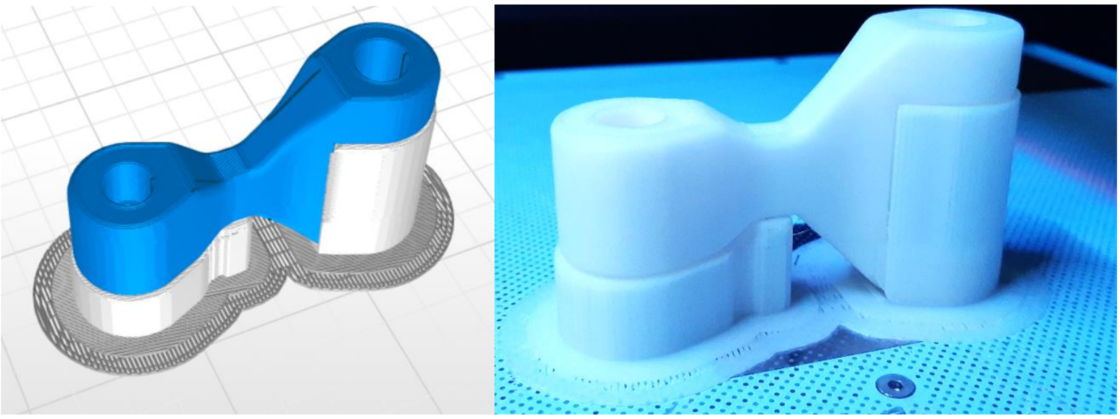
**Fig. 10.1.** Support

**Vertebral Body**

Because the data reading solution was changed during the manufacturing process (the position reading sensor was replaced with a potentiometer), the geometry of the Vertebral Body was adapted for the new configuration. Thus, the version used in the final assembly of the product is presented below. Table 10.4 shows the parameters used to manufacture the component, as well as the time and material consumption. Figure 10.2 shows the stages of the manufacturing process.

**Table 10.4.** AM parameters used for the Vertebral Body

| Crt. | Parameter | Value | | Crt. | Parameter | Value |
|---|---|---|---|---|---|---|
| 1 | 3D printer | M300Plus | | 9 | Print speed [mm / s] | 30 |
| 2 | Material | Z-HIPS | | 10 | Support structure angle [°] | 30 |
| 3 | Layer thickness [mm] | 0,14 | | 11 | Support structure type | Liniar |
| 4 | Wall thickness [mm] | 0,8 | | 12 | Support density [%] | 10 |
| 5 | Filling density [%] | 50 | | 13 | Platform adhesion type | Raft |
| 6 | Filling structure | Grid | | 14 | Print time [min] | 288 |
| 7 | Head temperature [°C] | 250 | | 15 | Material length [m] | 11,78 |
| 8 | Mass temperature [C] | 80 | | 16 | Material table [g] | 29 |



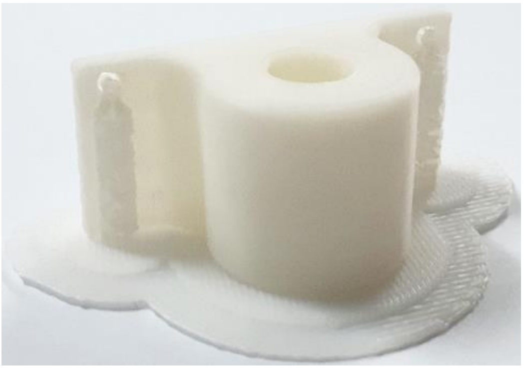
**a)** Simulated model **b)** Physical component

**Fig. 10.2.** Vertebral Body

### *10.2.6. Post-processing of manufactured components*

Layer lines are usually present on parts manufactured using FDM technology, making post-processing an important step in obtaining smooth surfaces. Some post-processing methods can also increase the strength of the printed parts which helps to attenuate the anisotropic behavior of the parts obtained by FDM technology.

The Lumbar Joint was manufactured on the Zortrax M300 Plus printer, given that this component has bores in directions perpendicular to each other, and the orientation was made considering the functional role of each of them. Thus, in addition to the basic support structure, the component was printed with support structures in the clamping bores. Subsequently, these structures were removed.



**a)** Printed component **b)** Post-processed component

**Fig. 10.3.** Lumbar joint

### *10.2.7. Causes of additive manufacturing defects*

In the process of preparing the code, Corp_Vertebral_3D_01-2.zcodex, for the manufacture of the Spine was set the material Z-PETG, and the machine was powered by Z-HIPS. Because the printing process parameters are different for the two materials, the code generated in this step has been replaced. The new code provides the same job orientation and positioning settings on the print platform, with important changes to the temperature setting for both the printhead and the print platform and print speed.

## 10.3. Electronic system design

As presented in Chapter 9, the Posture Correction Orthosis is composed of 3 systems, one being the electronic system for operating the entire assembly.

### 10.3.1. Description of components

Next are described the physical components that will form this system and their properties and how the connections between the components were created, the application architecture that will control the device was generated and the code for the application itself was developed.

### 10.3.2. Electronic circuit

The electronic circuit was drawn up starting from the main function that it must perform. Thus, 8 potentiometers were used which were all connected to the same ground pin and to the same power pin, then the signal pin of the potentiometer was connected to an analog pin on the development board. Four different pins were used for the display for each pin. The motors were connected to the specific ports on the Shield and here, two 9V batteries were connected in series to the power ports.

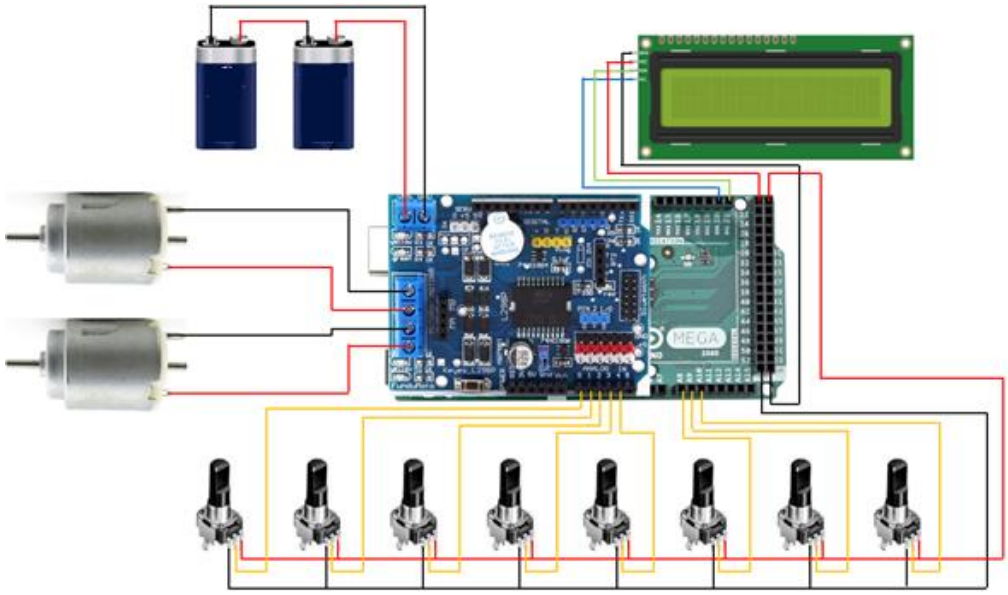


**Fig. 10.4.** The electronic circuit

### 10.3.3. Logical scheme

To materialize the product function, the software application loops a set of steps:

• reads the values of the user position points defined in the mathematical model. These are between 0 bits, potentiometer in closed position and 1023 bits, potentiometer in maximum opening position, then they are converted into angular values between 0 ° and 270 °, this being the rotation angle of the potentiometer (for all 8 potentiometers used);

• compares the actual values with the reference values. The values read from the potentiometers are compared with the constant values established after consulting a specialist doctor:

o if these values are within the prescribed tolerance range, the correct posture message is displayed and the loop resumes;

o if the values are different from the default values, the message incorrect position is displayed, wait 3 seconds and resume the reading and comparison process;

o if the user has corrected his posture independently, the first message is displayed and the reading loop is resumed;

o if even after the second comparison the values are different from those prescribed, the motors are operated in the same way until the user is returned to the correct posture position. The rest position is maintained for 3 seconds, after which the motors are operated in the opposite direction with exactly the same value;

• the process is resumed.

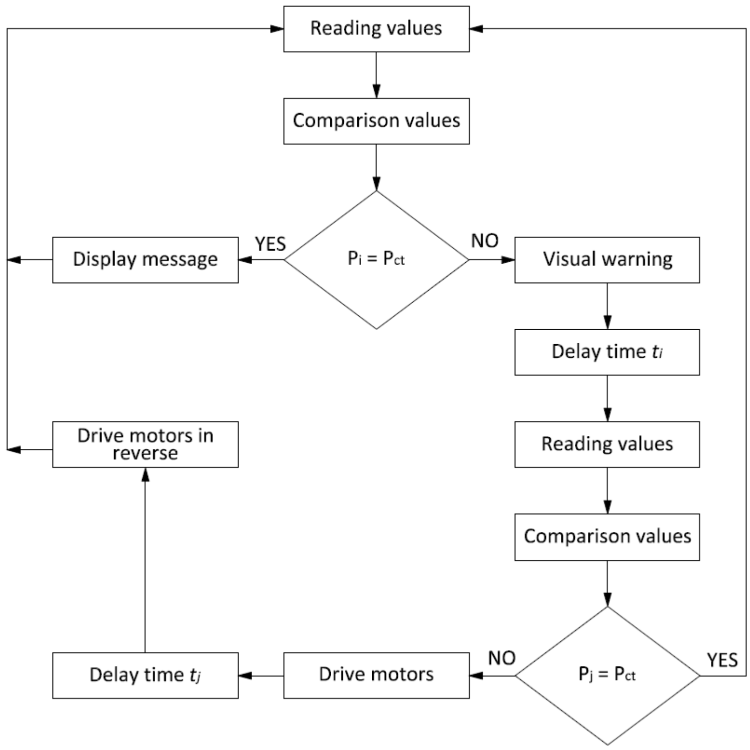



**Fig. 10.5.** Logic diagram of the developed software

### *10.3.4. Code structure*

The Arduino board is connected to a computer via the USB interface, being controlled via the Arduino development environment. The user writes the Arduino code in the Integrated Development Environment (IDE), then loads it to the microcontroller that executes the code, interacting with inputs and outputs such as sensors, motors and displays.

The code was generated with Arduino IDE version 1.8.10, the sketch is generically called Orthosis, and the presented code represents the 5th version, the 2nd revision. The software application starts with the identification data, they present information regarding: the title - Orthosis for Posture Correction, version - 5, revision - 2, written by - R. Murzac on 02.02.2020.

# Chapter 11
# Assembling and testing of the smart orthoses prototype

After the custom components have been manufactured and the standard components have been purchased, they are assembled, and the prototype obtained is tested to measure its performance and to validate the operating principle.

## 11.1. Product assembly

The technological assembly process is the final part of the production process through which subassemblies and assemblies that form the final product are obtained. The technological assembly process comprises all the operations of joining the parts, checking their relative position, and receiving after the final assembly, with the aim of obtaining a product that fully corresponds to the activity for which it was designed [D13].

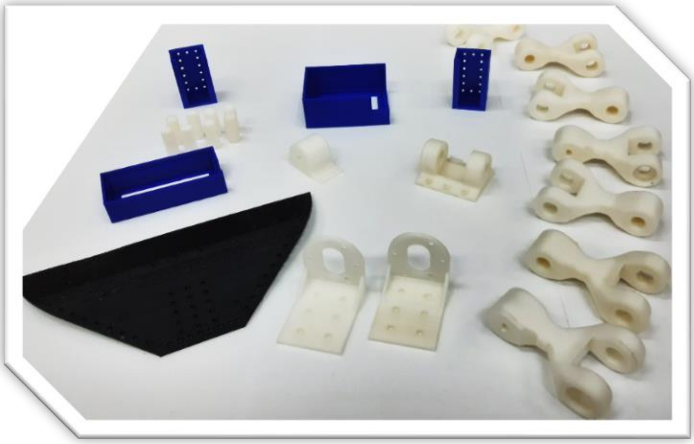
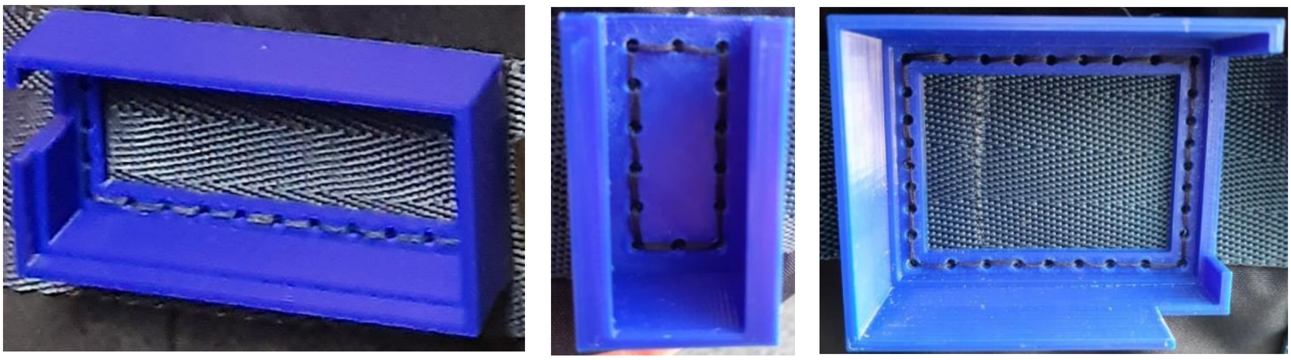


**Fig. 11.1.** Components to be assembled

### 11.1.1. Non-removable assemblies

Non-removable assemblies are assemblies for the disassembly of which it is necessary to destroy the assembly member or component parts. In the case of these assemblies, the parts no longer have the possibility of the relative movement of some in relation to others [D10].

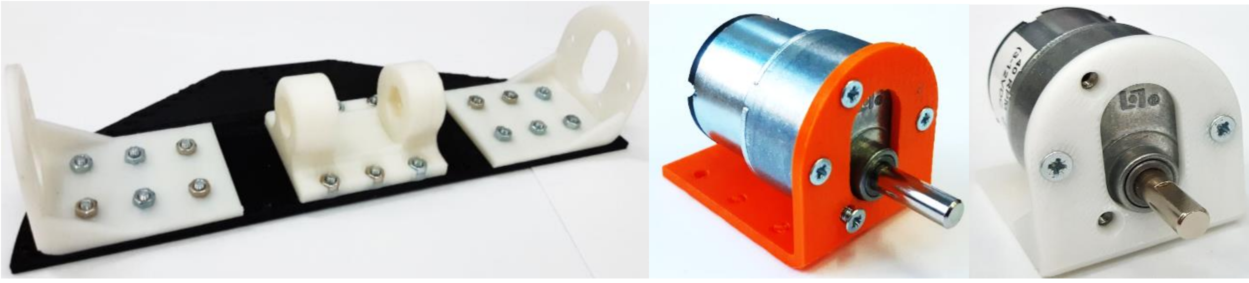


**a)** Display housing **b)** Battery box **c)** Arduino board housing

**Fig. 11.2.** Components assembled by sewing

### 11.1.2. Removable assemblies

To be able to easily intervene for the modification or change of a component obtained by additive manufacturing, they were assembled by threading through two constructive variants: in Figure 11.3 is shown the assembly of the components by the screw-nut version and the assembly of the components by the screw version fixed in the body component.



**a)** Screw-nut **b)** Screw in the body 1 **c)** Screw in the body 2

**Fig. 11.3.** Threaded assemblies

### 11.1.3. Bill of Materials

The manufacturing process of the prototype for Posture Correction Orthosis began after the detailed design stage. When manufacturing the prototype, constructive solutions were changed during the process, due to the unavailability of some commercial / standard components and the inconsistency of the designed systems with the real processes. This led to the manufacture and repeated replacement of components in the final prototype. The initial list of materials, which contains all the components purchased during the manufacturing process, is not presented in the doctoral thesis.

The assembly scheme of the vertebral assembly comprises nine types of main components, although only seven are shown in the assembly scheme, according to Figure 11.4. Thus, the vertebral assembly consists of 38 components plus consumables with which the components were assembled.

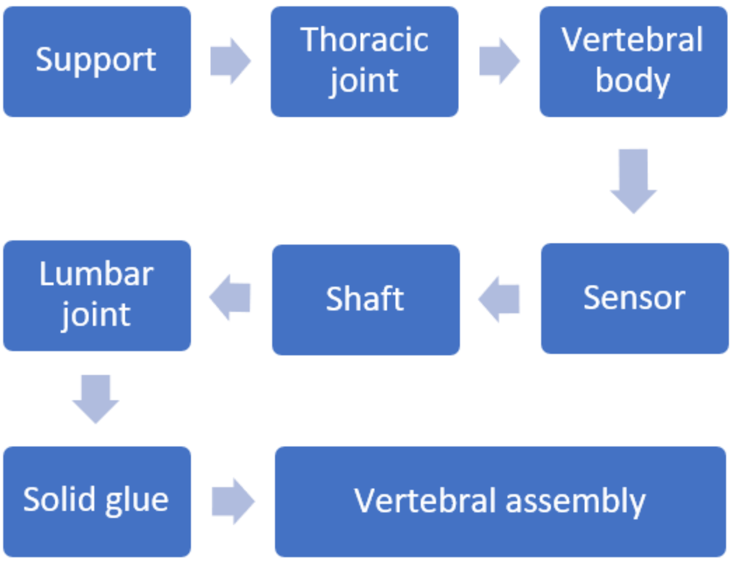



**Fig. 11.4.** Assembly scheme of the vertebral assembly

Figure 11.5 shows the stages of assembly of the vertebral system, in accordance with the assembly scheme shown in Figure 11.4. In this way, the diagram shows the assembly logic and the order of entry of each component as a whole and then in the final product. Once the operating and assembly logic of the product is generated, the geometry for the internally manufactured components can be defined according to the geometry of the commercial components and their functional role.

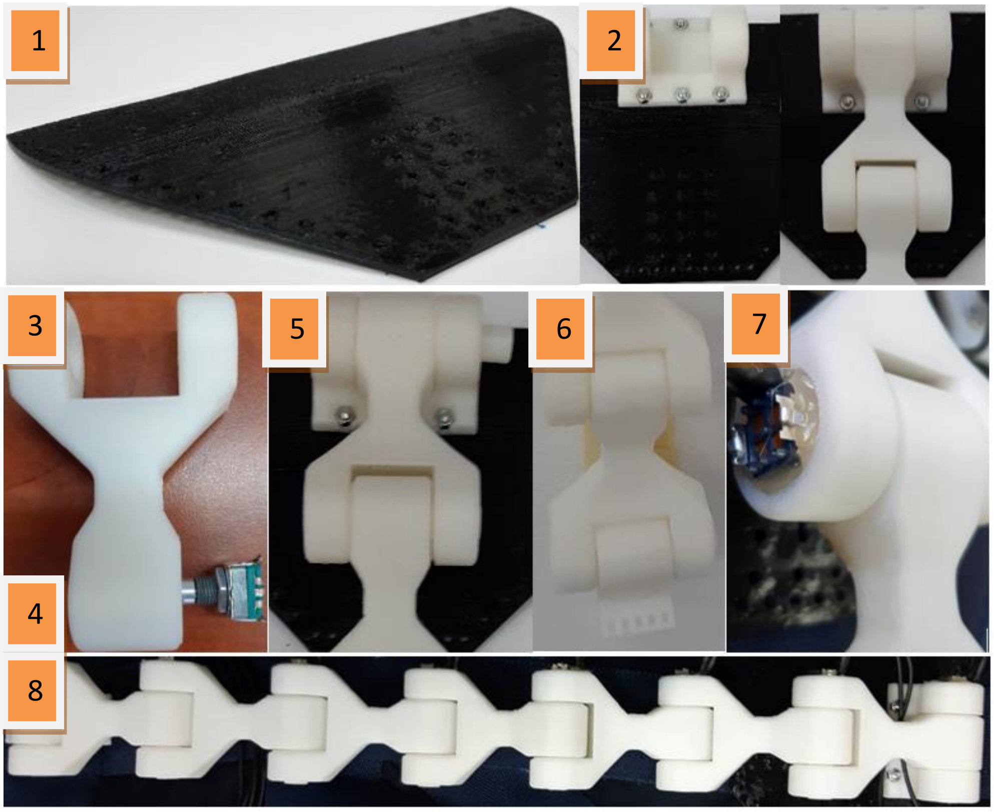



**Fig. 11.5.** The stages of assembling the vertebral assembly

The Posture Correction Orthosis product consists of five main assemblies, the motor assembly being used twice. A number of 31 unique components were used to assemble the final product and the total is 112 components shown in table 11.1.

**Table 11.1.** Bill of Materials

| No. | Component | Qty. | No. | Component | Qty. | No. | Component | Qty. |
|---|---|---|---|---|---|---|---|---|
| 1 | Support plate | 1 | 12 | M3 screw | 34 | 22 | Shield L298P | 1 |
| 2 | Thoracic art | 1 | 13 | M3 nut | 26 | 23 | Display box | 1 |
| 3 | Spinal body | 1 | 14 | cloth | 6 | 24 | 16x2 display | 1 |
| 4 | Potentiometer | 8 | 15 | Belt 50 mm | 6 | 25 | Battery box | 2 |
| 5 | Spine axis | 8 | 16 | Belt 25 mm | 2 | 26 | 9V battery | 2 |
| 6 | Lumbar art | 1 | 17 | Buckle | 2 | 27 | Solid glue | 100 ml |
| 7 | Brechet motor | 2 | 18 | Timing belt | 1 | 28 | Thread | 1 |
| 8 | Motor | 2 | 19 | Velcro tape | 1 | 29 | Tin | 15 g |
| 9 | Cogwheel | 2 | 20 | Plate housing | 1 | 30 | Therm. tube | 6 |
| 10 | Upper coupling | 2 | 21 | Arduino board | 1 | 31 | Cable | 16 m |
| 11 | Lower coupling | 2 | | | | | | |

The vest assembly represents the basic part of the finished product, on it the detachable assembly and the motor assembly are removably assembled and the control assembly and the peripheral assembly are non-removable, by sewing, on the basic assembly, the vest assembly. The integration of these assemblies in the finished product is given by the type of their assembly. Following the assembly process resulted the prototype of the product Orthosis for Posture Correction, presented in Figure 11.6.

**Fig. 11.6.** The final assembly of the prototype

## 11.2. Product testing

The custom functional test is used as a final step in the development process to provide a successful or unsuccessful response to the operation of the product before it is released to the market. Functional test methods are used to validate that the product has no defects that could adversely affect its proper operation [E04]. Performance testing allows the measurement, comparison and evaluation of product functionality, usability, durability, and performance [D03].

### *11.2.1. Software testing*

Software testing is an empirical investigation carried out to provide interested parties with information on the quality of the product under test, considering the operational context in which the latter will be used. Software testing provides an objective and independent view of the developing product, thus providing the opportunity to understand and assess the risks associated with the implementation of the software [K01].

To generate the Posture Correction Orthosis software, it was divided into subroutines. Each component subroutine of the software was written and tested separately, after performing the tests and validating the results, they were concatenated and the code variant for the entire product was tested.

### *11.2.2. Hardware testing*

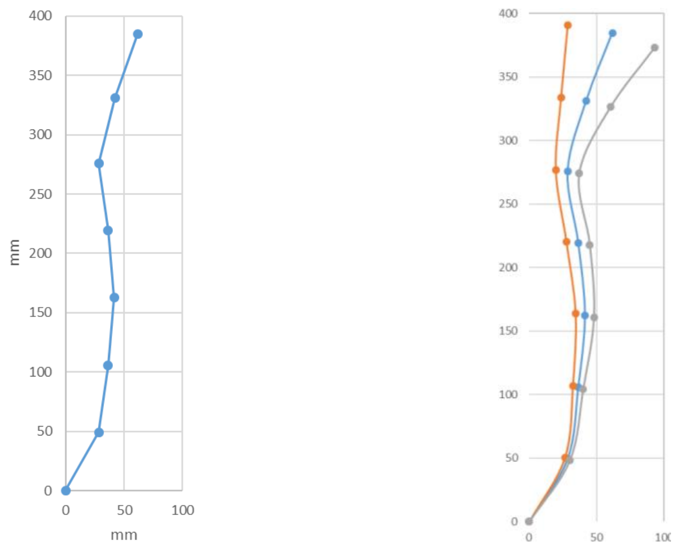
To test the correlation of the prototype operation with the mathematical model proposed in the doctoral thesis, the angular values of the 8 potentiometers in the usual position of the user were read. The data obtained were entered in column according to Table 11.2. The length of the vertebral bodies is constant with the value of 57 mm, the data being entered in column l. Applying the mathematical model, we obtained the coordinates from columns x, respectively y.

**Table 11.2.** Consulting table

| | x | y | a | l | $a_{min}$ | $x_{min}$ | $y_{min}$ | $a_{max}$ | $x_{max}$ | $y_{max}$ |
|---|---|---|---|---|---|---|---|---|---|---|
| **P1** | 0 | 0 | 30 | 57 | 28 | 0 | 0 | 32 | 0 | 0 |
| **P2** | 28.5 | 49.363 | 8 | 57 | 6 | 26.75 | 50.32 | 10 | 30.20 | 48.33 |
| **P3** | 36.43 | 105.80 | 5 | 57 | 2 | 32.7 | 1010.01 | 8 | 40.10 | 104.47 |
| **P4** | 41.40 | 162.59 | -5 | 57 | -7 | 34.70 | 163.98 | -3 | 48.03 | 160.91 |
| **P5** | 36.43 | 219.37 | -8 | 57 | -8 | 210.76 | 220.55 | -8 | 45.05 | 2110.83 |
| **P6** | 28.50 | 275.82 | 14 | 57 | 4 | 19.82 | 2710.00 | 24 | 310.12 | 274.28 |
| **P7** | 42.28 | 331.12 | 20 | 57 | 5 | 23.80 | 333.86 | 35 | 60.30 | 326.35 |
| **P8** | 61.78 | 384.68 | | | | 28.77 | 390.64 | | 92.99 | 373.04 |

Starting from the correct posture of the user, which corresponds to the blue curve in the figures below, the limit values, maximum and minimum, were established by a specialist doctor. The code is written so that each angular value of the 8 potentiometers tends to fall within the range set by the specialist, otherwise the user is forced by automatic activation of the vest to correct his posture until falls within the prescribed field.

Thus, by testing the operation of the prototype, the proposed operating principle was verified and confirmed, the correctness of the applied mathematical model, the written code, as well as the constructive variant achieved. All these tested elements led to a better understanding of the problems existing in the manufactured prototype, which will allow an optimization of the future version for the Posture Correction Orthosis.




**a)** Reference position **b)** Limit positions

**Fig. 11.7.** Graphical representation of geometry

### 11.2.3. Case Study

To verify the operation of the prototype in real conditions, it was tested in an operating cycle of one hour. In the case study, the limit values of the angles in each joint for the user's posture were established, the determined values were entered in columns $a_{min}$ and $a_{max}$ of Table 11.3. The initial values were read, at time $t_0$, in real operating conditions, when the user sat down at the desk, the values read from the potentiometers being entered in column a.

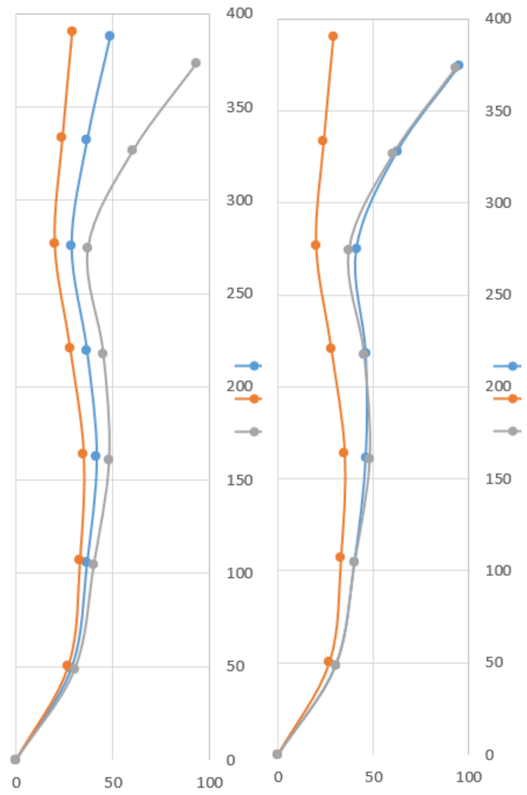
**Table 11.3.** Consulting table at the moment $t_0$

| | x | y | a | l | a min | x min | y min | a max | x max | y max |
|---|---|---|---|---|---|---|---|---|---|---|
| **P1** | 0 | 0 | 30 | 57 | 28 | 0 | 0 | 32 | 0 | 0 |
| **P2** | 28.5 | 49.36 | 8 | 57 | 6 | 26.76 | 50.33 | 10 | 30.21 | 48.34 |
| **P3** | 36.43 | 105.8 | 5 | 57 | 2 | 32.72 | 107 | 8 | 40.1 | 104.5 |
| **P4** | 41.4 | 162.6 | -5 | 57 | -7 | 34.71 | 164 | -3 | 48.04 | 160.9 |
| **P5** | 36.43 | 219.4 | -8 | 57 | -8 | 27.76 | 220.6 | -8 | 45.05 | 217.8 |
| **P6** | 28.5 | 275.8 | 8 | 57 | 4 | 19.83 | 277 | 24 | 37.12 | 274.3 |
| **P7** | 36.43 | 332.3 | 12 | 57 | 5 | 23.8 | 333.9 | 35 | 60.3 | 326.4 |
| **P8** | 48.28 | 388 | | | | 28.77 | 390.6 | | 93 | 373 |

The data read from the product potentiometers are automatically sent to the database in Excel format created for data storage, this allowed the generation of position verification charts in real time, the graph of the initial position can be seen in Figure 11.9.a. The graph shows the framing of the curve of the current position between the allowed limits, established by the specialist, which indicates a correct posture of the user. Images of the initial posture, both front (Figure 11.8.a) and rear (Figure 11.8.b) were captured at time $t_0$.

**a)** Front view **b)** Back view

**Fig. 11.8.** Office position at the moment $t_0$




**a)** Moment $t_0$ **b)** Moment $t_0$+1h

**Fig. 11.9.** Office position chart

After one hour, during which the user changed his posture, the values were reread, at time $t_0$+1h, the values read from the potentiometers are entered in Table 11.4, column a.

**Table 11.4.** Consulting table at the moment $t_0$

| | x | y | a | l | a min | x min | y min | a max | x max | y max |
|---|---|---|---|---|---|---|---|---|---|---|
| **P1** | 0 | 0 | 32 | 57 | 28 | 0 | 0 | 32 | 0 | 0 |
| **P2** | 30.21 | 48.34 | 10 | 57 | 6 | 26.76 | 50.33 | 10 | 30.21 | 48.34 |
| **P3** | 40.1 | 104.5 | 6 | 57 | 2 | 32.72 | 107 | 8 | 40.1 | 104.5 |
| **P4** | 46.06 | 161.2 | 0 | 57 | -7 | 34.71 | 164 | -3 | 48.04 | 160.9 |
| **P5** | 46.06 | 218.2 | -5 | 57 | -8 | 27.76 | 220.6 | -8 | 45.05 | 217.8 |
| **P6** | 41.09 | 274.9 | 22 | 57 | 4 | 19.83 | 277 | 24 | 37.12 | 274.3 |
| **P7** | 62.45 | 327.8 | 35 | 57 | 5 | 23.8 | 333.9 | 35 | 60.3 | 326.4 |
| **P8** | 95.14 | 374.5 | [redacted] | | | 28.77 | 390.6 | [redacted] | 93 | 373 |

The data read from the product potentiometers were automatically sent to the database created for data storage, the real-time position verification chart was generated. The position graph at time $t_0$+1h can be seen in Figure 11.9.b. The graph shows the curve of the current position outside the allowed limits, which indicates an incorrect posture of the user.

In this case, the user's posture will be corrected by the Posture Correction Orthosis and will be returned to the allowable limits. This cycle will be resumed whenever necessary, so that the user has a correct posture throughout the stay at the office.

# Conclusions

The doctoral thesis has as main objective the development of an orthosis to correct the posture. To achieve the main objective, during eleven chapters the main stages of the development process of this new product are presented.

To achieve the objective proposed in the doctoral thesis, a market analysis was carried out including identifying the needs of people with disabilities and people working in the office and establishing specifications for a product that would meet the needs identified in both market segments (categories of people). This led to the understanding of the existing needs in this field and to the correlation of the clients' requirements with the specifications of the product that was developed. Also, a documentary research was performed on the history, evolution, and current trends in the development of orthoses for the spine and the exhaustive bibliographic analysis on theoretical and experimental research in the field. This allowed us to understand the current capabilities of robotic devices and orthoses on the market, which helped to develop the concepts of orthosis for posture correction.

To be able to develop the orthosis for posture correction, a documentary research was performed on the existing methodologies for developing new products. The product development methodologies proposed by authors from various fields of activity were analysed. Based on the studied methodologies, a new methodology structure was defined for the development of new products, this was applied in the manufacturing process of the orthosis prototype.

A 3D model of the user's body and a mathematical model were developed, with the help of which the kinematics of the spine were defined. Starting from the data obtained from the elaboration of the mathematical model, it was possible to generate the mechanical structure of the product and write the code for its operation in accordance with the established specifications.

A prototype of the smart orthosis was designed and manufactured to correct posture. These stages were carried out based on the results of the stages presented above; customer requirements and the capabilities of current robots have allowed the development of orthosis concepts to correct posture and choose the best of them. For the selected concept, a detailed project was developed that allowed the simulation of functionalities in the virtual environment and the preparation of manufacturing strategies for each component. The product was manufactured in three distinct phases, the first phase consisted of the purchase of commercial components. Based on the actual geometry of the commercial components, the customized and additive-manufactured components were adapted. The last phase of the manufacturing process involved the assembly of the product, this phase led to the obtaining of an integral and functional prototype.

In the last stage, experimental studies were performed with the intelligent orthosis to correct the posture to validate the functionality, to achieve the process performance, as well as to customize it for different users. During the tests, the components that needed immediate redesign and integration of the new version into the whole prototype were identified. This led to the immediate optimization of the most obvious defects omitted in the design and manufacture of the product.

## Own contributions

Following the research carried out, the following own contributions are summarized:
1. Designing a new structure methodology for the development of new products;
2. 3D modelling and fabrication of a physical model of the user's body;
3. Elaboration of a mathematical model for modelling and simulation of the spine;
4. Design of 6 different, original conceptual solutions of Orthoses for Posture Correction;
5. Detailed design of the conceptual solution selected by Orthoses for Posture Correction;
6. Simulation and validation of materials and geometry for critical components;
7. Elaboration of the execution drawings for the developed product;
8. Elaboration of the economic analysis for the manufactured prototype;
9. Development of customized parametric component models;
10. Development of component models optimized for additive manufacturing;

## Future directions of research

From the analysis of the results obtained in the doctoral thesis, it is highlighted that the studies can be continued in the following directions:

- Clinical study on a sample of users after a certain period of use of a similar product, in order to best cover their requirements;
- Design, modelling, development and implementation of a unique parametric model of the orthosis that will allow the customization of the orthosis for each user in a very short time and without major implications in the manufacturing process;
- Design, modelling, development and implementation of components obtained with the help of the generative design option, which will lead to a manufacturing process with addition / removal of material with an optimized structure;
- Design, modelling, development and implementation of a model of the mechanical spine with overall dimensions on the X and Y axes much smaller;
- Optimization and implementation of a battery-based power supply system;
- Development and implementation of a software application that will allow the extension of the range of orthoses on other specific medical problems, so that the orthosis is provided with several operating regimes, starting with regimes to prevent the occurrence of medical problems, to intensive treatment of chronic problems;
- Development and implementation of an interface for medical investigation and communication with the specialist to obtain input data for product customization for each individual user;
- Development and implementation of a command and control interface that will allow the user to manage the interval and operating schedule of the device;
- Development and implementation of a mobile phone software application that will allow the management of the device's functionalities, as well as obtaining reports of results obtained during the use of the orthosis.

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