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IMPROVED LOWER-LIMB FUNCTION****Publication Classification**(51) **Int. Cl.⁷** A61N 1/18(52) **U.S. Cl.** 607/49(75) **Inventors:** **Roger H. Nathan**, Herzilia B (IL);
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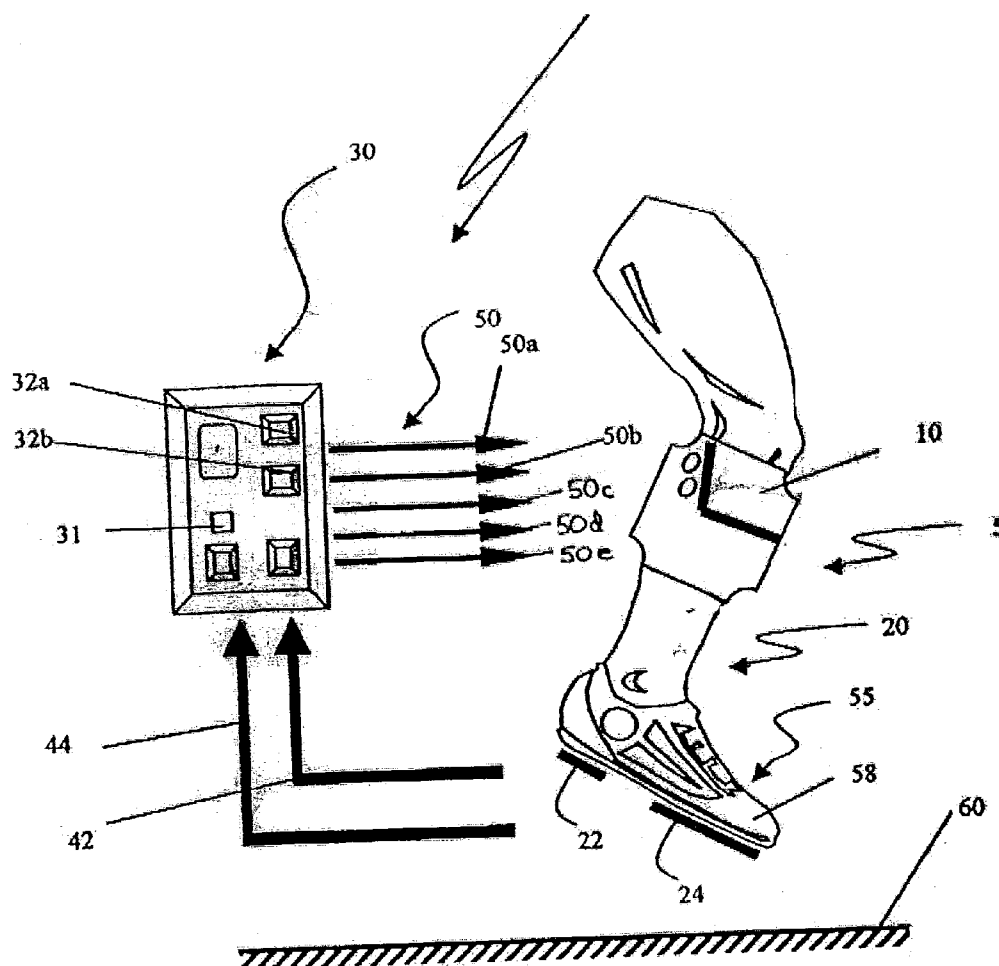
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ABSTRACT

A gait modulation system for improving lower-limb function of a patient having neuromuscular impairment of the lower limbs, including: (a) a sensor associated with a lower limb, for transducing a parameter related to the lower limb, so as to obtain gait information related to at least one gait event within a gait cycle; (b) a neuroprosthesis device including: (i) an electrode array operatively connected to an impaired lower limb, for performing functional electrical stimulation (FES) of at least one muscle of the impaired lower limb; (c) a muscle stimulator operatively connected to the electrode array, for supplying a muscle stimulation output to the array, and (d) a microprocessor operatively connected to the sensor, the microprocessor for processing the gait information and for controlling the muscle stimulation output via the muscle stimulator, wherein the gait modulation system has a sleep mode for autonomous reduction of the muscle stimulation output to the array, the microprocessor being designed and configured to control the autonomous reduction based on the gait information.



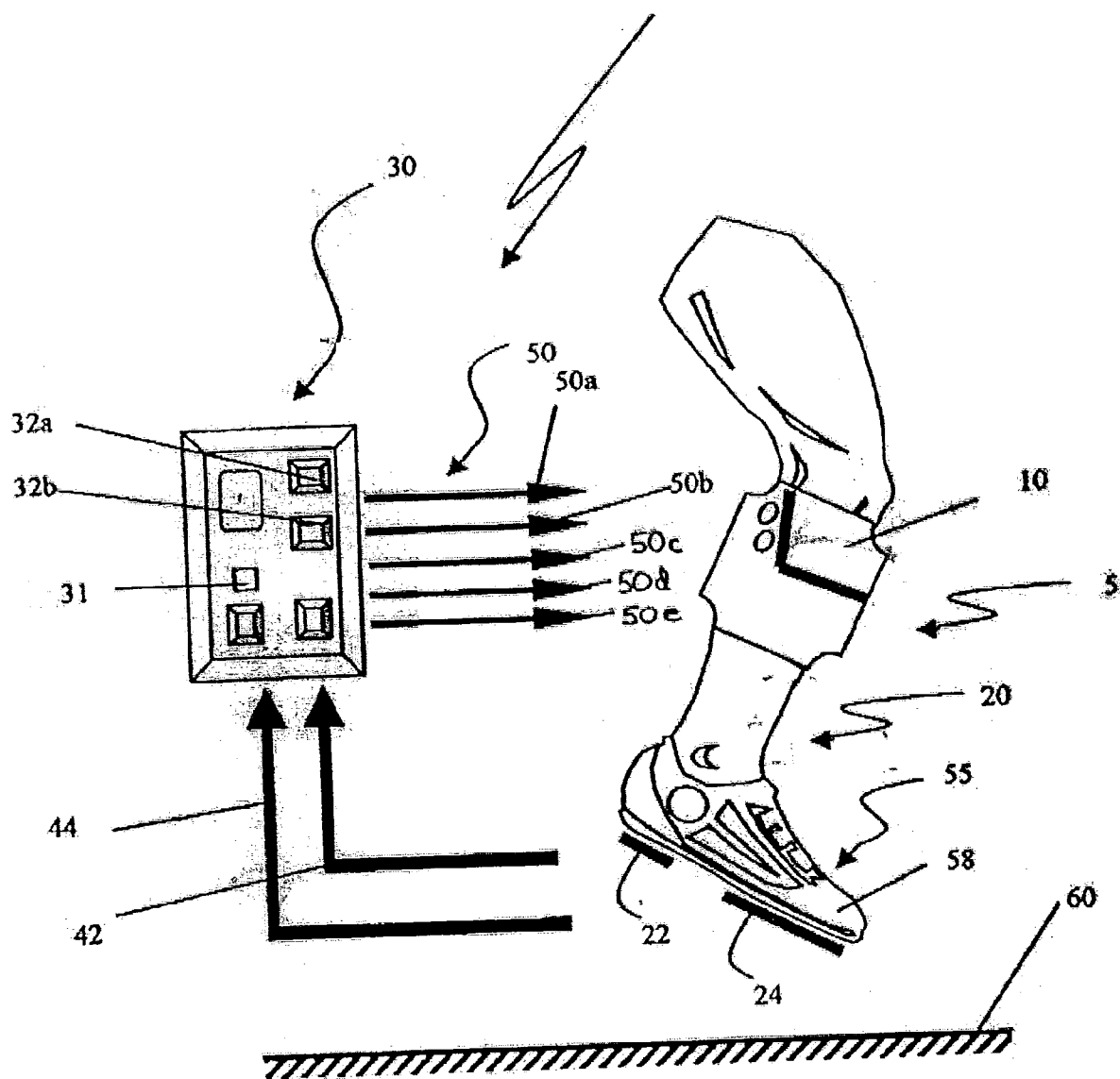


FIGURE 1

NEUROPROSTHESIS SYSTEM FOR IMPROVED LOWER-LIMB FUNCTION

[0001] This application draws priority from PCT/IL02/01020, filed Dec. 18, 2002, which draws priority from U.S. Provisional Patent Application Serial No. 60/340,277, filed Dec. 18, 2001.

FIELD AND BACKGROUND OF THE INVENTION

[0002] The present invention relates to a surface neuroprosthesis device and method for functional electrical stimulation (FES) of impaired lower limbs, and particularly, to a surface neuroprosthesis device and method for improving lower limb function of users having neuromuscular impairment of the lower limbs.

[0003] It is known that pathologies of the neuromuscular system due to disease or trauma to the central nervous system, such as stroke, spinal cord injury, head injury, cerebral palsy and multiple sclerosis, can impede walking and leg function. Gait, the biomechanical description of walking, can suffer static and dynamic parameter variations due to neuromuscular impairments, and can, as a result, become non-symmetrical, unaesthetic, require increased energy consumption and cause reduced walking speed. Typical gait patterns associated with specific pathologies can be identified.

[0004] Standing up, balanced standing, and gait are fundamental lower limb functions in human beings. Leg movement patterns are coordinated in closed loop by sensory inputs, such as pressure distribution between foot and floor, proprioceptive joint angle and body tilt. Gait, standing up, and balanced standing are lower leg functions that require fast, on-line, closed-loop limb control. For example, control of the ankle joint by the plantar flexor and dorsi flexor muscle groups is facilitated and inhibited by afferent feedback from the natural neurological sensors on the heel and on the anterior sole of the foot, the lower limb joints, and the inner ear.

[0005] When the electrical paths from the brain to the lower extremities are damaged, paralysis of the muscles and sensors in that region often ensues. However, the leg muscles can generally be activated with Functional Electrical Stimulation (FES). FES is a methodology that uses bursts of short electrical pulses, applied to motor nerves, to generate muscle contraction. The first neuroprosthesis rehabilitation system for improving or restoring gait function based on FES was proposed in 1961 by Liberson, et al., in an article "Functional Electrotherapy: Stimulation of the Peroneal Nerve Synchronized with the Swing Phase of the Gait of Hemiplegic Patients", Arch. Phys. Med. and Rehab., 42: 101-105 (1961).

[0006] The system of Liberson, et al., was developed to correct dropfoot, one of the most common neurological impairments associated with lower limb function. Dropfoot describes the gait attributable to weak or uncoordinated activation of the ankle dorsi flexors and resulting in insufficient lifting of the distal foot segment on the affected side of the body during the swing phase of the gait cycle. The result is usually dragging of the toes along the floor, or lifting them by ugly compensatory movements of the body such as exaggerated hip circumduction, or pelvic hiking.

These compensatory movements are unaesthetic, energy consuming, and slow down the gait.

[0007] The gait modulation system is now well known in the field of neurological rehabilitation. The first gait modulation system used FES in a closed loop arrangement in which a foot sensor activates the ankle dorsi flexor muscles and the toe-off event of the gait cycle corrects foot-drop. In the 40 years that have elapsed since the proposed system of Liberson, et al., this concept has been further developed, and today a variety of gait modulation systems in the field of neurological rehabilitation are available and are reported widely in the academic, medical, and commercial literature.

[0008] The first commercial system applied to stroke patients, and subsequently to incomplete Spinal Cord Injury (SCI) patients was disclosed by Bajd, et al., in "Functional Electrical Stimulation: standing and walking after spinal cord injury", CRC Press, Boca Ration, Fla., 1989. Bajd, et al., teach the use of an FES system with six stimulation channels. Two channels are used to stimulate the peroneal nerves bilaterally, and two channels serve to stimulate the quadriceps muscles bilaterally. The paraspinals or the gluteus maximus/minimus muscles are stimulated with the remaining two channels for those patients who cannot voluntarily extend the lower back.

[0009] In "Two channel stimulation for hemiplegic gait. Control algorithms, selection of muscle groups and the result of preliminary clinical trial", presented at the 6th Internet World Congress for Biomedical Sciences, INABIS 2000, Burrige, et al., report on state-of-the-art lower limb neuroprosthesis technology and emerging trends. Burrige, et al., describe neuroprostheses having two output channels delivering stimulation to the lower leg and/or thigh segments according to the requirements of the patient. Algorithms relating state value of feedback parameters to the activated musculature and limb joint are tabulated.

[0010] Today, feedback for lower limb neuroprostheses can be provided by a variety of artificial sensors, such as ON-OFF switches indicating foot contact on the floor, force and pressure sensors monitoring the foot—floor reaction and monitoring the position of the reaction along the foot; by gyroscopic tilt sensors or accelerometers monitoring the limb link angle with respect to the vertical, and goniometers or accelerometers to monitor the lower limb kinematics and dynamics.

[0011] Although 40 years have elapsed since the lower leg neuroprosthesis was first proposed, much room remains for improving the technological quality of these systems. This is reflected, inter alia, by the relatively small percentage of users who adopt a lower limb neuroprosthesis into their daily lives. The lower limb neuroprostheses of today have yet to approach and achieve their full potential in the rehabilitation field.

[0012] There is therefore a recognized need for, and it would be highly advantageous to have, an improved neuroprosthesis device and method for functional electrical stimulation (FES) for users suffering from gait problems, so as to achieve optimal muscle response for locomotion and balanced standing, and at the same time reduce the conscious contribution required from the user in operating the system.

SUMMARY OF THE INVENTION

[0013] The present invention is a surface neuroprosthesis device and method for functional electrical stimulation

(FES) for improving lower limb function of patients having neurological impairment of the lower limb.

[0014] It is an object of the present invention to provide a "timeout" and shutdown attribute that ramps down the stimulation when the system state input remains unchanged for a period exceeding a predetermined period of time, and to ramp up the stimulation and return to normal system operation when the device senses a genuine attempt by the user to renew activity.

[0015] It is also an object of the present invention to provide a sensor bias providing gait phase delay when triggering the muscle activation in response to an indication from the sensor system.

[0016] It is a further object of the present invention to provide an artificial balance-control algorithm for enhancing balance of the user during standing, by stimulating the appropriate muscles at the requisite time.

[0017] According to the teachings of the present invention there is provided a gait modulation system utilizing functional electrical stimulation for improving lower-limb function of a patient having neuromuscular impairment of the lower limbs, the gait modulation system including: (a) at least one sensor associated with at least one lower limb of the patient, for transducing a parameter related to the lower limb, so as to obtain gait information related to at least one gait event within a gait cycle; (b) a neuroprosthesis device including: (i) an electrode array operatively connected to an impaired lower limb of the patient, for performing functional electrical stimulation (FES) of at least one muscle of the impaired lower limb; (c) a muscle stimulator operatively connected to the electrode array, for supplying a muscle stimulation output to the array, and (d) a microprocessor operatively connected to at least one sensor, the microprocessor for processing the gait information and for controlling the muscle stimulation output via the muscle stimulator, wherein the gait modulation system has a sleep mode for autonomous reduction of the muscle stimulation output to the array, the microprocessor designed and configured to control the autonomous reduction based on the gait information.

[0018] According to further features in the described preferred embodiments, the microprocessor is designed and configured to identify a period of inactivity in the lower limb, and subsequently perform the control of the autonomous reduction.

[0019] According to still further features in the described preferred embodiments, the threshold time for the period of inactivity is T_1 seconds.

[0020] According to still further features in the described preferred embodiments, the parameter is a force-related parameter.

[0021] According to still further features in the described preferred embodiments, the parameter relates to a foot-floor reaction between the lower limb and a walking surface, and wherein the microprocessor is designed and configured to ramp down the muscle stimulation output when the gait information lies within a predetermined range for a first predetermined period of T_1 seconds.

[0022] According to still further features in the described preferred embodiments, the microprocessor is operative for

identification of an initiation of a period of activity in the lower limb, based on the gait information, and subsequently, for effecting an autonomous resumption of the muscle stimulation output to the electrode array, based on the identification.

[0023] According to still further features in the described preferred embodiments, the identification includes an algorithm for ignoring the gait information during a predetermined period of T_2 seconds, so as to inhibit inadvertent re-activation of the neuroprosthesis device.

[0024] According to still further features in the described preferred embodiments, the at least one lower limb includes the impaired lower limb.

[0025] According to still further features in the described preferred embodiments, the at least one lower limb is a single lower limb, and wherein the single lower limb and the impaired lower limb are different limbs.

[0026] According to still further features in the described preferred embodiments, the electrode array is for contacting at least a portion of a skin surface of the impaired limb, so as to deliver the FES via the skin surface.

[0027] According to still further features in the described preferred embodiments, the at least one sensor is selected from a group consisting of an on-off switch, force sensor, pressure sensor, gyroscopic tilt sensor, accelerometer, and goniometer.

[0028] According to another aspect of the present invention there is provided a gait modulation system utilizing functional electrical stimulation for improving lower-limb function of a patient having neuromuscular impairment of the lower limbs, the gait modulation system including: (a) at least one sensor associated with at least one lower limb of the patient, for transducing a parameter related to the lower limb, so as to obtain gait information related to at least one gait event within at least a part of a gait cycle; (b) a neuroprosthesis device including: (i) an electrode array operatively connected to an impaired lower limb of the patient, for performing functional electrical stimulation (FES) of at least one muscle of the impaired lower limb; (c) a muscle stimulator operatively connected to the electrode array, the muscle stimulator for supplying a muscle stimulation output to the electrode array, and (d) a microprocessor operatively connected to the sensor, the microprocessor for receiving and processing the gait information and for controlling the muscle stimulation output via the muscle stimulator, wherein the sensor has a bias introduced into the transduced parameter for time-biasing the muscle stimulation output with respect to the gait event, based on the gait information, so as to improve the lower-limb function of the patient.

[0029] According to still further features in the described preferred embodiments, the time-biasing of the muscle stimulation output is performed so as to anticipate the gait event.

[0030] According to still further features in the described preferred embodiments, the time-biasing of the muscle stimulation output is delayed with respect to the gait event.

[0031] According to still further features in the described preferred embodiments, the time bias of the muscle stimulation output is a function of a gait speed of the patient.

[0032] According to still further features in the described preferred embodiments, the time bias is proportional to the gait speed of the patient.

[0033] According to yet another aspect of the present invention there is provided a neuroprosthesis system for improving lower-limb function of a patient having neuromuscular impairment of the lower limbs, the neuroprosthesis system including: (a) at least one sensor associated with at least one lower limb of the patient, for producing a transduced parameter related to the lower limb, (b) a neuroprosthesis device including: (i) an electrode array operatively connected to an impaired lower limb of the patient, for performing functional electrical stimulation (FES) of at least one muscle of the impaired lower limb; (c) a muscle stimulator operatively connected to the electrode array, for supplying a muscle stimulation output to the electrode array, and (d) a microprocessor operatively connected to the sensor, the microprocessor for control, of the muscle stimulation output, using the transduced parameter, so as to improve a standing balance of the patient.

[0034] According to still further features in the described preferred embodiments, the microprocessor designed and configured to process the transduced parameter using an artificial balance control algorithm.

[0035] According to still further features in the described preferred embodiments, the electrode array is configured and disposed so as to perform the FES on an ankle plantar flexor.

[0036] According to still further features in the described preferred embodiments, the electrode array is configured and disposed so as to perform the FES on an ankle dorsi flexor.

[0037] The present invention successfully addresses the shortcomings of the existing technologies by providing:

[0038] an autonomous activation/deactivation system for reduced user involvement in operating the system,

[0039] a mechanism to fine-tune the timing of the activation of the muscles with respect to events in the gait cycle while allowing this timing to be linked to the gait speed of the user, and

[0040] a standing balance algorithm for improving the stability of the user during standing and walking.

BRIEF DESCRIPTION OF THE DRAWINGS

[0041] The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

[0042] In the drawings:

[0043] **FIG. 1** is a surface neuroprosthesis device for enhancing walking abilities of patients having lower-limb impairment, according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0044] The present invention is a surface neuroprosthesis device and method for functional electrical stimulation for improving walking abilities of patients having gait modulation problems.

[0045] The present invention reduces the need to involve the lower limb neuroprosthesis user in the control of his device, while increasing the efficacy of the device. The invention includes the transfer of certain low levels of hierarchical control from the patient to the device through a closed-loop feedback of relevant information to custom algorithms, which control the neuroprosthesis operation and output accordingly. When implemented, the enhanced neuroprosthesis device requires less conscious involvement on the part of the user and is conceived by the user as a part of the body. The device becomes less of an imposition and more of an assistant in daily life, significantly improving efficacy and practicability in routine home use. These enhancements address a number of specific issues associated with the use of the neuroprosthesis device, for example, when to activate or put on standby the whole system; standing balance; and modulation of the timing of onset or cessation of muscle activation in relation to the gait phases.

[0046] In general, the enhancements, included in the device reduce the voluntary control, or cognitive decision-making, required by the user in operating the neuroprosthesis device.

[0047] The principles and operation of the device and method according to the present invention may be better understood with reference to the drawing and the accompanying description.

[0048] Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawing. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

[0049] Referring now to the drawings, **FIG. 1** is a schematic illustration of a gait modulation system of the present invention. Gait modulation system **100** includes a surface neuroprosthesis device **5** worn by the user on a lower leg, typically on an impaired lower limb **20**, sensors **22** and **24**, and a microprocessor-controlled stimulator **30**. Surface neuroprosthesis device **5** includes an electrode array **10** for contacting a skin surface of lower leg **20**. Gait modulation system **100** is commanded and controlled by the user by means of push button inputs such as **32a** and **32b**, which are disposed on a face of stimulator **30**. The user can switch the system ON and OFF, select from a variety of operating modes, including exercise modes, such as reciprocal ankle joint excursions, and functional modes such as walking and

balanced standing modes. Additional push-button controls, disposed on a face of stimulator **30** and available to the user, allow for adjustment of global stimulation intensity, and for manually triggering a system standby mode when a pause in use of the system is required.

[0050] In addition to command communications from the user, system **100** receives feedback signals **42** and **44** from sensors **22** and **24**, respectively. Sensors **22** and **24** are typically proportional force sensors for sensing a foot **55**-floor **60** force reaction at the heel region (sensor **22**) and at the toe region (sensor **24**) of foot **55**. Sensors **22** and **24**, which are typically inserted between foot **55** and shoe **58** of the device-user, monitor the foot **55**-floor **60** reaction. It should be stressed that sensors **22** and **24** could be any other mechanism for sensing foot **55**-floor **60** contact or for otherwise sensing/determining, directly or indirectly, the position of a foot or lower limb within the gait cycle. Examples of such a mechanism include on-off switches, force and pressure sensors monitoring foot **55**-floor **60** reaction and/or the position of the reaction along foot **55**, gyroscopic tilt sensors or accelerometers for monitoring the limb link angle with respect to the vertical, and goniometers or accelerometers for monitoring lower limb kinematics and dynamics.

[0051] By way of example, U.S. Pat. No. 3,702,999 to Gradisar, which is incorporated by reference for all purposes as if fully set forth herein, discloses a force sensor. Two pairs of electrical conductors spaced by a resilient dielectric member, as the force sensitive means, are positioned in two predetermined locations in the shoe of the user. One pair is disposed beneath the heel and the other, beneath the ball of the foot.

[0052] Also incorporated by reference for all purposes as if fully set forth herein is U.S. Pat. No. 6,174,294 to Crabb, et al., in which force is sensed by measuring a change in electrical resistance disposed between two flat members embedded in the shoe.

[0053] In U.S. Pat. No. 4,745,930 to Confer, the feedback sensor is associated with a goniometer, while U.S. Pat. No. 4,647,918 to Gorforth discloses monitoring pressure points on the feet of the user. Both of the above are incorporated by reference for all purposes as if fully set forth herein.

[0054] Gait modulation system **100** of the present invention also conducts self-checks to ensure safe and reliable use by the user. For example, battery status is periodically monitored to reduce the danger of system shutdown or failure without prior warning.

[0055] Information of various kinds is input to a microprocessor **31** of microprocessor-controlled stimulator **30**. Subsequently, microprocessor **31** processes the information and determines an appropriate response, according to pre-programmed algorithms. System response is in the form of an electrical stimulation output **50**, which is schematically represented by stimulation channels **50a-e**, as well as visual or audio feedback to the user. Electrical stimulation **50** output is delivered to electrode array **10**, which is mounted on lower limb **20** in a position overlying the muscles to be activated. Microprocessor **31** switches each stimulation output channel (e.g., **50a** or **50b**) between the electrodes in electrode array **10**. Thus, stimulation sites underneath electrode array **10** may be selected, and stimulation output

delivered at intensities set by the control algorithms pre-programmed into microprocessor **31**.

[0056] Typically, force sensors **22** and **24** are utilized to detect the following gait phases:

[0057] Stance phase

[0058] Swing phase

[0059] as well as the following gait events (that relate to these gait phases):

[0060] Initial floor contact

[0061] Foot flat

[0062] Heel off

[0063] Toe off

[0064] As illustrated in FIG. 1, feedback signals **42** and **44** from force sensors **22** and **24**, respectively, are communicated to microprocessor **31**. Feedback signals **42** and **44** are proportional to the foot **55**-floor **60** reaction on the heel (sensor **22**) and on the front section of the sole of shoe **58** (sensor **24**). The signal is used both proportionally, and as a Boolean logic signal. Foot **55**-floor **60** reactions that are below configurable, pre-determined force thresholds ([Threshold₁] and [Threshold₂], respectively) are designated **0**. Foot **55**-floor **60** reactions that exceed Threshold₁ and Threshold₂ are designated **1**. Hence, in this arrangement, there exist 4 possible system input states:

S1 = 0, S2 = 0 $\Rightarrow$ State 1,	S1 = 0, S2 = 1 $\Rightarrow$ State 2,
S1 = 1, S2 = 0 $\Rightarrow$ State 3,	S1 = 1, S2 = 1 $\Rightarrow$ State 4.

[0065] where S1 represents arrow **42** in FIG. 1, the signal from force sensor **22**, and S2 represents arrow **44** in FIG. 1, the signal from force sensor **24**. The conversion of a sensed parameter to a feedback signal is termed "transduction".

[0066] Stimulation output **50**, directed to electrodes in electrode array **10**, is aimed to activate muscles of the lower limb, according to the state of the system.

[0067] A variety of mode algorithms, defining the stimulation output **50** for each system state input received from feedback signals **42** and **44**, are programmed into the system and are selectable by the system user. Table 1 provides an example of one of the gait modes.

TABLE 1

Muscle Group Activated	System State Input
Ankle Dorsi flexors	State 1
Ankle Plantar flexors	State 2
Ankle Dorsi flexors	State 3
Stimulation Off	State 4

[0068] As mentioned hereinabove, some preferred embodiments of the present invention reduce the voluntary control, or cognitive decision-making, required by the user in operating neuroprosthesis device **100**. These system enhancements are directed toward transferring, where appropriate, the operating commands of lower leg neuroprosthesis device **100** from the user to microprocessor **31**.

Microprocessor **31** receives feedback information from sensors **22** and **24**, and refers this input data to onboard algorithms. When indicated by sensors **22** and **24**, microprocessor **31** autonomously changes the system operating command and the system responds accordingly via stimulation channels **50a-e**.

[0069] In a preferred embodiment of the present invention, lower leg neuroprosthesis device **100** is configured with a "timeout" or "sleep" mode in which stimulation output **50** is curtailed. Normal daily activity usually involves periods of lower-limb activity, interspersed with periods of inactivity. It is required to switch ON the neuroprosthesis during activity, but desirable to switch OFF during periods of inactivity when no activation is required of the lower limb. Normally, in prior art devices, ON and OFF are operated by the user, and require his attention. Quite often, the user forgets to switch ON neuroprosthesis device **100**, or, upon completing a period of lower-limb activity, the user forgets to switch device **100** to an OFF position.

[0070] The "timeout" shutdown attribute ramps down stimulation output **50** when feedback information from sensors **22** and **24** remains unchanged for a period exceeding T_1 seconds. This indicates lack of user movement for a predetermined time T_1 , such that that device **100** automatically switches into "sleep" or "timeout" mode.

[0071] It has been found advantageous by the instant inventors to provide a window of several seconds after ramp down, in which any state change of sensors **22** and **24** is ignored. It has been observed by the instant inventors that the ramping down of stimulation output **50** promotes a relaxation of the activated muscles, often resulting in a movement of the limb. Such a movement effects a change in a state input of microprocessor-controlled stimulator **30**. This can happen, for example, when foot **55** drops to floor **60** during ramp-down, even though there is no intent to initiate activity on the part of the user. To prevent an immediate, inadvertent re-activation of the neuroprosthesis device **100** as the limb relaxes, changes in the feedback information from sensors **22** and **24** are ignored for a time period T_2 .

[0072] The values of time constants T_1 and T_2 can be configured into a memory associated with microprocessor **31**, according to user requirements.

[0073] After time T_2 , any further change in feedback information from sensors **22** and **24** causes device **100** to switch from "sleep" mode to activation mode, so as to resume stimulation output **50** according to the new state input.

[0074] For example, during quiet sitting, microprocessor **31** may monitor no change in feedback information from sensors **22** and **24** during a continuous period of time of 5 seconds. Stimulation output **50** is ramped down by microprocessor **31** and device **100** remains in "sleep" mode. A directed attempt by the patient to renew activity (e.g., to stand up and walk) will be sensed as a change in feedback information from sensors **22** and **24**. This results in a ramp-up of stimulation output **50** and a return to normal system operation.

[0075] It should be emphasized that this feature appreciably reduces user fatigue, as compared to conventional gait systems. In addition, device **100** is not subject to the power

waste that is inherent to conventional gait systems due to unnecessary operation of the neuroprosthetic device during periods of inactivity. This is of particular importance for neuroprosthetic device **100**, which is battery-powered, and hence attains a longer period of use between rechargings.

[0076] Another aspect of the present invention relates to a method and configuration for effecting a sensor bias, so as to enhance the efficacy of the gait modulation system. It is often advantageous to preempt the passing from one system state to the next in changing the muscle activation pattern. For example, at the end of the stance phase of the gait cycle, at toe-off, bringing forward the system state change to initiate ankle dorsiflexion a little earlier in the gait cycle can improve the gait in certain patients.

[0077] This is carried out by adjusting the values of Threshold_1 and Threshold_2 of the readings of sensors **22** and **24** in the memory associated with microprocessor **31**. The adjustment of such a threshold is termed in the present invention "sensor bias". Increasing sensor bias effectively introduces a delay in the system state change, when sensors **22** and **24** are being loaded. The length of the delay is the extra time taken until the force in sensors **22** and **24** reaches the level of the thresholds.

[0078] As sensors **22** and **24** are being unloaded, the thresholds preempt or anticipate the system state change by triggering the change as the force reduces to its threshold value, instead of to zero. This effectively allows the change in muscle activation, via stimulation output **50**, to be initiated earlier. As an example, sensor bias giving gait phase delay can occur between the gait events of heel-off and toe-off, where dorsiflexion is initiated at the end of the cycle phase, at toe-off. Here, the threshold value for the toe force S_2 in sensor **22** in passing from state 1 to state 0 can be increased. This will move forward in time the onset of State 1 in Table 1. The transition from plantar flexion to dorsiflexion is brought forward in time, eliciting certain benefits in the gait pattern of the patient.

[0079] In some advanced presently-available prior art gait modulation systems, a similar delay or preempt in muscle activation is provided by activating the stimulation at a preset time after the sensing of the appropriate gait cycle event. However, the delay or preempt of the muscle activation should ideally adapt to the gait speed or to events within the gait cycle. Since in these relatively advanced prior-art systems, the time delay is insensitive to gait speed, a mis-timing of the muscle activation results when the gait is slower or faster than the preset gait speed.

[0080] In the present invention, input from proportional sensors **22** and **24** is utilized by microprocessor **31** to trigger stimulation output **50** when the foot **55**-floor **60** force reaction is reduced to a preset force level. Since the time to reach this preset force level is proportional to the gait speed, the triggering of the muscle activation occurs at the correct time within the gait cycle.

[0081] Another aspect of the present invention relates to a method and configuration for providing artificial balance control, using natural balance reflex algorithms, so as to enhance the efficacy of the neuroprosthesis system. Natural balance reflex algorithms exist in the human neurological system for controlling the ankle and knee joints of the lower limb. As the body tilts forward, for example, afferent sensor

input to the neurological system tends to facilitate the ankle plantar flexors, while inhibiting the ankle dorsi flexors. The reverse occurs when the body tilts backwards—the ankle dorsi flexors are facilitated while the plantar flexors are inhibited.

[0082] In the present invention, this natural reflex loop forms the basis for an artificial feedback loop for enhancing balance control, using lower limb neuroprosthesis device 100. This “artificial balance control algorithm” is included in the lower limb neuroprosthesis as a separate mode, and is termed the “closed-loop standing mode”. Functional training or functional restoration of the ability to achieve balanced standing indicates use of the closed-loop standing mode.

[0083] Microprocessor 31 may be configured to control the balance algorithm proportionally, using the values of feedback signals 42 and 44 monitored by force sensors 22 and 24, or using the Boolean values of the sensor inputs of sensors 22 and 24 for “bang-bang” control, or using this feedback information in conjunction with any other control strategy.

[0084] Additionally, when the user is standing balanced and upright, and the values of sensors 22 and 24 are both 1, corresponding to state 4, the following programmed option is included:

[0085] (i) To zero the outputs of stimulation output 50, thereby deactivating the ankle joint musculature, and relaxing the joint.

[0086] (ii) To apply stimulation outputs of stimulation output 50 both to the dorsi and to the plantar flexors, activating the ankle musculature in “co-contraction”. This effectively stabilizes the ankle joint, but at a cost of fatigue.

[0087] Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

What is claimed is:

1. A gait modulation system utilizing functional electrical stimulation for improving lower-limb function of a patient having neuromuscular impairment of the lower limbs, the gait modulation system comprising:

(a) at least one sensor associated with at least one lower limb of the patient, said sensor for transducing a parameter related to said lower limb, so as to obtain gait information related to at least one gait event within a gait cycle;

(b) a neuroprosthesis device including:

(i) an electrode array operatively connected to an impaired lower limb of the patient, said electrode array for performing functional electrical stimulation (FES) of at least one muscle of said impaired lower limb;

(c) a muscle stimulator operatively connected to said electrode array, said muscle stimulator for supplying a muscle stimulation output to said electrode array, and

(d) a microprocessor operatively connected to said at least one sensor, said microprocessor for processing said gait information and for controlling said muscle stimulation output via said muscle stimulator,

wherein the gait modulation system has a sleep mode for autonomous reduction of said muscle stimulation output to said electrode array, said microprocessor designed and configured to control said autonomous reduction based on said gait information.

2. The gait modulation system of claim 1, wherein said microprocessor is designed and configured to identify a period of inactivity in said at least one lower limb, and subsequently perform said control of said autonomous reduction.

3. The gait modulation system of claim 2, wherein a threshold time for said period of inactivity is T_1 seconds.

4. The gait modulation system of claim 1, wherein said parameter is a force-related parameter.

5. The gait modulation system of claim 1, wherein said parameter relates to a foot-floor reaction between said at least one lower limb and a walking surface, and wherein said microprocessor is designed and configured to ramp down said muscle stimulation output when said gait information lies within a predetermined range for a first predetermined period of T_1 seconds.

6. The gait modulation system of claim 1, wherein said microprocessor is operative for identification of an initiation of a period of activity in said at least one lower limb, based on said gait information, and subsequently, for effecting an autonomous resumption of said muscle stimulation output to said electrode array, based on said identification.

7. The gait modulation system of claim 6, wherein said identification includes an algorithm for ignoring said gait information during a predetermined period of T_2 seconds, so as to inhibit inadvertent re-activation of said neuroprosthesis device.

8. The gait modulation system of claim 6, wherein said at least one lower limb includes said impaired lower limb.

9. The gait modulation system of claim 6, wherein said at least one lower limb is a single lower limb, and wherein said single lower limb and said impaired lower limb are different limbs.

10. The gait modulation system of claim 6, wherein said electrode array is for contacting at least a portion of a skin surface of said impaired limb, so as to deliver said FES via said skin surface.

11. The gait modulation system of claim 1, wherein said at least one sensor is selected from a group consisting of an on—off switch, force sensor, pressure sensor, gyroscopic tilt sensor, accelerometer, and goniometer.

12. A gait modulation system utilizing functional electrical stimulation for improving lower-limb function of a patient having neuromuscular impairment of the lower limbs, the gait modulation system comprising:

(a) at least one sensor associated with at least one lower limb of the patient, said sensor for transducing a parameter related to said lower limb, so as to obtain gait information related to at least one gait event within at least a part of a gait cycle;

(b) a neuroprosthesis device including:

(i) an electrode array operatively connected to an impaired lower limb of the patient, said electrode array for performing functional electrical stimulation (FES) of at least one muscle of said impaired lower limb;

(c) a muscle stimulator operatively connected to said electrode array, said muscle stimulator for supplying a muscle stimulation output to said electrode array, and

(d) a microprocessor operatively connected to said at least one sensor, said microprocessor for receiving and processing said gait information and for controlling said muscle stimulation output via said muscle stimulator,

wherein said sensor has a bias introduced into the transduced parameter for time-biasing said muscle stimulation output with respect to said gait event, based on said gait information, so as to improve the lower-limb function of the patient.

13. The gait modulation system of claim 12, wherein said time-biasing of said muscle stimulation output is performed so as to anticipate said gait event.

14. The gait modulation system of claim 12, wherein said time-biasing of said muscle stimulation output is delayed with respect to said gait event.

15. The gait modulation system of claim 12, wherein a time bias of said muscle stimulation output is a function of a gait speed of the patient.

16. The gait modulation system of claim 15, wherein said time bias is proportional to said gait speed of the patient.

17. The gait modulation system of claim 12, wherein said at least one sensor is selected from the group consisting of force sensor, pressure sensor, gyroscopic tilt sensor, accelerometer, and goniometer.

18. A neuroprosthesis system for improving lower-limb function of a patient having neuromuscular impairment of the lower limbs, the neuroprosthesis system comprising:

(a) at least one sensor associated with at least one lower limb of the patient, said sensor for producing a transduced parameter related to said lower limb,

(b) a neuroprosthesis device including:

(i) an electrode array operatively connected to an impaired lower limb of the patient, said electrode array for performing functional electrical stimulation (FES) of at least one muscle of said impaired lower limb;

(c) a muscle stimulator operatively connected to said electrode array, said muscle stimulator for supplying a muscle stimulation output to said electrode array, and

(d) a microprocessor operatively connected to said at least one sensor, said microprocessor for control of said muscle stimulation output, using said transduced parameter, so as to improve a standing balance of the patient.

19. The neuroprosthesis system of claim 18, said microprocessor designed and configured to process said transduced parameter using an artificial balance control algorithm.

20. The neuroprosthesis system of claim 18, wherein said electrode array is configured and disposed so as to perform said FES on an ankle plantar flexor.

21. The neuroprosthesis system of claim 18, wherein said electrode array is configured and disposed so as to perform said FES on an ankle dorsi flexor.

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