Design, Analysis and Simulation of a Novel Device for Locomotion Support

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ABSTRACT

The number of people with drop foot gait is increasing due to the increasing number of cardiovascular diseases, demographic ageing and neurological and musculoskeletal disorders. Current solutions for this problem are passive ankle-foot orthoses (AFO) that presents limitations as they do not add energy to the system, like active devices, restraining only foot motion.

This work aims the development of a novel AFO concept with passive/active duality. The conventional configuration, composed by a superior and inferior modules, connected through two lateral joints, is replaced by a new mechanism based on a modified four bar linkage with a two-rail system. The device has two particular features, a modular solution "off-the-shelf", easy to adjust to any patient, and an exterior mechanism able to assist different gait impairments.

An in silico CAD model of the orthosis is developed following mechanical design standards to establish dimensional and geometrical tolerances and the machine elements to assemble the device. Motion simulation is performed to validate the model and ensure that the device constrains the foot to one degree of freedom, which represents the dorsiflexion/plantar flexion, and the preservation of the biological foot axis.

Results of the simulation allow the successful characterization of one stride and its correlation with normal gait pattern. The device can be controlled by an actuator or simple mechanical elements, such as elastic bands and springs. Relations between bars motions and motor torque/ankle moment are presented, enabling the characterization of actuator's torque needs (velocity, power and engine torque).

Key words: Active Ankle-Foot Orthosis (AAFO), Modular Solution, Biomedical Device, Drop Foot

1. INTRODUCTION

1.1. Motivation

Nowadays the medical community is becoming more and more aware of the importance of improving the quality of life in patient healthcare. In a world where people can easily live until their 80's or 90's, the big question is if they have the necessary support to enjoy and live those years to the fullest.

The ability of walk, from one place to another, without depending on someone else to do it and with few or no limitations is a major factor to peoples' life quality. Walking is not only a tool for movement but also a key feature in social, work and personal fulfilment.

Ankle Foot Orthosis (AFO) are medical devices used to improve gait performance for persons with lower limb disabilities as assistive or therapeutic devices [1]. They are broadly prescribed to correct gait pathologies but the available market options only englobe passive solutions.

Many active orthosis are being developed at academic level but they don't make a leap through the market because these solutions need to be adjust for each patient.

There is the need to develop an active AFO that can be easily acquired and with the ability to be adjusted to each wearer by the orthotist.

1.2. Literature Review

In Orthopaedics field, orthosis were the first device to arise and the first design to appear is an knee stabilizer from around 2730-2625 B.C. [2] Egyptians [3] and Greeks (460-377 B.C.) [4] also gave their contribute to this field and since then the major developments in Science, Techology and Healthcare were the principal tools in Orthosis Design.

The structure of an AFO can be non-articulated (or "hingeless"), which are devices composed of a rigid structure with low or very low flexibility, or articulated (or "hinge"), which are orthoses that have a revolute joint (hinge) placed near the talocrural joint [5]
Considering the type of actuation some authors such as K. A. Shorter et. al. [6] and M. Alam et. al. [7], divide AFOs in three groups: Passive, Semi-Active and Active Orthoses.

The great difference between Passive devices and Semi-Active/Active devices is that the first group contain no control or electronic elements, the distinctive mark of Semi-Active/Active Orthoses. Active AFO are able to provide energy to the ankle, while Passive and Semi-Active can only dissipate, store and release available energy [6], [7].

Passive Dynamic devices (PD-AFO) rely on material properties, orthosis design, springs and fluid pressure dynamics to restrict bending and rotational stiffness as well as to accumulate and release mechanical energy [1], [8].

DACS (Dorsiflexion Assist Controlled by Spring AFO) was developed in Japan, International University of Health, to prevent foot drop in hemiplegic patients through a dorsiflexion control by spring elements [3]. Illinois University, USA, designed AFO to store energy during gait, the main goal is to support toe clearance in the end of stance phase. [6] Osaka University, in Japan, create an AFO with passive pneumatic elements activated by the weight of the wearer. It is intend to promote motion control and prevent foot droop during swing phase. The Rehabilitation Centre of Kanagawa, Japan, build an AFO with an oil damper to control viscosity. This will resist plantarflexion and avoid foot drop during swing phase [3].

Semi-Active devices are a sub group of active orthoses that has the particularity of not presenting a source of power in the design solution. The active elements are in fact electronics that are used to control the way that the system dissipates or stores energy [6] .

Osaka University developed magnetorheological dampers, controlled by computer to facilitate the use of active devices. This dampers create a resistive torque to plantar flexion during swing phase. Gait cycle is divided in four stages through the use of three sensors that adjust the viscosity of the damper fluid for each stage [3]. Arizona University, also develop an AFO with an actuator called Robotic Tendon, that uses a spring system to control ankle-foot motion [9]. Other semi active AFO, such as *BIONic WalkAide* and *NESS L300*, use FES (Functional Electrical Stimulation) to support ankle flexion.

Active devices are the only ones which have autonomy to generate their own energy. Active AFOs (AAFO) have a power source, actuators, sensors, and a computer to control torque during gait; they are usually tethered devices because of the energy requirements so they are mostly used in laboratories or clinical environments [6].

The first reference to an active device is a US Patent from 1935 (knee) [10]. In 1981, University of Titograd developed an active AFO which consisted on a DC motor that assisted flexion/extension of the ankle and was controlled by sensors localized on the soles of the device [11].

MIT Ankle-Foot-Orthosis was developed by the MIT Biomechatronics Group to assist drop foot gait. It was a modified passive AFO with an SEA, pressure and rotary senores that allowed a variation of impedance of flexion/extension direction of ankle motion. The Human Neuromechanics Laboratory at the University of Michigan (USA) developed several AFOs, all intended for rehabilitation environment since they are not fully portable. Carbon fibre and polypropylene modules are custom-built for each wearer and AFOs are mostly pneumatically actuated, through the use of artificial pneumatic muscles [12].

Currently prescribed AFOs are generic and have a standardized size, shape and functional characteristics, manually fabricated by ortho technicians that need to adjust the AFO to the specific gait characteristics of each patient. They are all passive AFOs [8].

To date, active AFOs are only used in laboratories for rehabilitation and research proposes. The major reasons are elevated costs, lack of clinical improvement evidence, the bulky design of some systems and the problem of a portable lightweight power supply [7], [13], [14].

1.3. Objectives and Main Contributes

The objective of this work is to present a novel paradigm for the design of Ankle-Foot Orthosis by changing the concept and structure that has been used since the first articulated AFO. This novel concept uses an external joint mechanism to support the movement of the ankle joint. The proposed solution can be applied both in passive and in active devices but it's with an active configuration that the major advantage is attained.

To achieve this goal the first step will be to use the software *Solidworks® (Solidworks Student Edition 2015/2016 version 23.2.1.0001)*, to develop a CAD model of the device and simulate its effectiveness and viability. Once this is achieved the next step is to make the mechanical engineering design of the model and then build a functional 3D prototype using the CAD model and 3D printing.

The main ambition is to design a modular and compact device that can be adapt to any person, avoiding the need of specific designs for every patient. The orthosis consist of three modules: two adaptable parts, the upper and lower members, specific for each person and fabricated by the orthotist, and a mechanical part, developed in this work, linking the other two parts and assisting the movement of the ankle joint. This last module is chosen accordingly to the patient's morphologic characteristics and impairments: it can be an active or passive device, with different features for each case.

The three-module orthosis is intended to improve the production process of an AFO. This is accomplished through the modular concept since the mechanism responsible for the motion is easily acquired and fully constructed. This modular part can be send to anywhere in the world and, once there, adjusted to the patient morphology and support needs. This way the fabrication process is simplified considering that the complex part of the orthosis, i.e. the action mechanism, is already built. It is intended to be a product "off-the-shelf" with several sizes, each one englobing a range of leg and foot lengths; and with different features for each gait disorder and the degree of disability of each patient.

2. Gait Cycle

2.1. Ankle-Foot Complex

The interface between the human body and the ground is ensured by the ankle-foot complex. This anatomical structure has an important role on weight baring, locomotion and maintaining a standing upright posture.

Most motion at the ankle occurs at the talocrural joint that is a synovial hinge joint with only one degree of freedom allowing movement on the sagittal plane: dorsiflexion and plantar flexion [15].

The Range of Motion (ROM) is the full movement potential of a joint. The neutral position of the foot is when the foot makes a right angle with the leg during stand position and the maximum range of motion is near 90°: with dorsiflexion having a range of 30º and plantar flexion of 50º [15].

2.2. Gait Cycle

During walking, each lower limb performs a sequence of movements that are repeated; the left and right limbs work alternately with a phase shifting between them to provide support and propulsion, and this process is called the gait cycle [16].

The gait cycle usually starts when a foot contacts the ground – Initial Contact (IC) – and ends when that same foot makes a new IC [16].

The duration of a complete cycle is known as stride period and can be divided in two phases: the stance phase, which is the support or contact phase and takes about 60% of the cycle and the swing phase, when the foot is moving forward through the air that lasts the other 40%.

Between dorsiflexion and plantar flexion the average range of ankle motion during walking is 30° (20° to 40°), usually the ROM is wider in plantar flexion than in dorsiflexion.

2.3. Gait Pathologies

Some pathological gait patterns can be easily detected because of the abnormal movements that are the result of the adaptation of people to pain and disorders in some part of the locomotor system such as brain, spinal cord, nerves, muscles, joints and skeleton. In other cases, the changes in gait are not compensating some flaw but are consequence of weakness, spasticity (excessive muscle contraction) or deformity [16].

Drop foot is one of the most common gait dysfunctions it is characterized for a weakness of the foot dorsiflexors and/or plantar flexor muscles that leads to a longer limb [17].

Impairment of the plantar flexor muscles affects the push-off phase. The major consequences are in the energy cost of walking, because most of the power is generated during ankle push-off and an alteration in gait pattern know as foot slap, where there is an uncontrolled strike of the foot on the ground at heel strike [7].

Insufficient dorsiflexion leads to complications during midswing phase because the muscles are incapable of lifting the foot causing an inadequate ground clearance, this affects the gait pattern since there is dragging of the toe during swing (toe drag) [7].

AFO's are usually design to assist the ankle-foot flexors and extensors during the gait cycle and are commonly prescribed to improve drop foot gait.

3. CONCEPT DEVELOPMENT: FROM AN IDEA TO A *IN SILICO* WORKING MODEL

3.1. Novelty

In pursuing a solution easier to implement, arises the idea of a modular solution with 3 distinct modules: the upper and lower members (the same modules existent in the conventional solution) and the action module. This later module is where the innovation resides, due essentially to two peculiarities: first it does not require any joint to be connected to the lower part, which facilitates the assembly of the orthosis; secondly this action module is a product "off-the-shelf", i.e., the module can be acquired according to the stature of the patient and its gait impairments and easily mounted at the workshop, to the upper and lower modules that were made specifically for the wearer morphology.

3.2. New Concept

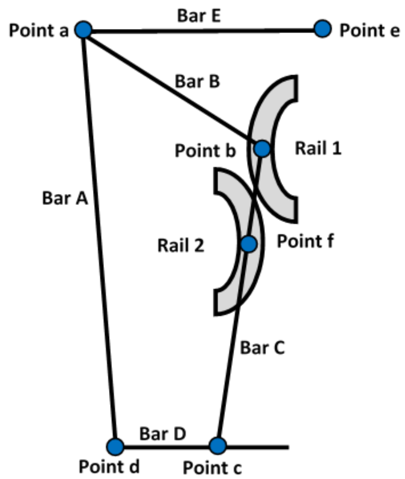

Figure 1: Draft of the device with key points, bars and rails

In Figure 1 is represented a draft of the orthosis concept. The model have 5 rigid bodies, each body has 3 degrees of freedom (DOF): two translations along de X and Y axis and one rotation, which means that 3 coordinates are needed to describe the position and orientation of each rigid body on a 2D dimension. Multiplying the number of rigid bodies by the number of DOF gives the total number of DOF of the unconstrained system which is 15.

Looking to Figure 1 it is possible to identify 6 revolution joints (2 at *point a*, 1 at *points b, c, d* and *e*), each one retrains 2 DOF, the two translations, therefore there are 12 joint constraints. The number of DOF of the system is calculate by subtracting the number of constraints to number of DOF, allowing 3 degrees of freedom.

Rail 1 is fixed to the upper module and controls the path of the pin linking bars B and C: the *point b*. Its function is to control the rotation of bar D, and consequently the rotation of the foot, since this bar is connected to the inferior module. This rail adds another constraint to the system, reducing the DOF from 3 to 2.

When the bars A, B, C and D are linked like in the sketch, they form a four-bar linkage. One of the characteristics of this mechanism is that when one of the bars is fixed, the other three are able to adjust their position and rotate around the fixed point. In order to avoid a deviation of the bars, rail 2 was created. The *point f* is a fixed

point that constraints the path of bar C and the angle between bars B and C in each point of rail 1. Similar to rail 1, this rail also restrains 1 DOF leaving the system with only 1 degree of freedom, as wanted.
The shape of the curves were determined through the CAD model developed in *Solidworks®*.
After implementing polynomial regression on the curves, the results were two very similar functions with two high R^2. The differences between the two equations can be ignored since the order of magnitude is really small, so the rails have the same curvature and are characterized by a second degree equation.

It is important to notice that the values and equations characterizing the rails are not generalized. This means that these results were obtained according to the stature of the leg and foot used as well as the length of the bars.

3.3. Model Description

Function/Aim

The main function of the orthosis is to support dorsiflexion and/or plantar flexion, preserving the normal axis of rotation of the ankle-foot complex and allowing the wearer to correct and assist his/her gait disabilities. The other main goal is to have a mechanism easy to adapt and simple to acquire.
This is achieved by an association of a four bar linkage mechanism with a two-rail system. A representation of the CAD model of the actuation unit is depicted in Figure 2.

Figure 2: Orthosis' CAD Model

Four bar linkage

A four-link bar mechanism is fully described when the position and orientation of every link can be determined. Freudenstein introduced an algebraic expression, the *Freudenstein equation*, which relates the input and output angles in terms of the link lengths The kinematical relationship between these angles is not affected by the overall size of the linkage as long as the relationship between the links is preserved. So it is possible to set the value of one of the link dimensions and in scale up the other link lengths, preserving all the other system's characteristics [18].

Applicability

The most relevant feature of this new concept is probably its capacity to be adapted to different gait impairments and different patients. Whether the patient needs a passive static device, a passive dynamic orthosis to support dorsiflexion or even an active AFO to overcome the lack of muscle tonus, all these configurations are achievable with this concept. The same mechanism can be adapted and adjusted to the uniqueness of each case.

Usability

Achieving the functions considered for the device and analysing real life situations where the device can be used is the final step to conclude concept' development. This device have the potential to be used in three different environments: rehabilitation session, home recovery, and daily use and it is important to acknowledge these possible scenarios and their peculiarities to understand the full potential of the AFO.
Gait impairments can result from neurologic or musculoskeletal causes and each disorder needs a specific device, adjusted to the degree of the disorder and the type of aid needed. This can be translated into different configurations of the orthosis, to address the specificity of each patient.

Passive Device

The device's multitasking nature allows the adaptation to the patient best interest. To fulfil the requirements of each disability with a passive device, there are different connection elements that can be used coupled with the selection of the correct location site.
There are three types of connection elements: elastic bands, stiff bands and springs; and two connection sites: the top and bottom sites, both localized on the support unit. The value of the

mechanical characteristics of the elements such as stiffness is another variable when talking about passive dynamic orthotics.
Hooke's law or law of elasticity states that the displacement or deformation (Δx) of an object is directly proportional to the deforming force or load ($\vec{F}$), as expressed in the next equation:

$$\vec{F} = K\Delta x \qquad (1)$$

The constant K represents the material property: stiffness. This constant can be chosen accordingly to the function of the element. The deformation or displacement Δx represents the variation of element's length. The main difference between the spring and the bands is that this variation can be positive and negative for the spring, because there is storing of energy when the force is applied on both ways and the bands only have positive variation of length, since there is only storing of energy when the force is applied in this direction.

When there are two pairs of stiff bands – characterized by very high stiffness to act like an inelastic band – linked on both sites of the support, the device acts like a non-articulated orthosis. These bands lock any possible motion.
Considering a pair of elastic bands, when the lower site is chosen and setting the normal length of the band to the peak of dorsiflexion, the device will promote toe clearance during gait, as well as prevent drop foot. There will be controlled dorsiflexion and plantar flexion will occur against the strength of the band. The value of stiffness can't be too high to assure that it doesn't interfere with normal plantar flexion.
The use of two pairs of elastic bands allows a choice of different stiffness values for each pair. Thus one pair plays the main role while the other only supports motion.
When both pairs have the same stiffness values the elastic bands can be replaced by one pair of springs, with the same stiffness. This way, for the same purpose, the device has a simplified configuration.
When the resting length in coinciding with the beginning of dorsiflexion, the device will prevent drop foot gait. When the foot touches the ground, the device is working against the spring, reducing its length and storing energy, with the help of body weight. At the end of stance phase, after push off, the spring releases its energy supporting dorsiflexion and assuring toe clearance. This configuration will also prevent foot slap because at the beginning of the stance phase, the foot is working against the spring promoting controlled contact with the ground.

Active Device
An active solution implies the use of an actuator, usually encompassing an engine, an energy source and sensors adjust the actuator to the wearers' dynamics. If these elements are placed on patient specific modules, like in most active solutions [14], the adjustment of the control mechanism is dependent of the completely assembly of the orthosis, making it difficult to implement without further help.
In this new concept, the control of the actuator would be related to the position of Bar E. The sensor would be placed in the action unit and the control of the motion and actuator would be included in the orthosis model. The orthotist only needs to attach this unit to the other modules.

The best actuator for this orthosis need to be a compact solution with variable impedance, in order to create the best response to the wearers needs in each phase of the gait cycle. In 2005, Hollander K. et. al. developed an adjustable robotic tendon that uses the properties of a spring to simulate a human tendon, it's called Jack Spring [19]. The desirable actuator should be develop in the future and could be based on their work.

4. Mechanical and Technical Design Considerations

4.1. CAD model

The orthosis has five bars that are responsible for the motion of the foot. Bars A to D form the four bar linkage; Bar E connects this structure to the support unit and Bar C contains rail 2.

The support unit plays an important role in the mechanism once it is part of six different features essential for the function of the device. As the name implies four of these features have a bearing function: this part it the attachment site for the device, through bar E, and for the superior connection that is made at the back of the unit. It is also the link site of the connection elements described in section 4.3.; the four bearing bracket have the same dimensions and each pair is placed at the same distance from the centre of the part, which is the location of the connection bars on *point a*; and is where the cover is attached.

The other two features are related to the two rail system. Rail 1 is contained in this part, and is as wider as the sleeve of *point b*, to avoid gaps between the surfaces. Rail 2 is not part of the support unit but this part is the key actor of this feature, since the pin that constrains the rail is part of the piece. The pin of *point f* is placed bellow rail 1 and is built to be a perfect fit in the rail.

4.2. Machine Elements and Tolerances

To ensure a successful assembly of the device, some mechanical design' details must be establish to avoid flaws or defects in the final mechanism. The correct planning of constructive aspects such as adjustments and the choice of machine elements is a fundamental step to build an operating device.

The tolerance class chosen followed standard ISO 2768 fH. [20]

4.3. Motion Analysis

Motion analysis uses assembly's mates and part contacts to simulate motion. Image sequences are processed to produce information (related to a specific image and time point) based of the apparent motion in the images.

Some elements were add such as the gravity force (value $9.80665\, m/s^2$), contact forces between bars and a motor characterized by an oscillating motion with a displacement of $55°$ and a frequency of $0.1\, Hz$. It is applied to bar E, controlling the mechanism through the rotation of this bar.

The simulation has a duration of 5 seconds and starts with maximum dorsiflexion ending with maximum plantarflexion, as depicted in Figure 3. It is important to notice that although there are no limb connecting the upper and lower members, the anatomical axis of rotation is preserved.

4.3.1. Bar D and Bar E: angles

Bar E is the motor's point of application and analysing its motion give us information about the motor characteristics and requirements. Bar D is connected to the inferior module and its range of motion is the same range of the orthosis.

There is a linear relation between their motions: for each degree rotate by Bar D, Bar E needs to rotate almost the double, 1.8 approximately. The great advantage of this disparity is that since the motion of bar E is controlled by an actuator, it is easier to manage high angle variations than small values of rotation, with higher accuracy.

4.3.3. Applied Moment and Motor Torque

The best way to determine the response of the motor is to apply a force that will generate a unitary moment and describe the motor torque required to maintain the position of the foot.

Changing the position of the foot for different values of angulation from plantar flexion to dorsiflexion and calculating the motor torque for those values it is possible to see the response of the motor to a unitary moment, represented in Figure 4.

The motor torque required to counteract the applied force is always lower than one, i.e. the moment needs for the actuator are less than those induced by the external moment. With the equation of the curve and knowing the ankle moment for a normal gait it is possible to calculate the moment of bar E during one stride. Comparing the curves of ankle moment and bar E moment it is easy to see that the moment of bar E is lower than the moment of the ankle, this is explained by an attenuation of the ankle moment caused by the motor torque, which may

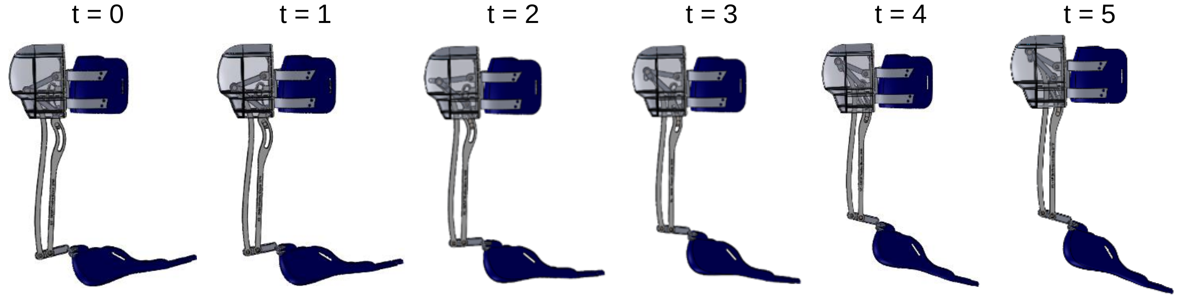

Figure 3: Frames of the simulation, from dorsiflexion (first) to plantar flexion (last), t (sec)

implies energetic advantages.

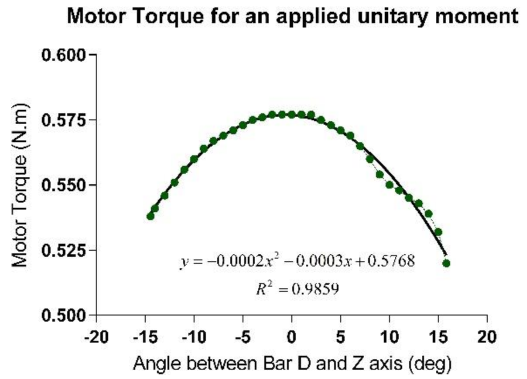

Figure 4: Relation between motor torque and rotation angle of bar D for a unitary moment

4.3.4. Torque needs: moment

The graphics of moment per angle for a natural cadence are depicted in Figure 5 (left), for the ankle moment and respective angle (red dashed line) [21] and for the bar E moment and respective angle (blue line).

Moment peak on both curves represents weight acceptance and is right before push off, when the foot reaches the peak of plantar flexion. The sudden change in the ankle angulation is represented by the sharp fall of the moment, after the peak.

Analysing the graphic is easy to acknowledge that bar E moment has lower magnitude, this happens because the motor torque attenuates the moment of the ankle and that the displacement of bar E is wider than the movement of the ankle, that can increase motor requirements.

4.3.4. Torque needs: velocity and power

Considering a stride period of 1.08 sec [21], and using the finite difference method is it possible to plot the velocity of Bar E during one stride. In Figure 5 (centre) this curve and ankle velocity curve are represented.

There is a high similarity between the curves, where the velocity of bar E has higher values, as expected, since there is a greater movement amplitude in this bar, for the same stage of the stride period.

Knowing the velocity of Bar E during stride and the required torque in the same period, it is possible to calculate the required power of an engine in order to have a functional actuator. These values are given in power per kg. The peak of power is in the transition from stance to swing phase, in the end of push off, a stage that has high energy consumption, and is maximum value is approximately 3.12 W/kg. This means that for a male individual with 80kg, the actuator must provide a power of 250W.

4.3.5. Torque needs: engine torque

In Figure 5 (right) the values of torque for bar E were plotted in function of the velocity of the same bar.

The curved area on the right of the graphic corresponds to the initial contact of the foot, when the foot is dorsiflexed. After that, the curve rises almost vertically and that stage is the weight acceptance.

The torque peak corresponds to the second peak of velocity, which is the end of the push off phase represented by the left top side of the closed binary curve, where there is high velocity and a high moment of Bar E.

With this analysis it is possible to see that the major energetic requirements will happen during the push of phase, where there is the need of high velocity with high moment values.

4.4. Rapid Prototyping

Rapid Prototyping is the fast creation of a full-scale, functional, 3D model of a part or product providing 3D visualization of a CAD model and allowing efficiency tests related to its shape or size.

The process utilized to build the orthosis' functional prototype was fused filament fabrication, an additive manufacture technique that builds the model through material extrusion. It uses a thermoplastic material that is melted in a heated nozzle and extruded to form each layer, deposited on a building platform. [22]

The CAD model of the orthosis had to suffer some alterations in order to respect the characteristics of the 3D printer. After the conversion into a .STL file, in the software of the printer, the model was scaled to fit the printer dimensions, so every part was transformed to 30% of its dimension. The density of the parts were chosen accordingly to their function, so that the mechanism had strength enough to support the leg and foot. Pictures of the process and of the functional prototype are displayed in Figure 6.

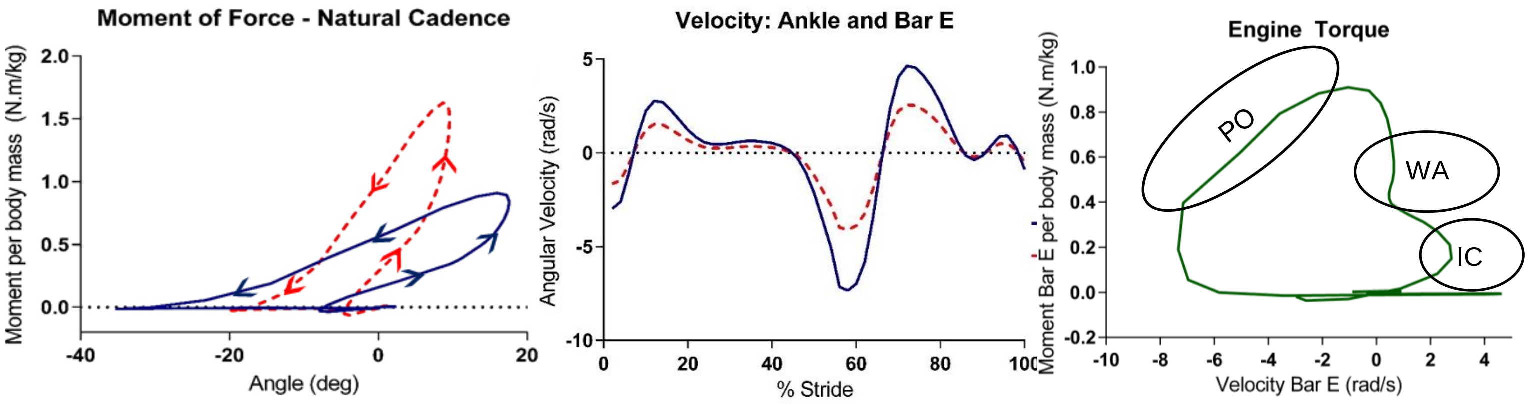

Figure 5: Left: Moment of force: ankle (red dashed line) adapted from [21]*; and bar E (blue); Centre: Angular velocity: ankle (red dashed line) adapted from* [21] *; and bar E (blue line); Right: Engine Torque*

End-part finishing included polishing, sanding, removal of the support structures and painting. In some parts tweaks were made because of some errors in the dimension of the pieces, due to calibration flaws.

The machine elements are the only pieces that were not printed, their dimensions and characteristics had to be adapted from the original project to fulfil the changes on the parts.

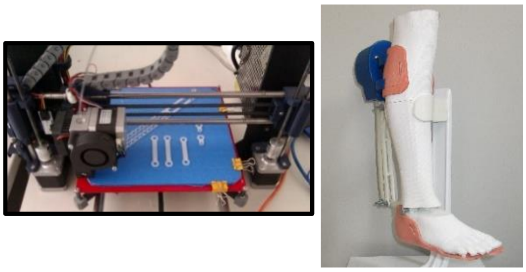

Figure 6: 3D printing – parts of the orthosis; functional prototype

5. Conclusions

In this work a novel Ankle-Foot Orthosis (AFO) was developed for locomotion support and assistance.

The modular solution is based on a combination of a four-bar linkage with a two-rail system, the mechanism responsible for the motion. Through the analysis of the degrees of freedom of the mechanism it was ensured that it had only one degree of freedom, allowing dorsiflexion and plantar flexion of the foot. The rails were design to allow a range of motion of 30°.

The duality of the device that can act as articulated or non-articulated orthosis, depending on the type of mechanical element used and as a passive or active orthosis, depending on the type of actuation. It can be applied to assist different pathologies and patients with different degrees of gait impairments.

AFO's design characteristics allows the building of devices with distinct configurations, adapted to each situation. The orthosis is built to function with springs or elastic bands that should be chosen accordingly to the wearers needs. For instance, the non-articulated configuration can be achieved if an elastic band with high stiffness is chosen; on the other hand, choosing a spring it's possible to have a device which promotes dorsiflexion and controlled plantarflexion, preventing drop foot gait. The device is designed to include an actuator to actively assist gait. The ideal actuator would work with a spring with variable impedance to allow a better adjustment to the distinct phases of gait and to different patients.

As result of the characteristics mention above, this device has three working environments: rehabilitation/physical therapy facilities, acceleration the rehabilitation process by working together with the physiotherapist; home recovery, assisting simple activities such as walking and giving more support and security to the wearer; and daily use, improving the quality of life of people with gait impairments by correct and/or assist gait.

Motion analysis was made considering the motion from the peak of dorsiflexion until the peak of plantar flexion. This analysis intend to a better understand of some features of the device and to allow a rude characterization of the motor requirements. From the results obtain is important to notice that: there is a linear relation between the length of the actuator and the rotation of the foot; the rotation of bar E is bigger than bar D, reducing the precision required to move the foot and the mechanism converts the moment applied and decreases its value and, consequently, the demand of actuator's motor torque. Information regarding actuator torque needs are important to understand the strong and weak points of gait cycle to motor functioning.

This last chapter also describes the creation and assembly of a 3D functional prototype, through addictive fabrication. Having the possibility to produce a prototype is of extreme relevance for every research work. The prototype allowed an in-depth understanding of the device and its operation. It enhance the importance of tolerance values and the dimensions of the machine elements, key factors to the good performance of the device.

A long path needs to be pursued until the device is ready to be commercialized and used by individuals with gait disorders. Future work should be developed to create an actuator that works with the wearer; to choose the best material through a structure analysis; to optimize orthosis dimensions into a model more compact and to study the effects of wearing this AFO in walking performance.

When thinking about orthotic and prosthetic devices, it is important to acknowledge the big difference between them. While with prosthetic devices the main objective is to replace a biological structure by an artificial ones, in orthotic devices the disable limb that must work in parallel with the device. So every orthoses design must respect the normal performance of the limb and reduce to a minimum the interference that the device can cause to the limb. That's why it is so important to decrease the patient dependent parts in a device and reduce the contact areas with the wearer.

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