A HYBRID ORTHOSIS FOR PARAPLEGICS INCORPORATING FEEDBACK CONTROL

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ABSTRACT

A hybrid FES orthosis is described comprising a rigid ankle foot brace, a multi-channel FES stimulator with surface electrodes, body mounted sensors, a 'Rule Based' controller and an electro-cutaneous display for supplementary sensory feedback.

The mechanical brace provides stability, without FES activation of muscles, for standing postures normally adopted by patients. This avoids inducing muscle fatigue during prolonged standing. However, stability is conditional upon the position of the ground reaction vector (GRV). The closed loop FES controller reacts automatically to destabilising shifts of the GRV by stimulating appropriate anti-gravity musculature to brace the leg. The FES system also features a control mode to initiate and terminate flexion of the leg during forward progression.

A simple mode of supplementary sensory feedback was used during the laboratory standing tests to assist the patient in maintaining a set posture.

Preliminary results of laboratory tests for two spinal cord injured subjects are presented.

KEYWORDS: Hybrid Orthosis, Closed Loop Control, Sensory feedback.

INTRODUCTION

A prototype neuromuscular orthosis based on the "Hybrid Orthosis" concept (1,2) is described. The main mechanical component used was a modified form of the floor reaction ankle foot orthosis (FRO) (3).

The clinical application of the FRO to paraparetic patients having partial voluntary control of knee extensors and hip flexors has been reported (3,4). The device was found to be cosmetically acceptable and is easy to donn and doff with standard footwear. Conditional stabilisation of the leg, without muscle activity, was possible provided that the ground reaction force vector (GRV) passed the knee joint axis anteriorly. The rigid FRO also provides protective immobilisation for the joints of the ankle and foot. The brace also prevents foot drop whilst stepping and partially compensates for ankle plantar flexor paralysis during stance and push off.

The leg will destabilise whenever the direction of the GRV lies posterior to the knee joint axis, for example, whilst transferring or at heel contact during walking. Such destabilising events are often of short duration and occur infrequently. Previous applications of the FRO required the patient to be able to maintain a sufficiently strong contraction of quadriceps for the duration of the destabilising event. In addition, the patient was required to be able to flex and extend his leg to step forward.

In the present application, patients with a more extensive upper motor neurone paralysis of the lower limbs are considered. Here we describe the application to spinal cord damaged paraplegic patients. FES was applied efferently to the quadriceps during such destabilising transients and afferently to withdraw the leg during stepping.

Many patients with spinal lesions above the segmental level of T5 have poor trunk stability. This can produce an exaggerated lordosis if the patient stands with braced knees and hyperextended hips. Even if the patient has sufficient upper limb function, poor trunk stability often precludes independent KAFO assisted locomotion. In order to extend the present application to some of these patients a moulded plastic spinal brace was used. This brace is normally worn underneath the patient's clothing. The spinal brace also provides a convenient structure within which parts of the electronic system could be incorporated.

An electro-cutaneous display, providing supplementary sensory feedback, was incorporated into the system. During standing, postural information was derived from transducer signals within the FRO. These signals were encoded on-line and fed back to the patient via the display.

CONTROL MODES

Standing Posture Control.

The strategy for maintaining a stable anterior/posterior (A/P) standing posture is discussed with reference to the angle-angle, posture space, diagram and associated multi-link model shown in figure 1. Consider the typical application of FES standing in which the knee joints are maintained in extension by activation of quadriceps and the ankle joints are free to move. If the upper limbs are not used then the hip and ankle angles must lie exactly on the line BF for the model to be metastable. The model is critically stable: any slight deviation would result in collapse due to the action of gravity. However, if the ankle joint is fixed in the neutral position, a region of stability bounded by OBC is created in the posture space. In this region no muscular action is required to stabilise the model. Excursions within this region will tend to return to the upper boundary BC due to the influence of gravity extending the hip. The region OBC is further extended to include: region stabilised by activation of the hip extensors; region OHAB if the knee joint is stabilised by activation of quadriceps; region OHGF if both hip and knee angles are stabilised. The existence of such stable regions suggests a number of strategies for standing posture control. The ankle joint may be fixed by muscular activation, bony fusion or external mechanical bracing. In practice, postural movements would normally occur in the right half of the posture space shown in figure 1. Thus the ankle joint need only be stopped for dorsiflexion movements. This may already be present in some paraplegics due to contracture or increased tone in the ankle plantar flexors.

The following simple ON/OFF strategy was used for the tests reported here. The hip joint was maintained in hyperextension by the patient. In order to maintain stability without quadriceps activity, sway movements must remain within the points BC. At C the forward inclination is given approximately by arctan(foot length/leg length) i.e. about 16 degrees. At this point and beyond, the patient will topple forward. Should this occur, the knee extensors remain activated until the patient has returned himself into the stable region using his upper limbs. For backward movement along line AB the gravity line passes behind the knee joint axis. To prevent knee flexion, the quadriceps were maximally activated. Movement beyond A will result in the patient toppling backwards. Again, in this situation, the quadriceps remain activated until the patient has restabilised himself.

In order to appropriately switch the activation of quadriceps, the points B and C must be detected i.e. the points of onset of knee flexion.

In the present implementation, the onset of knee flexion was detected using a flexible knee goniometer. A small amount of knee flexion then extension was observed as the quadriceps restabilised the leg. In addition, force actions between the limb and brace were used to estimate the displacement of the GRV relative to the knee joint. It then became possible to set thresholds within the boundary limits set by points B and C, for example B′ and C′, to brace the leg prior to destabilisation.

Figure 1(a) shows the GRV passing anteriorly to the ankle and knee joint axis. In this posture, the FRO maintains the knee joint in full extension without the need of quadriceps action. The GRV is balanced by a limb/brace reaction force producing localised pressure on a pad positioned below the patella tendon. A tension (T) is produced in the cable restraining the pressure pad to the brace uprights. The tension was monitored by means of an in-line strain-gauged ring dynamometer. The output tension signal is a function of both the magnitude and line of action of the GRV relative to the ankle joint. A thin, flexible, limb load insole, shown in figure 2, was used to produce a signal proportional to the magnitude of the ground reaction force (GRF). This insole was based on force sensing resistive films supplied by Interlink Electronics (7). The cable tension signal was normalised by the limb load to produce a signal proportional to the anterior displacement of the GRV. The appropriate control rule is that the quadriceps are switched off if the knee is extended and A/P inclinations occur within B′ and C′, otherwise they are activated.

This control rule provides a simple artificial knee extension reflex (KER). Furthermore, the stimulation is applied in a simple ON/OFF manner at preset maximal levels. In order to obtain a rapid, fused and forceful response, the stimulus was initially applied at a relatively high frequency up to 100Hz. The patient should then restabilise his posture using his upper limb(s). Should the patient continue to maintain an unstable posture for more than 4 seconds, the stimulus frequency is progressively reduced to 20Hz within 15 seconds with automatic compensation of pulse width.

Control of Transfer.

Initially, the FES system is reset to the STAND UP mode and there is no output stimulation. The patient moves to the edge of the seat with both feet positioned on the floor. In this position, the legs are flexed. The patient prepares for the manoeuvre by gripping the supporting frame or crutches. He then signals his intention to stand up by pressing a miniature pressure switch against the supporting frame. The switch was incorporated into a ring usually worn on the the thumb. Once the signal to stand has been given, the FES control system checks that both legs are flexed before activating the quadriceps. The stimulus was applied bilaterally and progressively increased from zero to a preset maximum, in two seconds. The patient may regulate his rate of ascent by taking more or less body weight through his upper limbs. Once upright, with the hip and knee joints extended, the FES system assumes the posture control mode described above. When ready to sit down again, the subject presses the ring switch twice within 2s. Maximal stimulus is applied to the knee extensors, and this progressively decreases over a period of 6s enabling the subject to return slowly to his seat. The FES system then assumes the reset mode. The patient´s rate of descent is controlled by the amount of body weight he takes through h is upper limbs. The thumb mounted ring switch enables the patient to signal his intention to the controller without having to remove his hand from the support.

Control of ´Swing Through´ and ´Swing To´ Gait.

With the patient standing the KER operates as described above. When the patient unloads his legs to make a swing forward, the KER´s of both legs are automatically evoked. The activated quadriceps maintain the legs braced in extension throughout the swing-through and foot-contact phases until the GRV again moves anterior to the knee joints. Thus during the stance phases the quadriceps are inactive.

Manual Control Of Stepping.

When the patient intends to make a step he first shifts his body weight onto the support leg. Stimulation is then applied to flex the leg. When sufficient flexion has been achieved the quadriceps are activated to extend the leg prior to foot contact. This operation can be manually controlled using a finger operated switch mounted onto the support handgrip.

From the patient´s control point of view, the gait cycle was divided into stance and swing phases. For each leg the transition from one phase into another was achieved by pressing a corresponding hand switch. These hand switches were mounted onto the handgrips of the forearm crutches, walking frame or rollator. When a switch was not pressed the KER was enabled. In order to take a step forward, the subject first transferred his body weight onto the support leg and then pressed the ipsilateral hand switch. Whilst the switch was pressed, the ipsilateral KER was disabled and the common peroneal nerve stimulated. Stimulation of this mixed nerve results in dorsiflexion of the foot and reflex flexion of the knee and hip. The amount of flexion was dependent upon the preset stimulus intensity. In order to terminate the swing phase prior to foot contact, the hand switch was released. The KER was then re-enabled and the knee extended. The peroneal stimulus was removed after a delay of approximately 0.3s. This overlap of the withdrawal stimulus was required to maintain hip flexion until foot contact. The duration of the swing phase was regulated by the time of pressing the switch. The quadriceps stimulus was maintained until shortly after foot contact when the GRV shifted anterior to the knee joint. Thus, the quadriceps were activated only during terminal swing and early stance phases.

Automatic Control of Stepping.

A method was devised to automate the initiation and termination of the flexion stimulus in the above scheme. The patient's intention to make a step is detected from sensor signals. The KER is then inhibited and stimuli applied to elicit a withdrawal reflex to flex the leg. When the desired preset hip angle is reached the KER is re-enabled and the withdrawal stimulus removed shortly afterwards as described above. The patient's intention to step was detected using the limb load insole described above. Also an Interlink Electronics sensor was positioned on the crutch handgrip as shown in figure 3 to give a measure of crutch contact and load. The detection scheme was based on the following observed sequence of crutch aided walking events prior to stepping. The contralateral crutch is lifted off the floor and brought forward to make contact again during double support. The patient then unloads the ipsilateral leg by transferring body weight onto the contralateral leg just before ipsilateral flexion is required to initiate the step. This gives three events that can be detected from the crutch and insole sensors, namely crutch contact, progressive crutch loading to a preset threshold followed by leg unloading below a set threshold. The crutch loading and leg unloading events occur within a short preset time window following crutch contact. The intention to step is detected by a set of rules based on the temporal course of these events. Once the intention is detected, the KER is inhibited and the peroneal nerve stimulated at preset maximum intensity to initiate flexion. The hip angle is measured using a flexible goniometer (not shown). Once the hip has flexed to a preset angle the KER is re-enabled and the peroneal stimulus removed after a short delay as described above. A typical set of sensor signals for a single step is shown in figure 4.

SYSTEM COMPONENTS

The Floor Reaction Brace.

The plastic ankle foot component was fabricated in a similar manner to that described in (3,4) using either high density thermoplastic or reinforced laminate formed on to a rectified plaster model of the patient´s shank and foot. The FRO shoe insert was extended beyond the toes and had a stiffened rim to give a rigid footplate. To be effective, the plastic brace must be rigid, particularly in the region of the ankle and footplate.

Spinal Brace.

The totally contacting spinal jacket was thermoformed onto a plaster model of the patient´s trunk and pelvis. The two overlapping edges of the anterior join were designed to interlock when brought together using the two velcro straps. The effect is to produce a rigid tube around the patient that effectively immobilises the trunk without restricting hip joint movement.

Supplementary Sensory Feedback.

Sensory feedback was used to warn the patient whenever he deviated from a preset inclination (within the boundary points B´ C´ shown in figure 1) or a preset level of relative leg loading. A small inclinometer was used to monitor the patient´s fore and aft sway. The insole limb load monitors were used to determine relative limb loading. The feedback stimulus used for these tests was 200Hz, 0.03ms duration pulses; the intensity adjusted until comfortable. The feedback stimuli were at four sites symmetrically positioned on the anterior, posterior, left lateral and right lateral aspects of the upper trunk in the sensate regions. The stimulus was applied such that when the patient leaned forward beyond the set incline threshold, the anterior stimulus was applied. Similarly, when he leaned backwards beyond the threshold, the posterior stimulus was applied. Also, if the left/right leg loads exceeded the set ratio, then the left lateral stimulus was applied and vice versa for the right lateral stimulus. An adjustable ´dead space´ was incorporated centred on the set regulation point. This dead space allowed small amplitude sway movements to occur about the set point without stimulus being constantly switched between the four sensory sites.

FES Control System.

For these laboratory tests the FES system comprised a BBC microcomputer as the central controller. This computer was linked to a microprocessor based multi-channel stimulus pulse generator with regulated current outputs. For these tests the output pulses were monophasic in shape with parameters programmable within the following ranges: pulse width 0.02 - 1ms (resolution 10us), pulse repetition frequency 15 - 200Hz, amplitude 0 - 120mA.

The BBC microcomputer´s role was to continuously sample the sensor signals and patient controls, apply the control rules and send control codes as necessary to the programmable stimulator to change the stimulus pulse parameters. The rules were implemented as a set of logical IF (logical expression) THEN (adjust output) statements where the logical expression was a function of past and present sensor outputs and their temporal relationships (i.e. a finite state automaton). Typically the BBC cycled round this process fifty times per second.

LABORATORY TESTS

Two patients with spinal cord lesions are presented. In each case, the quadriceps muscles were conditioned using an FES exercise regime similar to that described in (5).

PATIENT A:

Male, aged 21yrs, mass 57kg, height 1.6m, lesion T6/7 complete, 1yr post injury.

At the time of injury he also sustained fractured ribs and a punctured lung. This patient was initially fitted bilaterally with the FRO without a spinal brace. He used the system for standing. He was able to stand for periods up to 30 minutes. These periods were limited by discomfort and difficulty with breathing due to an exaggerated lordosis. During repeated 30 minute standing sessions, undertaken in parallel bars using both hands, quadriceps activity was observed for approximately 17% of the standing time. This was because he found it necessary to periodically lift himself off the ground in order to relieve chest discomfort.

He was subsequently fitted with a spinal brace as shown in figure 5. The spinal brace controlled his lordosis and stabilised the trunk. During subsequent standing tests for periods in excess of 30 minutes he did not report any further discomfort. Apart from the initial quadriceps activity during the standing up manoeuvre, he was consistently able to demonstrate standing for periods in excess of 30 minutes without quadriceps activity.

This patient was also fitted with the electro-cutaneous sensory stimulus array. To illustrate the effect of this mode of sensory feedback on posture regulation the following test was performed. The patient stood on a Kistler force platform and the centre of force (COF) was monitored. The sensory feedback was initially disabled and the patient was asked to maintain a steady posture using one hand with his eyes open. The COF variations for a typical 2 minute period are shown superimposed on the computed regulation point marked in figure 6. The set point of the sensory feedback controller was adjusted to position 1 together with a small offset to correspond to position 2. He was then asked to close his eyes and the sensory feedback was enabled. He quickly adjusted himself to the new position and was able to maintain it without difficulty. A typical 2 minute record of the COF variations about this new position are shown superimposed on figure 6.

PATIENT B:

Male, aged 23yrs, mass 70kg, height 1.8m, incompletely lesioned at the level C6, 6yrs post injury.

This patient presented with a functionally complete paralysis of his left leg. He was unable to stand independently. However, once assisted into a stable standing position, he had sufficient voluntary control of his right leg and trunk to enable him to remain standing for short periods using forearm crutches without FES. He had previously used a 2 channel FES device fitted unilaterally to his left leg. The FES orthosis enabled standing, walking and negotiation of steps and uneven terrain (6). He was limited by the onset of quadriceps fatigue after approximately 15-20 minutes. This subject used the FRO unilaterally for standing and walking using forearm crutches. Quiet standing was possible without any assistance of the upper limbs. He was able to remain standing using crutches for periods in excess of one hour. This time was not limited by quadriceps fatigue. He was able to ambulate for periods in excess of 30 minutes limited by habituation of the withdrawal reflex. This patient preferred the option of automatic triggering of flexion whilst walking on level ground (see figure 7). A typical set of sensor signals and stimulus activation times for one cycle is given in figure 4.

DISCUSSION

These preliminary trials indicate that the application of the FRO may be extended to cases where the quadriceps are paralysed but electrically excitable and where the withdrawal reflex is intact. The duty cycle of stimulation delivered to the quadriceps was found to be greatly reduced during standing and walking. This avoided fatigue and prolonged the time for which the device could be used . The quadriceps were stimulated in an ON/OFF manner thus eliminating the need for periodic adjustment of stimulus intensity. During quiet standing, only a minimum of upper limb action was found to be required to maintain stability. The electro-cutaneous feedback was useful in maintaining a fixed posture. In future applications, an alternative vibro-tactile display will be investigated.

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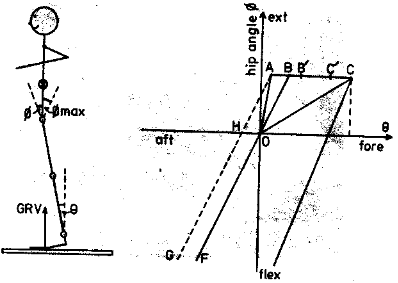

Fig 1 Posture control (a) Multi-linkmodel;
(b) Posture space diagram.

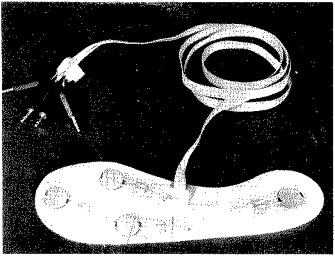

Fig 2 Insole limb load sensor incorporating force-sensitive resistors in four locations beneath the foot surface.

Fig 3 Crutch load sensor using a single force sensitive resitor on the handgrip.

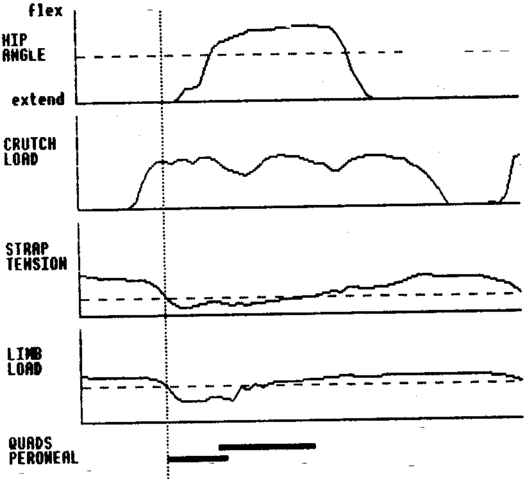

Fig 4 Time plot showing the sensor outputs during automatically controlled gait. The broken lines indicate the threshold levels used to trigger and terminate stimulation of flexion and knee extension.

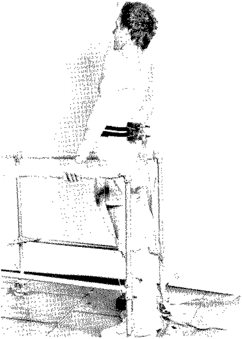

Fig 5 Patient A standing with FRO extension feedback system and spinal brace.

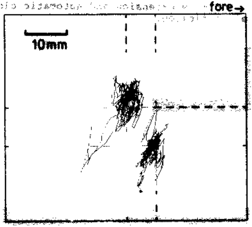

Figure 6 Two-minute traces of centre of force during quiet standing in two different postures.

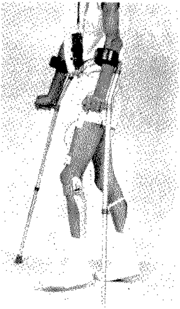

Fig 7 Patient B using FRO-based walking system with feedback control of knee extension and automatic closed-loop control of flexion.

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