Title: ANKLE AND KNEE MOTORIZED ORTHOSIS

Abstract: The invention relates to an ankle and knee orthosis (100) motorized and of modular type, comprising a knee articular unit (1) and an ankle articular unit (2). Each of these articular units (1, 2) is formed by two elements (11, 13; 21, 23) angularly movable relative to one another between which is interposed a torsion spring (12, 22) or an equivalent elastic element. The overall arrangement is such that, in use, this elastic element is induced in a condition of elastic loading by a corresponding motor or pair of motors (111, 112; 211, 212) of the orthosis associated with one of the two elements angularly movable in such a way as to exert a corresponding elastic action on the other articular member, which elastic action assists a motive act of the subject.

Declared under Rule 4.17:

- of inventorship (Rule 4.17(iv))

Published:

- with international search report (Art. 21(3))
ANKLE AND KNEE MOTORIZED ORTHOSIS

DESCRIPTION

Technical field of the invention

The present invention relates to an ankle and/or knee orthosis, of motorized type. In particular, this orthosis is intended for the rehabilitation of gait by acting on the ankle and/or knee articular joints of children with disorders that affect motive function, the standing posture and the transition from sitting to standing position and vice versa.

Background

Currently in the market ankle and knee orthosis of passive type are available, i.e. orthosis without an engine that enables the dynamic interaction between patient and active orthosis.

The active dynamic interaction is required by the characteristics of the human gait.

With reference to the ankle, a typical description of the gait begins with the placement of the heel on the ground to which follows a rotation of the ankle that brings the sole of the foot in contact with the ground. This stage is followed by a progression of the tibia with front passive closure of the ankle angle and subsequently observing the lifting of the heel by sealing effect of the triceps that determines an opening of the ankle angle until the big toe is detached from the ground, as consequence of the angle variation of the axis of the leg relative to the ground. At this point it is necessary to raise the tip of the foot with a bending of ankle and knee to make sure from stumble the limb oscillation during the first flight step of the foot and a second activation of the ankle dorsal flexor is
necessary to ensure the following contact of the heel with the ground.

In this complex gait cycle the knee makes a transition from a relative extension to a slight bending followed by a second slight extension in order to contribute to the absorption and the acceptance of the load on the loaded limb controlled by an active co-contraction between agonist and antagonist muscles (increased articular stiffness). Subsequently, a knee extension is observed mostly due to the kinematic configuration and to the configuration of the field of external forces (gravity, inertia and the configuration of ground reaction vector) under full positioning step. In the pre-oscillation step of the limb and in the first step of the limb oscillation, the knee bends mostly caused to the above mentioned forces that act as flexors on it by virtue of the change of the kinematic configuration of the lower limbs with respect to the direction of the reaction force with the ground. Knee bending is favored by the oscillation of the leg in the gravitational field and slightly accelerated by a small pulse of the extensors in the first step of oscillation which follows, in the final step of extension, of a co-contraction activity of agonists, antagonists groups that anticipates the receipt of the load in the subsequent positioning on the ground.

It follows that no passive device can allow a control of different transition steps that are repeated in a cycle gait having a duration of little more than a second.

In addition, the diseases that affect the gait may involve different defects that can lead to both an absence or a reduction of weight support and an excess of not suitable and/or uncontrollable support activities or dynamic activities. In all of this we can observe the presence of pain with or without degeneration of body structures (skeletal and soft tissue).

Functional orthosis must be able to perform support function of the weight, limitation of joint movement, increase of the excursion, acceleration and deceleration of the rotations in relation to the problem of the individual patient and the step in which the joint is with respect to the gait cycle. In this sense, the
distinction between defects and outcomes is critical to 'choose' the active behavior of the orthosis.

It follows that an orthosis as 'intelligent' is not currently feasible, but it is possible to start the construction of an orthosis that provides a fundamental support, and which offers the greatest assurances of versatility in order to achieve the best active dynamic interaction with the assist and/or re-educate function. The modification of the active control can allow the orthosis adjustment determining the temporary coaching function for rehabilitative or permanent correction scopes of the function and then assistive scope. It should be considered that, even in the case of an assistive orthosis design it must ensure the widest possible versatility because especially in pediatric age is observed a continuous remodeling during the time of the function. Such remodeling in the age of growth is influenced by the use and therefore the effectiveness of an orthosis is linked to the ability to prevent with greater or lesser efficiency the pathology from non-use. This occurs in a manner directly proportional to the versatility of the dynamic interaction of the orthosis with the patient that uses the orthosis.

Motorized devices generally known as "exoskeletons" are also known, that can be grouped into three main categories, namely:

(a) exoskeletons developed for adult patients with spinal cord injuries (for example, the system "Re-Walk" of Argo Medical Technologies, Israel);

(b) exoskeletons developed by the military for the upgrading of the gait of the soldiers (eg the system "HULC" of Lockheed Martin, USA);

(c) exoskeletons agents on both the upper and lower limbs for the enhancement of motor functions in healthy adult subjects (e.g. the system HAL-5 of Cyberdyne, Japan).

None of the above exoskeletons meets the above requirements, necessary for the rehabilitation of children with limitations of use of the lower limb.
The gait and the standing position are also characterized by a distribution of
stability in non-equilibrium conditions. The workout for stability is not guaranteed
by devices described in paragraphs (a), (b), (c) because they do not enable to
exert the self-organization dynamics processes of the above mentioned functions.

In particular, the exoskeletons of paragraph (a) are for adult patients with spinal
cord injuries who have lost their mobility. In this case the exoskeletons are
devices that generate the gait function for substitutive scopes and do not have
useful functionality in the solicitation of mobility learning processes. The
substitutive aspect of the function can induce a process of improper learning
and control of the dynamics of movement, namely a potential functional
deterioration.

The exoskeletons referred to in points (b) and (c) are used for the so-called
"empowering" of healthy adults and as such are suitable only to amplify the
strength of a movement generated independently from the subject. Their use in
pathological conditions only determines the 'fixation' of the movement strategy
of the subject, or a potential increase in the inertia of the subject with respect to
new learning.

Further known orthotic devices are bulky and not generally completely
wearable. For example, such devices can only operate in conjunction with
external systems, in particular to a walker or to a support device for supporting
the operator and/or the energy sources used.

In general terms, there are no known active ankle and/or knee orthosis self-
contained and that are appropriate for use in rehabilitation of pediatric subjects.
Summary of the invention

A scope of the present invention is therefore to provide an orthosis for use in pediatric rehabilitation that allows to realize the mechanical interactions mentioned above useful to the rehabilitation and/or assistance of mobility function, of the erect posture and of postural changes between the two functions.

This problem is solved by an orthosis according to claim 1.

Preferred features of the present invention are object of the dependent claims. The orthosis of the invention is completely self-contained and therefore completely wearable and lends optimally to realize an embodiment of minimum size and weight.

The orthosis is specifically designed for use in mobility and functional rehabilitation involving the use of the ankle and/or knee joints of the pediatric subjects, both in orthopedic and neurological field.

The orthosis also lends to a modular effectively implementation, as will be better appreciated from the detailed description given below.

The orthosis can also be understood both as a temporary aid (rehabilitation of the function) or permanent aid (assistance to the function).

When used to re-educate the function the orthosis generates forces that are transmitted to the patient by means of interposition of an elastic element, in function of the task, so as to ensure the conditions of motor learning as defined by the most recent scientific hypotheses. In general terms, these forces are applied in a synergistic manner such as to facilitate the movement or to amplify the error to induce corrective activities.

During a merely assistive use, the action of the orthosis will consequently be addressed primarily to control the absorption of impact with the ground, to the guarantee of weight support, to the assistance on the energy required for
progression and to ensuring adequate release of foot from the ground during an oscillation, as well as to prevent major deviations of the movement, ensuring greater safety, speed of execution and effectiveness.

Preferably, these main activities are phase-dependent and controllable, as such, by means of the measurement of angles of the orthosis joint, of the forces exchanged and through the coupling of the motor of the orthosis to the lower limb of the subject guaranteed by an interposed passive elastic joint.

This feature can be used both to correct or assist the gait, but also in the maintenance of the upright posture and in the assistance of postural passages like that from sitting to standing and vice versa, where muscle weakness, pain or muscle control can prevent the wrong correct functionality.

These and other advantages, features and the modes of the employ of the present invention will be made evident in the following detailed description of a preferred embodiment thereof, given by way of example and not for limitative purposes.

**Brief description of the figures**

Reference will be made to the figures of the accompanying drawings, in which:

- Figure 1 shows a side view of a preferred embodiment of the orthosis of the present invention, in the represented example an orthosis that affects both knee and ankle that is shown in a configuration worn by a subject in the pediatric age;

- Figure 2 shows a front view of the orthosis of Figure 1;

- Figure 3 shows the support structure of the orthosis;

- Figure 4 shows a section of the articular unit 1;

- Figure 5 refers to the ankle portion of the orthosis of Figure 1, showing
Detailed description of preferred embodiments

With reference initially to Figures 1, 2 and 3, an orthosis according to a preferred embodiment of the present invention is generally denoted by 100. The orthosis 100 is apt to be worn on at one or each of the lower limbs of a subject in pediatric age and comprises a first articular unit of knee, overall denoted with 1, and a second articular unit of ankle, the latter overall denoted by 2. These two articular units 1 and 2 are functionally related and also, in the present example, structurally related to one another.

Alternative embodiments may provide that the orthosis of the invention concerns only one of the knee or ankle joints.

The orthosis 100 comprises a support structure 3, which represent precisely the bearing structure of the articular units 1 and 2.

The knee articular unit 1 comprises a first articular member or motor group 11, apt to be fixed, in use, to the thigh of the subject, and a second articular member 31, belonging to the support structure 3, apt to be fixed to the leg of the subject and connected to the first articular member 11 so as to be angularly movable with respect to it. The elements 11 and 31 are connected together by a moving system 13, which in this example consists of belt 131 and pulleys 132, 133.

Similarly, the ankle articular unit 2 comprises a first articular member or motor group 21, apt to be fixed, in use, to the leg of the subject, and a articular member 32, belonging to the support structure 3, apt to be fixed to the foot of the subject. The elements 21 and 32 are connected together by a drive system 23 consists of, always in the present example, a belt 231 and pulleys 232, 233.
Between each pair of articular members 11-13 and 21-23, is interposed an elastic element, respectively 12 for the knee unit 1 and 22 for the ankle unit 2.

Each elastic element 12 and 22 is constituted by a torsion spring, preferably a helical spring.

The support structure 3 also comprises two valves 33 and 34, connected by adjustable belts to the thigh and the leg of the subject. The valves 33 and 34 are realized ad hoc according to the circumferential dimensions of the lower limb. The motor groups 11 and 21 are connected to valves 33 and 34, through crossbars 35 and 36. In the present example is provided a second crossbar connected to the valve 34 to ensure the highest anchorage.

The crossbars 35 and 36 are lockable in a plurality of mutual positions by means of connections to respective uprights 37 and 38. The upright 37 is constituted by an upper strut 371, bound to the crossbar 35, and a lower strut 372, bound to the crossbar 36, connected each other by a universal joint 373, the axis of which is coaxial with the axis of the knee.

Similarly, for the ankle module, the upright 38 is constituted by an upper strut 381 and by a lower strut 382 connected by a universal joint 383, the axis of which is coaxial with the axis of flexion-extension of the ankle.

The presence of a plurality of seats of screws between the uprights and crossbars above mentioned serves to ensure an adaptability of the device to the anthropometry of the specific subject.

Alternative embodiments may provide retaining means on the leg other than this described here.

Furthermore, there is provided a yoke retaining means 6, suitable to engage the bottom of a shoe worn on by the subject, for the detention of the second ankle articular member 32 to the foot of the subject. Even in this case, different kind of
retaining means may be provided.

In the present example, the orthosis 100 is completely self-contained and includes so-called "onboard" motor means associated with each articular unit 1 and 2.

In particular, with reference to Figure 4, as already said the first articular unit 1 comprises a knee motor group 11, connected via the elastic element 12 to the movement group 13, fixed to member 31. Similarly, the second articular unit 2, comprises the already mentioned ankle motor group 21, connected via the elastic element 22 to the movement group 23, fixed to member 32.

The specific arrangement of the components of each articular unit 1 and 2 will now be illustrated in greater detail. As an example, we will refer to the knee articular unit 1. A similar description applies to the ankle articular unit 2.

Therefore, with reference to Figure 4, the articular unit 1 in section is shown. The motor group 11 is composed of a motor 111 to which a further motor 112 can be associated in case of need. In the present example, the motors 111 and 112 are electric battery powered and transmit the torque via gear wheels 113 and 114 to a shaft 115 which present the housing of the first end of the torsion spring 12. The second end of the torsion spring 12 is constrained to the pulley 132 belonging to the movement group 13. The angular difference between the shaft 115 and the pulley 132 is measured by an encoder 14 housed in a seat made in the pulley 132. The connection between the encoder 14 and shaft 115 is secured by a rubber tube 116. The axial position of the elements 115, 132 and 14 is guaranteed by the presence of a frame 15 which also allows the connection of the articular unit 1 to the crossbar 35.

Alternative embodiments may provide alternative means to the encoder sensors or transducers above mentioned.

In use, the motor 111 is activated so that the shaft 115 performs a rotation by a predetermined angle, rotation that is induced also on the first arm of the spring
In this way, the motor 111 produces an elastic loading condition of the spring 12. The spring 12 will transmit a rotational movement to the pulley 132 via an elastic moment. This elastic action, typically equal to the product of the elastic constant of the spring 12 with the angular displacement induced between the elements 115 and 132, assists the displacement of the leg compared to the thigh of the subject, so assists a motive act of the subject wearing the orthosis.

The orthosis 100 may also include a belt or backpack shoulder module for positioning batteries or equivalent energetic means.

Moreover, at the articular units 1 and 2, means sensors 4 and 5, apt to detect kinematic quantities such as rotation, speed and acceleration, are provided. Preferably, such means 4 and 5 at least include an accelerometer and a gyroscope.

Means 4 and 5 are apt to detect the movements of the subject that wearing the orthosis 100.

Figure 5 shows in greater detail the ankle articular unit 2, as already said, a description similar to that mentioned above for the knee unit, being valid for the ankle articular unit. Therefore, for example, two motors 211, 212, two gear wheels 213, 214, torsion spring 22 and the movement group 23 are visible.

The orthosis 100 is advantageous inserted into a system for the rehabilitation of pediatric subjects that also includes a control unit apt to control the motor groups 11 and 21 associated to the orthosis in function of the measurements of the above mentioned sensor means 4 and 5 or other parameters, preferably in a manner adaptive with specific rehabilitation needs and/or above mentioned assistance.

It will be appreciated that each articular unit 1, 2, and in particular the
association of the motors groups 11, 21 with the elastic means 12, 22, simulates a virtual spring characterized by a stiffness variable in function of the displacement imposed by the motors groups 11, 21 to the shafts. So, a fine-adjustment of the active interaction that the orthosis can offer to the patient during the moving performance is allowed.

The orthosis according to the invention may therefore interfere in a maximally effective manner with the moving attempts of the subject who wears it. The value of the supporting action to such motive attempt can be calibrated - by an operator or automatically - depending on the specific therapeutic needs, in particular depending on the kind of correction to be obtained and/or the learning process that wants to trigger, and/or the entity of the values recorded by the sensor or transducers means, in particular in the present example the amplitude of the measured angle or the kinematics of the knee and ankle moving joints.

In other words it is possible to change the interaction level of the orthosis with the patient by adjusting the degree of stiffness of the simulated virtual spring.

The adjustment of the spring stiffness is required to start motive learning processes.

In this way it is also possible to adapt the orthosis to the characteristics of the patient difficulties and to the development of motive skills during the treatment. When there is a limit of the subject recovery, the orthosis may apply articular torque able to assist and optimize the function, increasing the autonomy of the patient.

The motorized joints have the additional characteristic to act with a motive action not directly on the segment body to rotate (tibia for the knee joint and foot for the ankle joint ), but by moving the equilibrium point of the elastic element mounted between the motor and the same segment body. This provides the
advantage of decoupling the motor from the subject, ensuring a high safety factor in case of malfunction of the orthosis or part of it. Furthermore, this solution allows to apply to the joint a virtual force control, by acting with a position control directly on the displacement of the equilibrium point of the elastic element, allowing the use of an instrumentation much more simple and already partially included within the motor itself.

It will be appreciated also that the orthosis is completely modular and can be assembled in a specific way depending on the needs and anthropometric dimensions of users.

It will be understood that the orthosis can be easily used by the patient during both the functional rehabilitation and, at a later stage, during normal daily activities. The orthosis is in fact completely wearable by the patient, especially with no hardware or cables external to the device that would limit the movement of the patient, making it impossible to use in the free walk.

As mentioned above, the orthosis according to the invention allows re-educating the functional use of the lower limb by acting on the ankle and knee joints. The orthosis according to the invention has the characteristic of being able to act simultaneously on both joints or on one joint only.

Will be better appreciated at this point that the orthosis according to the invention, particularly in the embodiment described above, is apt to be used both in the neurological and orthopedic rehabilitation.

In the neurological field, the orthosis can be used in all the lesions of the central nervous system that involve transient or permanent alterations of the mechanisms of motive control. Further, the orthosis is suitable for use in diseases that involve a temporary or permanent impairment of peripheral nerves. This is guaranteed by the fact that the orthosis can act as an 'expert' tutor in a mode dependent on the gait step by exerting adequate value torques
to the subject and to the function to integrate, creating force fields apt to amplifying known mechanisms of motive learning. Furthermore, the orthosis allows a prolonged functional modification of the lower limb use which is able to interfere with the morphological development especially of soft tissues. In this sense it is possible to change the available peripheral resources used by the central nervous system to implement the strategies of motive control. More these resources will be and more will be the adaptability of strategies to the environmental variability and thus to their usability in everyday activities. In this direction the orthosis also finds application in the orthopedic field, where it can be applied to rehabilitation after trauma or poly-trauma articular and to treatment of surgery results. Even in this field, the orthosis can be used in rehabilitative mode to restore correct movement patterns or in assistive mode where its interaction with the subject will be adapted to the progressive functional recovery.

In more general terms, the orthosis is suitable to be used for rehabilitation or functional assistance in all those pathological conditions which result in a reduction of motive skills.

The present invention has been hereto described with reference to a preferred embodiment thereof. It is understood that other embodiments might exist, all falling within the concept of the same invention, and all comprised within the protective scope of the claims hereinafter.
CLAIMS

1. An ankle and/or knee orthosis (100),
comprising at least one articular unit (1; 2) motorized or motorizable and apt to
be worn on at the ankle or knee joint,
which articular unit (1; 2) in turn comprises:

- a first (11; 31) and a second (21; 32) articular member, angularly
  movable the one with respect to the other and each apt to be fixed to an
  articular segment forming a subject's joint, and
- an elastic member (12; 22) interposed between said first (11; 31) and
  second (21; 32) articular member,
the overall arrangement being such that, in use, said elastic member (12; 22) is
induced into an elastic loading condition by a corresponding motor (111; 211) of
the orthosis associated with the first articular member (11; 31) so as to exert a
corresponding elastic action on the second articular member (21; 32), which
elastic action assists a motive act of the subject.

2. The orthosis (100) according to claim 1, comprising a moving system (13; 23)
arranged between said first (11; 31) and second (21; 32) articular member,
wherein said elastic member (12; 22) is interposed between said first articular
member (11; 31) and said moving system (13; 23), which moving system (13;
23) is preferably based on a belt-pulley coupling.

3. The orthosis (100) according to claim 1 or 2, wherein said elastic member
(12) has a first end arm operated or operable by the motor (111) of the orthosis
and a second end arm exerting, in use, said elastic action on said second
articular member (31).

4. The orthosis (100) according to any one of the preceding claims, wherein
said elastic member (12) has an end fastened to a shaft (115) operated or
operable by the motor (111) of the orthosis and a second end fastened to a
pulley (132) and exerting, in use, said elastic action on said second articular
member (31).
5. The orthosis (100) according to any one of the preceding claims, wherein said elastic member is a torsion spring (13), preferably a helical spring.

6. The orthosis (100) according to any one of the preceding claims, comprising at least one on-board motor (111) associated to said first articular member (11).

7. The orthosis (100) according to any one of the preceding claims, comprising a knee articular unit (1) and an ankle articular unit (2), preferably mutually connected.

8. The orthosis (100) according to any one of the preceding claims, comprising sensors or transducers (14) apt to detect the relative motion of said first and second articular member (11, 21), preferably comprising at least one angle encoder.

9. The orthosis (100) according to any one of the preceding claims, comprising sensors (4; 5) apt to detect kinematic quantities such as rotation, velocity and acceleration, which sensors (4, 5) preferably comprise at least one accelerometer and one gyroscope.

10. The orthosis (100) according to claim 8 or 9, wherein said sensing or transducing means (14; 4, 5) is apt to detect a motive attempt of the subject wearing on the orthosis.

11. A system for the rehabilitation of gait, standing position and postural passages, from on one's feet to seated and vice versa, in pediatric age subjects, comprising an orthosis (100) according to any one of the preceding claims, and a control unit apt to control the motor(s) (111, 112; 211, 212) associated to the orthosis, preferably based on the detections of said sensor or transducer means (14; 4; 5).

12. An active dynamic system, comprising an orthosis (100) according to any one of the claims 1 to 10, apt to carry out an effective assistance in walking, standing position and postural passages, through modulation of the equilibrium point of the elastic torque, defined by the adjustment of rigidity and damping, acting on one or more articular joints (knee and/or ankle).

13. An active dynamic system, comprising an orthosis (100) according to any
one of the claims 1 to 10, apt to carry out an effective learning or relearning of walking, standing position and postural passages, through modulation of the equilibrium point of the elastic torque, defined by the adjustment of rigidity and damping, acting on one or more articular joints (knee and/or ankle).
## A. Classification of Subject Matter

**INV.** A61H3/00 A61H1/02

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC.

## B. Fields Searched

Minimum documentation searched (classification system followed by classification symbols):

- A61H
- B25J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched.

## C. Documents Considered To Be Relevant

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<td>WO 2012/100250 AI (IWALK INC [US]; HAN ZHIXIU [US]; W LLIAMS CHRISTOPHER [US]; WEBER JEFF) 26 July 2012 (2012-07-26) paragraphs [0025], [0052] - [0056], [0065], [0066]; figures 5,8A-8C</td>
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**Further documents are listed in the continuation of Box C.**

**See patent family annex.**

* Special categories of cited documents:

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**Date of the actual completion of the international search:** 14 February 2014

**Date of mailing of the international search report:** 24/02/2014

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