Exoskeleton-type medical rehabilitation system with embedded sensors, designed using digital-twin solutions

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Abstract

INTRODUCTION: Exoskeleton-type medical rehabilitation systems are the main solution for recovery of the mobility of patients affected by strokes, spinal cord injuries, or muscular atrophy. These systems feature detection and actuation components, such as sensors and actuators, whose typology and integration are essential for the device's ability to withstand wear under intensive use conditions.

OBJECTIVES: To increase the lifespan of exoskeletons, the main objective of the project presented in this article is to integrate sensors into the exoskeleton's structure, for them to be better protected from external factors, such as shocks or moisture.

METHODS: A virtual model of an exoskeleton component for the lower limb that ensures the plantar flexion (movement of the sole), made of polyurethane, was designed using a digital-twin modelling solution, namely the SolidWorks Simulation software. Our choice was motivated by the fact that the use of digital twin solutions allows functional testing, by simulating the impact factors existing in real systems, of the exoskeleton with embedded sensors, by coating with polyethylene (PE) and ethylene vinyl acetate (EVA) layers. Thus, it will be possible to observe the inconsistencies and defects that can appear on the surface of the materials used and to determine the best choice of material that can protect against wear.

RESULTS: The values of all parameters analysed following the simulations demonstrate that PE and EVA are materials that can be used to embed sensors into the structure of exoskeletons. Layers with thicknesses of 0.5 mm, 1 mm, and 1.5 mm are resistant and display stable structures during the patient's walking, thus protecting the sensors integrated into a lower limb exoskeleton from wear factors.

CONCLUSION: Following the comparative analysis of the results obtained from testing by digital simulations, the main conclusion is that the 1.5 mm thick ethylene vinyl acetate layer is the one that presents superior tribological properties, being the most useful for application in real systems.

Keywords: exoskeleton, digital twin, sensors

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1. Introduction

The exoskeleton-type medical rehabilitation system is an electromechanical device created to improve or restore the functionality of the human body affected by certain dysfunctions, and it can be: fixed, mobile or wearable by the patient on the affected area of the body.

These paralysis-type dysfunctions are very common in patients who have suffered strokes, traumatic brain injuries, spinal cord injuries, brain tumours, ischemia or aneurysm, patients who have had limb amputations following various accidents, as well as in elderly people suffering from muscle atrophy. [1]

The use of exoskeletons is an excellent solution for rehabilitation, helping to recover or improve patients'



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mobility, giving them the opportunity to regain their independence of movement, by lifting, sitting or walking and the ability to stand. [2] This helps them to rise from the wheelchairs, stay active, and lead an independent, as normal life as possible. [3]

Exoskeleton-type devices have been designed to facilitate the movement of all joints (total exoskeleton systems), the lower or upper extremities, or a single joint (partial exoskeleton systems), such as the hip, ankle, or shoulder.

There are two types of exoskeletons: passive and active. Passive exoskeletons provide stability during the transfer of body weight to a limb, monopodal support and increased muscle efficiency. A passive system is based on the principle that a set of elasto-plastic actuators store energy and return it during a lift or a joint movement. On the other hand, active exoskeletons are those that contribute to the realization of movements. [4], [5]

These are composed of rigid elements and contain detection and actuation components, such as sensors and actuators, mechanical structures, algorithms and control strategies that collect the information necessary to perform each action. [6] The sensors are designed to detect and capture changes of electrical signals emitted by the body when the patient tries to move, activating the exoskeleton's actuators to facilitate the movement of the immobilized person. For example, in the lower limb exoskeletons, pressure sensors can be used to detect forces exerted on the legs or electromyographic sensors to capture electrical signals emitted by muscles. Based on this data, actuators (which can be electric motors, pneumatic or hydraulic systems) apply the appropriate movements, helping the user to perform various actions, from lifting the leg to walking or balancing. [7]

Each type of exoskeleton is unique and different depending on the purpose it is designed for. Some are made of rigid materials, such as metal or carbon fibre, to provide durability and support, while others are constructed from elastic and soft materials, which allow for greater flexibility and comfort.

Although these devices bring significant benefits in improving mobility, they are inherently quite heavy and inflexible. This can affect the user's comfort, especially in cases where the exoskeleton needs to be worn for extended periods of time. Therefore, the materials used must also offer the possibility of creating exoskeletons that are light enough to allow patients to perform easily the necessary movements.

Carbon fibre, for example, is used for its strength and lightness, while metals can provide a solid structure, and elastic materials can add flexibility and comfort, essential for the mobility of users. Carbon fibre has a specific strength of over 2,400 kNm/kg, while steel and aluminium have specific strengths between 100 and 250 kNm/kg.

Fiberglass is another high-enduringness material, with a strength of about 1,300 kNm/kg, which can be used to build a durable exoskeleton.

In addition, the recent materials such as carbon nanotubes exceed 40,000 kNm/kg, with a tensile strength of 62 GPa. It is even estimated that carbon nanotubes could reach a theoretical tensile strength of 300 GPa. A notable example is Cyberdyne's HAL (Hybrid Assistive Limb), which uses carbon fibre legs, and many other companies use the same material to build exoskeleton suits. [8]

It should be noted that the stiff elements of the exoskeletons, made of rigid materials, can cause discomfort to the patient, especially when they come into direct contact with their skin, as friction can cause damage to the skin surface.

To mitigate these problems, researchers from the Linkoping University and Borås University in Sweden have attempted to create artificial muscles from textile material with characteristics similar to those of the skeletal muscles, as textile materials offer flexibility and reduced weight, which would make the exoskeletons more comfortable for patients. By customizing the spacing between woven fibres, the exoskeletons could be adjusted to support specific and complex movements, which would improve mobility and allow for finer actions, such as walking or manipulating objects. Combining textiles with electroactive polymers to create texturizers represents a significant step in the development of exoskeletons and soft robots. Texturizers, which can amplify the force by arranging fibres in an extensible pattern, allow for greater flexibility and performance in a lightweight and cost-effective design. In exoskeletons, these texturizers could be used to assist in joints' movement or even simulate the muscles' contraction, thus providing a much more fluid mobility and closer to the body's natural movements. Also, adding sensing threads to the fabric would allow the exoskeleton to sense the user's body movements, monitor them, and automatically adjust the support according to his needs, and consequently, transforming exoskeletons into a much more efficient and precise device. [9]

The durability of an exoskeleton and its long-term effectiveness depend on several factors, such as the materials used, the type of sensors and actuators, and the way these devices are used in the rehabilitation process. In addition, the design and integration of components are essential for patient's comfort and the device's ability to withstand daily wear, especially under conditions of intensive use.

It should also be mentioned that sensors must be properly protected to withstand moisture or shocks, in order to function optimally in the long term.

Therefore, the project whose results are presented in this article had as its main goal to increase the lifespan of exoskeleton-type recovery and rehabilitation systems by embedding the sensors and using biocompatible materials with superior tribological characteristics, namely high hardness and elasticity, with a low degree of wear. Besides, a new positioning of the sensors can help to protect them from external factors with negative influence.

The project has as a secondary objective the study of the tribological behaviour of the biocompatible materials from which the exoskeleton is made, along with that of the materials covering the sensors, in order to determine the material with the best tribological properties and high wear resistance, which can ensure the best protection of the sensors and increase the lifespan of the exoskeleton systems.



2. Methods

The main objective of the activities described in this article was the design and implementation of an exoskeleton-type medical rehabilitation system with embedded sensors. Consequently, a virtual model of an exoskeleton component for the lower limb that would ensure plantar flexion (sole's movement) was designed using digital-twin solutions.

The use of digital twin solutions to create an exoskeletontype medical rehabilitation system with embedded sensors will allow the observation of inconsistencies and defects that may appear on the surface of the materials used, at the end of technical-functional testing. Via this method, the authors were able to identify a proper material for covering the sensory network in order to protect it against wear, but without affecting the sensor's response to changes in the body signals.

The choice of this method is associated with several benefits. First of all, the Digital Twin concept refers to the ability to virtually represent and optimize a real-life product or process. [10]

Thanks to this novel capacity, the authors can represent products and processes with perfect accuracy in the virtual environment and simulate their behaviour in real life. This makes the Digital Twin superior to CAD-CAM-CAE solutions, which have existed for decades, as it refers to the capturing, structuring and synchronization of all product data from idea, design, manufacturing, launch, use, maintenance and up to decommissioning and recycling.

With the help of Digital Twin, the conception, design, operational simulations and manufacturing are carried out simultaneously, based on the imposed specifications, and using real-time feedback from the products that are in use and that communicate with the development team. Thus, this novel technology allows for the optimization of all phases of the product life cycle. This is why, virtual simulations of the design and functionality developed in parallel with manufacturing planning lead to a much faster launch on the market, to a significant reduction of the costs, and to a higher quality. [11]

Additionally, the Digital Twin technology allows analysing multiple variants for a product or process and translating into reality only what really matters and produces value.

2.1. Simulations of the functionality of the exoskeleton-type medical rehabilitation system with embedded sensors

Simulations of the operation of such a system containing the embedded sensory network, covered with different materials were performed using SolidWorks Simulation software in order to choose a material that would provide a superior tribological quality to the final system.

An exoskeleton for the lower limb, the ankle part, was analysed.

Common materials used in this field for the manufacture of exoskeleton-type systems were used.

Polyurethane (PU) is a polymer obtained by the condensation of polyols combined with polyisocyanates (MDI), finally linking the molecules through carbamate (urethane) groups. It is a lightweight, thermosetting material, particularly elastic and displaying a high resistance to impact and compression, to chemical agents, to solvents, offering benefits such as: energy saving and thermal comfort.

Thanks to the above properties, PU is a material commonly used for the manufacturing of moulded soles, with high resistance and excellent flexibility, in general, footwear manufactured on this sole having a high degree of comfort. Moreover, PU foam is useful for damping and shock absorption, keeping the wearer's feet comfortable. Resistant and long-lasting, this foam maintains its shape and damping over time, providing a reliable comfort. However, under the action of environmental agents, PU soles can deteriorate after 2-3 years even if they have been worn very little. [12]

Another commonly used material is Ethylene-Vinyl Acetate (EVA), a foam obtained by mixing copolymers of ethylene with vinyl acetate. In a single sheet of EVA foam, the weight percentage of vinyl acetate varies between 10% and 40%. EVA foam materials are defined by an excellent performance, water and moisture resistance, damping and shock absorption, strong thermal insulation, long-term durability, etc. EVA maintains its flexibility even at low temperatures, being a copolymer frequently used in applications that require flexibility, durability and wear resistance.

A notable characteristic of EVA is its high friction coefficient, which contributes to its stability and safety. This property improves its adherence and traction, making it an excellent choice for applications where the slipping resistance is crucial and ensuring a secure fixing is essential. EVA plays a key role in the medical sector, where it is used to manufacture various devices such as tubes, catheters, and surgical instruments thanks to its high chemical resistance and flexibility. [13]

Further, the advantages and disadvantages of using polyethylene (PE) will be discussed. Polyethylene is made up of non-polar saturated hydrocarbons with very high molecular weights, so it is considered a partially crystalline plastic. The higher is the crystallinity of the polymer, the higher is its density and chemical stability. PE is waterresistant and durable, this material is less likely to deteriorate when exposed to natural or chemical elements compared to other polymers, being a thermoplastic material with excellent chemical resistance to acids, bases or oxides. [14]

The most well-known types of PE are: high-density polyethylene (HDPE) and low-density polyethylene (LDPE). HDPE is a robust, moderately rigid plastic material with a crystalline structure, while LDPE is a very flexible material with unique flow properties, high ductility, but low tensile strength, a property highlighted by its tendency to stretch when stressed. The amorphous form of PE is hard, strong, slightly brittle and more soluble, while the crystalline form is elastic, deformable, slightly soluble and more brittle.

Given all these superior properties, PE is a polymer that can be used in various fields, including the medical industry for the production of various devices, prostheses, or joints



replacements. PE distinguishes itself by its exceptional flexibility, which ensures ease of use and adaptability in various medical fields such as rapid prototyping and medical device processing. Its lightweight nature further contributes to the production of disposable medical items, where a balance between flexibility and low weight is essential.

In the following, the properties of the materials used in the simulations performed for the exoskeleton's sole component and its covering are presented in Table 1.

Table 1. Properties of materials used in the simulations performed

Model reference	Properties			
	Name:	Polyurethane		
035	Tensile strength:	1.85e+07 N/m ²		
	Modulus of elasticity:	7.84e+08 N/m ²		
	Poisson's ratio:	0.308		
	Mass density:	417 kg/m ³		
	Name:	Ethylene-Vinyl		
		Acetate (EVA)		
	Tensile	1.52e+07 N/m ²		
	Strength. Moduluo of	1.500 ± 0.00 N/m ²		
	elasticity:	1.59e+06 N/III-		
	Poisson's ratio:	0.48		
	Mass density:	930 kg/m ³		
	Name:	Polyethylene		
	Tensile strength:	1.32e+07 N/m ²		
	Modulus of elasticity:	1,72e+08 N/m ²		
	Poisson's ratio:	0.439		
	Mass density:	917 kg/m ³		

2.2. Gait analysis – determination of pressure force

The virtual model created by the authors was functionally tested, by simulating the impact factors existing in the real systems.

To model the effect of leg movement on the exoskeleton components in SolidWorks Simulation as realistically as possible, it was necessary to know the patient's pressure force on the exoskeleton. This force was determined by measurements made with a gait analysis and simulation system dedicated to biomechanics studies.

Biomechanical studies are carried out using component subsystems, which ensure the acquisition of movement data, simulation, and modelling in real time, through sensors to determine the forces in the lower limb in a bipedal position, while walking or running, and the displacements, speeds, and accelerations in the body's joints. The gait analysis and simulation system consists of the following subsystems (Figure 1):

- A. Sensor-based treadmill type plantar pressure measurement subsystem;
- B. Integrated real-time tracking, motion acquisition, simulation, modelling subsystem;
- C. Integrated optical (non-contact) subsystem, intended for measurements in 3D coordinates in dynamic and static conditions.



Figure 1. Gait analysis and simulation system

Sensor-based treadmill type plantar pressure measurement subsystem is composed of:

- Treadmill with pressure sensors;
- Software for the acquisition, analysis, processing, storage and display of data taken from the podiatric measurement system;
- Wireless motion sensors for detecting both slow and fast movement;
- Accessories: signal acquisition system; data recording system; systems for attaching sensors to the limbs.

Integrated real-time tracking, motion acquisition, simulation, modelling subsystem allows detailed analysis and comparison of positions and movements. 3D visualizations, graphical representations of motion parameters and biomechanical models provided facilitate understanding and analysis of movement.

Integrated optical (non-contact) subsystem, intended for measurements in 3D coordinates in dynamic and static conditions is used for analysing the movement of prosthetic/ endoprosthetic elements mounted on the testing equipment, such as: deformations (torsion, bending, displacements, etc.), speeds, accelerations, vibrations.



Thus, based on the correlation of the digital images, the system helps to understand the deformations and movement of the implant, at the interface with the fixation system or with the plastic mould that simulates the bone. Moreover, the measurements results can also be used to validate numerical simulations.

3. Results

3.1. Exoskeleton-type medical rehabilitation system

A virtual model of an exoskeleton-type medical rehabilitation system with embedded sensors for the lower limb (ankle), designed using the SolidWorks software, was obtained (Figure 2).



Figure 2. Exoskeleton-type medical rehabilitation system with embedded sensors for the lower limb (ankle) and 3D solid geometric model

The main components of this system are:

- The orthotic shoe that offers support to the lower limb for the purpose of ankle/sole recovery;
- The sensory network, consisting of force sensors, positioned inside the shoe (similar to an insole), and which will be covered with different materials. This network can measure the pressure that the patient puts on the exoskeleton and, therefore, can measure how balanced it is.
- The integrated electronic module (data interface system) for the acquisition of data taken from the sensors;
- A specialized software developed within INCDMTM.

3.2. Pressure force exerted by the patient on the exoskeleton's surface

To determine the real average value of the pressure force with which the patient presses on the surface of the exoskeleton or its component, while walking, measurements were made over 5-minute movement cycles (Figure 3), at a speed of 0.3 m/s.



Figure 3. Sequences in the measurement process within a walking cycle with a speed of 0.3 m/s

Following these measurements, a series of parameters measured by the system were analysed and, thus, the maximum pressure force with which the patient presses on the surface of the exoskeleton with his right and left legs while walking was determined.

The pressure force varies in the different areas of the sole, therefore the surface area on which the foot stepped was divided into these areas when the average force values were calculated (Figure 4(a). In Figure 4(b), the force values with which an 85 kg patient presses with his left foot on the surface of the gait analysis band are presented.



Figure 4. Distribution of a patient's pressure force on the surface of the exoskeleton (a) and the variation of



the pressure force values on these areas in the case of stepping with the left foot (b)

The average values of the pressure force of an 85 kg patient, which were determined following these measurements and used in SolidWorks software to simulate the functionality of the exoskeleton and the behaviour of the materials used for sensor integration, are presented in Table 2.

Table 2. Average values of the pressure force for a	n
85 kg patient – left and right legs	

		Left leg	Right leg
Pressure force (N)	HM	191,7	188,48
	HC	67,44	84,14
	HL	99,42	156,7
	MF	199,54	199,6
	M1	72,7	81,7
	M2	81,66	84,86
	M3	48,96	38,78
	M4	32,9	28,68
	M5	62,14	52,16
	Т	51,68	45,16

The simulation tests were performed taking into account a fixed general constraint under the moulded PU sole for an average adult feet dimension, with the loaded forces applied to the upper area of the assembly, made of sole and protective material with different thicknesses, where their distribution is according to the values in Figure 2 and Table 4. For this simulation tests we used a normal curvature-based mesh with basic density made by the Simulation module of the SolidWorks software (Figure 5).



Figure 5. The constraints (boundary) and loading conditions distributed on the 3D mesh

3.3. Results of the simulation of the exoskeleton-type medical rehabilitation system's functionality with embedded sensors

To integrate the sensory network into an exoskeleton-type medical rehabilitation system for the lower limb, the sole made of PU was covered with layers of EVA foam and PE layers, with thicknesses of 0.5 mm, 1 mm and 1.5 mm.

The objectives of this study are to identify the biomechanical aspects of the materials behaviour covering sensory networks used in exoskeletons with predictive value of the fracture risk and displacements, expressed in millimetres, as possible indicators of the balance deficiencies risk, having consequences on the functionality and integrity of support structures.

By applying forces with values equal to those in Table 2 on the surface of these components, the mechanical parameters were determined, which allowed obtaining useful information for choosing a material with superior tribological properties, which could protect the embedded network in the exoskeleton structure.

Exoskeleton systems are subjected to the heaviest and most varied loads: complex tension-compression-bending and torsional stresses.

The most important parameters for their study are: the von Mises stress, the displacements (layers displacement/ dislocation), the equivalent strain (tension/stress), and the factor of safety.

The Von Mises criterion is used to better study the elastic or plastic behaviour of a material at the contact level, under complex (simultaneous normal and shear) stresses, and to determine whether the material will yield (break or undergo plastic deformation) or not, considering that if the von Mises stress of a material under load is equal to or greater than the yield strength of the same material under simple tension, then the material will begin to deform plastically and yield.

This parameter is useful to study the material's yield stress, which is the maximum stress that a material can withstand before undergoing a permanent deformation and it is used especially in the study of ductile materials, that undergo severe deformations before breaking [15]

The tensile strength is the maximum stress that a material can withstand before breaking, following a tensile force. It is the point at which the material changes from elastic (temporary) deformation to plastic (permanent) deformation and finally breaks. It is used to evaluate the ability of a material to resist to tensile forces (stretching) and is an essential parameter in the case of brittle materials (such as some types of steel, concrete, or ceramics). It is particularly relevant in the analysis of materials that are subjected to tensile stresses, to determine the point at which they will finally yield (break).[16]

The displacement parameter refers to the movement or change in position of a point or part of a material or structure under the action of a force or load. In the context of structural analysis and mechanics of materials, it represents the distance that a point or section of a structure passes through from its initial position, following the application of an external force.



It is used to assess how much a structure deforms when it is subjected to various loads, thus helping us understand the elastic or the plastic behaviour of the material, as severe structural deformations can lead to a structural instability or even collapsing. Moreover, displacement is an important parameter in structural analysis, which helps us to understand the magnitude and direction of displacement of a structure or component under various loading conditions, material and geometry. By comparing displacements, vulnerable areas can be identified, structural performance can be assessed, and measures can be taken to improve the safety and stability of a structure.

The equivalent strain (or von Mises strain) is a measure of the total deformation of a material under complex stresses (which include both normal and shear stresses), considering only the plastic component of the deformation and it is used to evaluate the evolution of deformations in a material and to quantify the plastic deformations in a similar way to the von Mises stress. It can be used to assess whether a material has reached or exceeded its plastic deformation limits.

Interpreting the equivalent strain values can provide valuable information about the behaviour of a material under complex loadings, allowing to see if a material is in the elastic or in the plastic range. Comparing the equivalent strain values in a structure or a component can provide essential information about the critical areas that may require special attention in the design or maintenance process. In the areas with high stress concentrations (for example, at corners or at changes in cross-section), equivalent strain values will be higher and this may indicate the need to strengthen this area to prevent the structural defects and premature failure. [17]

The factor of safety is the ratio between the maximum load capacity of a material or component (or the structure as a whole) and the actual load to which that component is subjected. In short, the factor of safety indicates the safety margin existing in a design or structure, with the role of preventing the material from breaking or destroying under the action of stress forces during the operating cycle.

If the value of the safety factor is 1, this means that the structure or material is subjected to its very strength limit. A factor of safety greater than 1 suggests a sufficient margin of safety that allows avoiding defects or failure. For example, a factor of safety of 2 means that the material can withstand twice the load that it is subjected to. On the contrary, a factor of safety of less than 1 suggests that the structure or material is not strong enough to withstand the applied loads, and the failure is imminent or likely within a short time frame.

The type of material, the type of loading, environmental factors, the manufacturing method and material tolerances are factors that influence the safety factor. Thus, materials with higher strength (e.g. steel, titanium) will allow for a lower factor of safety compared to weaker materials (e.g plastic). Similarly, if the loading is dynamic (e.g. vibrations, shocks, fluctuating loads), the factor of safety may be higher, because the structure may experience fluctuations and must have an additional margin to cope with.

The variation of these parameters for the EVA foam and PE layers is similar. For both materials the von Mises stress,

displacement, tensile stress, and factor of safety increase with increasing the layer's thickness.

The EVA layers have lower average von Mises stress values than the PE layers, but both materials have values close to their yield points (i.e. the stress at which the material begins to deform plastically). This shows that there is a possibility that the deposited layers can permanently deform and crack or flake, especially if the stress remains high for a longer period of time or the material undergoes repeated stresses (fatigue).

The value at which the material breaks depends on the specific properties of the material. EVA is a material more susceptible to plastic deformation under high stresses, meaning it can undergo a significant elongation before breaking, compared to more rigid materials, and PE is a more ductile material, meaning it will undergo a considerable deformation before breaking.

In the case of the simulations performed, during the patient's walking, respectively the repeated application of pressure on the exoskeleton, these layers can deform plastically over time, in the heel area, where the von Mises stress values are maximum.

The von Mises stress map for the PU sole covered with a layer of EVA foam with a thickness of 0.5 mm, 1 mm, and 1.5 mm are presented in Figure 6, Figure 7, and Figure 8. The von Mises stress map for the PU sole covered with a layer of PE with a thickness of 0.5 mm, 1 mm, and 1.5 mm is presented in Figure 9, Figure 10 and Figure 11. The deformations that occur as a result of the effect of the pressure force that occurs during walking at a speed of 0.3 m/s can be observed.

The displacement for each node of the exoskeleton model was calculated via a simulation to estimate how the layers covering the sensory network will react to loading. The values obtained show that both materials used to cover the network do not deform very much, being stable structures that withstand during the use.

The EVA layers feature lower displacement values than the PE layers (differences by the order of microns), which shows the greater stability of this polymer.

In the case of using both materials, the most vulnerable areas, with the highest displacement rate, are in the heel area, on the inner side of the sole, and those with the lowest vulnerability are the tip and centre of the sole. Thus, the heel area and the edge of the sole are the areas where the two materials display the lowest stability.





Figure 6. Map of von Mises stresses, displacement, equivalent strain and factor of safety on a PU lower limb exoskeleton covered with a 0.5 mm thick EVA layer, simulated under load, evincing regions of high and low stresses



Figure 7. Map of von Mises stresses, displacement, equivalent strain and factor of safety on PU lower limb exoskeleton covered with a 1 mm thick EVA layer, simulated under load, evincing regions of high and low stresses



Figure 8. Map of von Mises stresses, displacement, equivalent strain and factor of safety on a PU lower limb exoskeleton covered with a 1.5 mm thick EVA layer, simulated under load, evincing regions of high and low stresses



Figure 9. Map of von Mises stresses, displacement, equivalent strain and factor of safety on a PU lower limb exoskeleton covered with a 0.5 mm thick PE layer, simulated under load, evincing regions of high and low stresses

The equivalent strain obtained from the simulations shows that both materials, regardless of the layer's thickness, are in the elastic area, their deformations being minimal and reversible. The low equivalent strain values show that the materials are subjected to light stresses, with minimal deformations, that do not affect their structural behaviour.

The equivalent strain of the 0.5 mm thick EVA layer is higher than that of the 0.5 mm thick PE layer. The equivalent strain's value of the 1 mm and 1.5 mm thick EVA layers is lower than that of the 1 mm and 1.5 mm thick PE layers.

The maximum values of this parameter were determined in the heel area, in the centre and tip of the sole, the equivalent strain having the average and minimum values, respectively. Thus, the heel is the critical area, which suffers the greatest deformations, this area being at risk for the material's breakage or fatigue.



Figure 10. Map of von Mises stresses, displacement, equivalent strain and factor of safety on a PU lower limb exoskeleton covered with a 1 mm thick PE layer, simulated under load, evincing regions of high and low stresses





Figure 11. Map of von Mises stresses, displacement, equivalent strain and factor of safety on a PU lower limb exoskeleton covered with a 1.5 mm thick PE layer, simulated under load, evincing regions of high and low stresses

All PE and EVA layers deposited to cover the sensory network have a factor of safety greater than 1. This shows that the materials have a resistance greater than the load applied when stepping on the exoskeleton component, indicating a sufficient safety margin to avoid defects or destruction of the layers.

The safety factor of the EVA layers with thicknesses of 0.5 mm and 1 mm is lower than the PE layers of 0.5 mm and 1 mm, and that of the EVA layer with a thickness of 1.5 mm is higher than that of the PE layer with the same thickness. All these values obtained show that the materials can withstand a load which is two to nine times higher than the one to which it is subjected. The factor of safety is also higher due to the fact that the deposited material is part of the exoskeleton's component, which is subjected to shocks when stepping and it must cope with them. The factor has an additional margin to ensure that the exoskeleton can cope with the shocks.

Since the studies performed were linear, the only difference between them being the value of the applied force, the stresses and strains maps were not different from one case to another. Only the values obtained for them differed.

The values of all parameters analysed following the simulations performed demonstrate that PE and EVA are the best materials that can be used for embedding sensors into the exoskeletons structure. Layers with thicknesses of 0.5 mm, 1 mm, and 1.5 mm can withstand the pressure exerted during the patient's walking, being stable structures that do not deform very much and when it occurs, it is only temporarily. Following a comparative analysis, an important result is that the 1.5 mm thick EVA layer is the one that presents the best properties and could be the most suitable for practical applications.

Until now, researchers have tried to improve the strength and increase the durability of sensors in exoskeletons by modifying the materials (e.g. new silicone rubber) or the sensors' design. [18], [19] In other projects, EVA polymer insoles have been investigated with the aim of being used to reduce the risk of diabetic foot ulcers in diabetic patients. A mathematical model has been built to determine the thickness of the insole that would allow for reduced plantar pressure distribution. [20] Insoles with sensors have been developed for rehabilitation footwear, but they do not provide a very large increase of sensors' durability. Although different materials have been used, which have improved the quality of the exoskeleton and increased the resistance of the sensor, with as little reduction in its signal as possible, an efficient method that ensures a good correlation between the degree of decrease in the sensor response and its resistance has not been found. [21]

The digital modelling presented in this article represents a first stage of the project, following that in the future tests for experimental validation on a physical model will be carried out. The materials presented in this article will be tested, along with other combinations and thicknesses, trying to determine the best material-thickness option that will help to increase the resistance of the sensors, without affecting their response. Their wear resistance will help to improve the tribological properties of exoskeletons and implicitly to their use for longer periods of time.

4. Conclusions

In the project presented in this article, a virtual model of an exoskeleton-type medical rehabilitation system with an embedded force sensory network was designed and built. The functionality of this virtual model was tested using digital twin solutions, namely the SolidWorks software.

The virtual model, which contains the embedded sensory network, covered with different materials, was functionally tested by simulating the impact factors existing in the real systems, in order to choose a material that would provide the best tribological quality to the real system that could be made later. The usual materials used in this field for the manufacture of the exoskeleton-type systems were used, namely PU, EVA, and PE.

Following the analysis of the von Mises stress, displacement, equivalent strain and safety factor of the EVA and PE layers with thicknesses of 0.5 mm, 1 mm, and 1.5 mm used for the integration of the sensory network into a PU exoskeleton, it was concluded that these materials feature resistant and stable structures. The 1.5 mm thick EVA layer can be used, ideally, for the tribological protection of the sensory network and increasing the lifespan of the exoskeleton.

Thus, using digital twin solutions, it was possible to determine the material with superior properties and that ensures a correct and prolonged functioning of a lower limb exoskeleton.

Before concluding, we would also like to mention that we deem that the results of this researches could be extremely useful to doctors and biomedical engineers who study the operating conditions of biomechanical components.

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