A PROTOTYPE MODULAR HYBRID FES ORTHOTIC SYSTEM FOR PARAPLEGICS

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ABSTRACT

A prototype modular hybrid system is described comprising a multichannel surface electrode FES control system and various brace options from ankle foot orthoses AFO's to hip knee ankle HKAFO devices.

The following mechanical brace options were implemented; KAFO's with automatic bale locks at the knee; knee stabilising floor reaction type AFO's; a compact reciprocating hip and trunk orthosis (RO). In the latter the hip hinges are coupled by a flexible linear bearing resulting in improvements over the traditional Bowden cable arrangement in terms of lower friction and no stretching.

Typically the FES component and the leg braces, AFO or KAFO, are worn continuously throughout the day to facilitate basic locomotor functions. Optionally, the RO can be added to further extend the overall functionality of the system.

Unlike previous HKAFO based systems the patient is able to quickly donn and doff the most encumbering of the mechanical brace components as and when required from the wheelchair. This feature significantly reduces the encumbrance to the patient during transfers and other activities of daily living.

So far the modular system has been used by one paraplegic subject for laboratory feasibility trials.

KEYWORDS: Hybrid FES Orthosis, Paraplegic locomotion, Modular systems.

INTRODUCTION

During FES assisted locomotion paraplegics expend energy at a relatively high rate compared with able bodied walking or wheelchair propulsion. As a consequence, the activity can only be sustained for a short time without frequent rest breaks. These rest stops should be taken whilst standing, otherwise a low pressure seat would have to be found. Ideally, the rest breaks should be sufficiently long to allow the FES activated musculature and withdrawal reflexes to recover. However many FES systems over-stimulate and rapidly induce muscle fatigue.

As an alternative, mechanical bracing can be used to stabilise the legs during weightbearing postures and FES applied only in short bursts to facilitate stabilization and forward progression. A number of such hybrid systems have been reported [Andrews et al. 1984, Andrews et al. 1988, Jaeger et al. 1988, Petrofsky et al. 1985, Schwirlitch & Popović 1984, Solomonow et al. 1989] with some incorporating externally powered actuators [Hausdorf & Durfee 1988, Popović & Schwirtlich 1987]. The term "Hybrid Orthoses" was used by both Schwirtlich & Popović 1984 and Andrews & Bajd 1984 at the same meeting to describe their systems following the concept described earlier by Tomovic, Vukobratovic and Vodovnik in 1972.

The Parawalker or Hip Guidance Orthosis (HGO)(Rose 1979) and LSU-RGO (Douglas et al. 1983) HKAFOs have been shown to facilitate level ground ambulation, both with and without FES, in paraplegics including those with high and low thoracic lesions. However the mechanical hardware, particularly that above the thigh, is encumbering to some patients for many activities of daily living such as transfers or toileting. Also the braces are inconvenient to repeatedly donn and doff and transport outside the home. Many adult paraplegics do not regularly wear the braces for extended periods and mainly use them for exercise where they are donned for each session (Cochrane & Whittle 1989).

This paper presents the initial experience in using a hybrid FES concept that attempts to integrate some useful principles and features of previous systems. The new system is modular in that a subsystem based on AFO or KAFO is worn continously, with minimal encumbrance, to which the RO component may be added as and when required.

BACKGROUND TO THE ORTHOTIC PRINCIPLES

The Floor Reaction AFO The stabilising effect on the knee of an anteriorly directed ground reaction force (GRF) when ankle dorsiflexion is restricted has been used to clinical advantage in facilitating weightbearing with a minimum of quadriceps activity. Restricted dorsiflexion may be naturally due to an equinus contracture as a result of muscle shortening or spasticity in the ankle plantarflexors. Mechanically imposed restriction of ankle dorsiflexion has also been used clinically to stabilise the leg in cases of quadriceps weakness due to various neurological disorders such as poliomyelitis and incomplete spinal cord injury. In these applications, dorsiflexing movement was restricted either by surgical arthrodesis (Matsuo & Wada 1976), ligament transfer or AFOs [Saltiel 1969, Lehneis 1972, Harrington et al. 1984, Yang et al. 1986] or rigid boots e.g. 'The Bologna Boot' (supplied by the Officine Ortopediche Rizzoli S.P.A., Bologna). In all cases patient must have sufficient muscle strength and control to stabilise the leg(s) and avoid dangerous collapse whenever the GRF becomes directed behind the knee joint axis e.g. when descending a slope or pulling on a door handle.

Reciprocating Orthoses The principle of reciprocally linking the hip joints in a HKAFO was developed in the late 1960's. At the Ontario Crippled Childrens Centre in Toronto Canada Motloch and collegues described a mechanism based on the use of gears [Annual Report 1968, O.C.C.C., Rumsey Rd., Toronto] and in the Paediatric

Research Unit of Guy's hospital in London England Scrutton described a mechanism based on the use of a pair of Bowden cables [Scrutton 1971]. Douglas et al. in 1983 described the LSU-RGO which is a refinement on the design of Scrutton.

Two useful features of such linking mechanisms are; the hip joints and trunk are stabilised against bilateral flexion during the double support stance phase; during the swing phase hip extension of the single support leg causes the contralateral hip to flex. The latter feature is useful for FES since direct hip flexion is difficult to achieve reliably using surface electrodes. However flexion and extension are coupled in a 1:1 motion which is abnormal.

THE PROTOTYPE MODULAR HYBRID FES ORTHOSIS

The overall system comprises two basic systems using AFO and KAFO braces respectively. To each of these basic systems the RO brace can be added as and when required. Each of these systems is described below with the FES control methods presently used.

The FES and Floor Reaction AFO Combination. The prototype AFO brace is shown in figure 1. The ankle joint was stopped between 0 and 5 degrees of dorsiflexion. The rigid footplate inserts into standard footwear and extends to the forefoot region. The footwear was of the sports trainer type with wedge shaped heels.

The principles of this hybrid combination and its control have been described elsewhere [Andrews et al. 1988,1989]. Whilst standing quietly, the patient was trained to adopt the 'C' posture. Vertical stabilization was achieved using preserved muscle actions of the trunk and upper limbs. The hips were stabilised in full hyperextension against the ilio- femoral ligament. In this posture the GRF is applied in the metatarsal region and is directed in front of the knee joint and behind the hip joint. In this posture, the leg is mechanically stable without muscle activation. The dorsiflexion stopped ankle joint and rigid footplate also provide a measure of vertical stabilization. Any tendency to lean forward will shift the region of support ahead of the vertical projection of the centre of gravity, producing a moment tending to restore verticality.

The knee stabilising action is due to stopped dorsiflexion, it is not nessessary to prevent plantarflexion and future designs are planned to utilise FES plantarflexion for propulsion.

Should the GRF shift behind the axis of rotation of the knee, then the knee would buckle. In response to such an event, the FES control system immediately stimulates the hip and knee extensors. The control system sensed knee buckling by means of a low profile flexible goniometer (Supplied by Penny & Giles Ltd. UK.) attached laterally to the skin across the knee joint using double sided adhesive tape.

To stand up from the seated position the user presses the 'Stand' control. The controller checks both knee angles and provided they are both suitably flexed the sequence continues otherwise the function is cancelled. A tone confirms the start of the stand-up sequence and the user has approximately three seconds to grip the support frame. Stimulation is applied bilaterally to quadriceps and hamstrings by means of a closed loop control system using the flexible goniometer signal as

Figure 1. Paraplegic subject fitted with RO and AFOs.

described by Andrews in 1990. Once both knees are extended, as detected by the brace goniometers, the controller for maintaining standing is enabled.

Sitting down is essentially the reverse procedure and begins when the user presses the 'Sit' control. The controller checks that the system state is 'double support', if so the sequence continues otherwise the function is cancelled. A tone confirms the start of the sit-down sequence. Stimulation is applied bilaterally to quadriceps and hamstrings initially with maximal intensity that progressively reduces to zero as the user is gradually lowered down.

An artificial knee extending reflex was implemented using the flexible goniometer to sense knee buckling and automatically stimulate the quadriceps and hamstrings according to the repeated application of following rules:

IF (knee angle is less than a preset value of knee flexion)

THEN (switch ON stimulation)

IF (knee joint is fully extended for 3s)

THEN (switch OFF stimulation)

Full extension is taken to be when the derivative of knee angle remains close to zero for 3s. This condition is also used to automatically reset the baseline knee angle for full extension. In the present implementation these rules were cyclically applied approximately every 10ms. This simple ON/OFF control loop limit cycles if the GRF is maintained close to the knee joint axis. However when the user leaned forward slightly, shifting the GRF anteriorly, the oscillations cease.

The methods used to control gait using floor reaction AFO's have been previously described for 4-point gait [Andrews 1989] and for swing through gait [Heller et al. 1990].

The AFO/RO system A prototype version of the RO is shown in figure 2. A flexible push-pull linear bearing (Bowdenflex, Supplied by Bowden Cables Ltd UK) was used to replace the usual bowden cables on standard LSU-RGO hip joints. Compared with Bowden cables the flexible linear bearing has a very low friction and does not need the periodic adjustments that are required with Bowden cables due to stretching in use. The linear bearing is attached to the RO by two self aligning spherical bearings (supplied by Rose Bearings Ltd UK) to accomodate the cyclical angular misalignment. Details of the modification are shown in figure 2. Once adjusted the reciprocal mechanism requires minimal maintenance. The distal shaft of the hip joint was modified by the addition of the lever actuated quick release locking mechanism to connect/disconnect the thigh cuffs. This release mechanism facilitates easy donning and doffing from the wheelchair.

FES assisted standing up and sitting down manoeuvres can be undertaken (with the linear bearing mechanism disconnected) as described above for the basic AFO system. Whilst standing, the knee stabilising artificial reflex is enabled (as described above for the basic AFO) and the reciprocating linear bearing mechanism is engaged to prevent bilateral hip flexion.

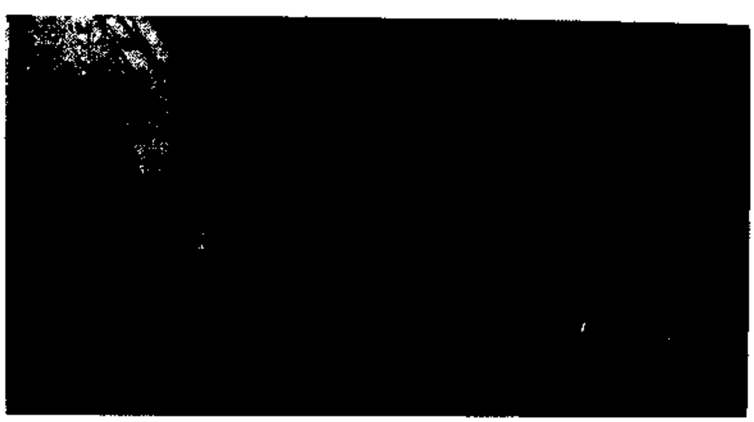

Figure 2. Details of the RO illustrating; flexible linearbearing (A); the self aligning spherical bearings (B) and the quick release lever actuated locking mechanism (C).

The same FES control may be used as indicated above for the basic AFO hybrid system. FES assisted 4-point walking may be undertaken with or without engaging the reciprocating mechanism. Swinging gaits must be undertaken with the mechanism disconnected. The free knee of the swinging leg facilitates ground clearance. The RO brace helps prevent hip adduction and the leg(s) from scissoring during the swing phases of gait. The RO also substitutes for the lack of hip abductors on the stance side during the single leg support phases of gait.

The KAFO/RO system The KAFO sections are usually worn continuously and may again be used with or without FES. The latter option provides a 'get you home' feature should the FES part fail.

The KAFO features an ankle joint stopped for dorsiflexion and a rigid footplate. The knee joints are of the bale type that automatically lock when the knee is fully extended if the control lever is free.

Without FES control the KAFO's may be used in the traditional manner with locked knees. With FES control, the KAFO knee locks are held disengaged and the same FES control system described for the above AFO system may be used for standing-up, sitting-down and prolonged standing.

As and when required, the RO can be connected or disconnected to the proximal lateral uprights of the KAFO sections using the quick release lever operated locking mechanism illustrated in figure 2. Without FES control the combination can be used in a functionally similar manner to the conventional LSU-RGO.

With FES control, the control of locomotion is similar to that described by previously in Cliquet et al. 1986, i.e. during the swing phase FES activation of the ipsilateral hip abductors and extensors of the supporting leg together with contralateral hip flexion using reflex stimulation of the common peroneal nerve. The hip abductors helped to prevent loss of ground clearance of the swing leg (since the brace is not absolutely rigid in the A/P plane). Because of the mechanical cross coupling of hip joints, stimulation of ipsilateral hip extensors caused the contralateral hip to flex. The latter may be reinforced by simultaneous stimulation of the contralateral withdrawal reflex causing hip flexion knee to facilitated reciprocal stepping. Alternatively rectus femoris may be stimulated, on the swing side, instead of the withdrawal reflex as described by Solomonow et al. 1989.

PRELIMINARY PATIENT LABORATORY TESTS

The volunteer subject shown in figure 1; male aged 22 yrs; mass 57 kg; height 1.6 m; traumatic lesion T6/7 motoric and sensory complete; 5 yrs post injury.

The subject had used KAFO's regularly for standing exercise and drag-to gait with a Zimmer frame. He had previously been fitted with an LSU-RGO orthosis and had achieved a good gait performance without FES. However he infrequently used the LSU-RGO only for exercise stating that it was too encumbering for everyday use. He had also previously completed a program of FES muscle restrengthening exercises for his quadriceps and was able to stand using bilateral quadriceps stimulation for periods up to 15 minutes. He had also been trained to perform 4-point gait using FES and a rollator in a similar manner to that described by Bajd et al. 1983.

The following observations were made during level ground straight line walking in the locomotion laboratory of the Bioengineering Unit. Electrical stimulation was applied using surface electrodes (Pals Plus, Supplied by Axelgaard Manufacturing Co.;Ltd., USA). Computer generated stimuli were frequency and pulse width modulated monophasic rectangular pulse trains (pulse width in the range 0.2-0.5ms, current regulated in the range 50-120mA). Electrodes were positioned on each leg to stimulate the quadriceps (external vasti and rectus femoris), the hip extensors (hamstrings) and the common peroneal nerve near the head of fibulae.

The IBM PC(AT) control computer and stimulator hardware are mounted on a trolley pushed along behind the patient and all interconnecting cables were supported on an overhead gantry.

The AFO/FES system He was fitted bilaterally with the AFO's and surface electrodes and was requested to remain standing in parallel bars until either leg showed evidence of uncontrollable buckling or after a one hour period had elapsed. He repeatedly demonstrated an ability to remain standing for the one hour test period. The total period of muscle activation was typically less than 3.5 minutes. This activation was attributed to occasional gross posture changes (raising up on the bars using the upper limbs) performed to relieve discomfort/boredom. He was able to demonstrate both 4-point and a drag to gait. He stated that he liked the AFO's and would use them regularly if they were made available to him.

The AFO/RO/FES system He was able to donn and doff the hip brace in less than 35 and 30 seconds respectively whilst seated in his wheelchair and wearing the AFO/FES components. He considered this to be an advantage over the LSU-RGO orthosis. Once in the upright position he was able to engage/disengage the joint linkage mechanism. With the linkage engaged he was able to stand without hand support. He liked this feature and thought it would be useful to him. He was able to walk reciprocally in parallel bars with the handswitch controls being operated by the investigator. The brace prevented adduction and axial rotation of the leg. The knee flexion provided adequate ground clearance. The gait pattern was symmetrical with stride length of approximately 0.75m. He is presently being trained to walk using a rollator and crutches and for this reason it is too soon to compare his gait performance with that achieved in the LSU-RGO system. However at this stage he has stated a preference for the present system because of its reduced encumbrance and improved cosmesis.

The KAFO/RO/FES system In the laboratory, this combination provided him with similar function to that of his previously fitted LSU-RGO system. He stated that he liked the option to remove the encumbering hip/trunk section and would be more inclined to make more use the present system if it were supplied to him.

DISCUSSION

The RO provides passive stabilisation of the trunk and control of the hip motion in the saggital and frontal planes. These functions are difficult to realise in practical systems using FES especially using surface electrodes. The flexible linear bearing was found to be reliable and mechanically superior to bowden cables.

Further work is required to refine and clinically evaluate the mechanical components. For example, the above RO joints have been modified so that the extension to contralateral flexion can be set to a ratio greater than unity to assess the improvement in step length and cadence.

Although only the technical feasibility of the system has so far been demonstrated it would appear that this modular arrangement of the HKAFO system significantly reduces the encumbrance of the user. The physical arrangement also suggests how presently used HKAFOs (HGO or LSU-RGO) may be adapted and also how future RO designs, possibly involving actuators or braking mechanisms, may be ergonomically implemented.

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REFERENCES

1. Andrews, B.J.,Bajd, T.(1984) Hybrid orthoses for paraplegics., **Proc (Supplement) 8th Internat. Symp. on Ext. Control of Human Extremities**, Dubrovnik, p55-59, ETAN, Belgrade.

2. Andrews, B.J.,Baxendale, R.H.(1986) A hybrid orthosisincorporating artificial reflexes for spinal cord damaged patients, J.Physiol, vol 38, P19, 1986.

3. Andrews, B.J.,Baxendale, R.H., Barnett, R., Phillips, G.F.,Yamazaki, T., Paul, J.P., Freeman, P.A.(1988) Hybrid FES orthosis incorporating closed loop control and sensory feedback., J. Biomed. Eng., vol 10, 2, p189-195.

4. Andrews B.J., Barnett R.W., Phillips G.F., Kirkwood C.A.,Donaldson N., Rushton D.N., Perkins T.A.(1989) Rule-Based control of a hybrid FES orthosis for assisting paraplegic locomotion, Automedica, vol 11, pp 175-199.

5. Andrews B.J.(1990) Hybridorthese fur die Fortbewegung vonQuerschnitts-gelahmten, Medizinisch-Orthopadische Technik, 110, pp84-88.

6. Bajd T., Kralj A., Turk R., Benko H., Sega J.(1983) The use of a four channel electrical stimulator as an ambulatory aid for paraplegic patients, Phys. Ther., 63, 1116-1120.

7. Bajd, T., Andrews, B.J., Kralj, A., Katakis, J.(1985) Restoration of walking in patients with incomplete spinal cord injuries by use of surface electrical stimulation: Preliminary results, Prosthetics and Orthotics Internat., vol 9, pp 109-111.

8. Cochrane G.M., Whittle M.W.(1989) A comparative trial of the Hip Guidance Orthosis (HGO) and the Reciprocating Gait Orthosis (RGO), Health Equipment Information, No 192, Department of Health, UK.

9. Cliquet A., Nene A.V., Barnett R., Andrews B.J.(1986) FNSaugmentation of reciprocating HKAFO and KAFO braces, Proc 2nd Vienna Internat. Workshop on FES, pp83-86.

10. Douglas R, Larson P.F., D'Ambrosia R., McCall R.E. (1983) The LSU reciprocation-gait orthosis, Orthopaedics 6:834- 838.

11. Harrington E.D., Lin R.S., Gage J.R.(1984) Use of the anterior floor reaction orthosis in patients with cerebral palsy, Orthotics and Prosthetics, vol.37:4, pp34-42.

12. Hausdorf, J.M., Durfee, W.K.(1988) Hybrid FES Gait Orthosisusing controllable damping elements, Proc. ICAART 88, pp 348- 349, Montreal, Canada.

13. Heller B., Granat M.H., Kirkwood C.A., Delargy M., Andrews B.J.(1990) Preliminary studies of swing-through gait using surface FES, in **Advances in external control of human extremities X** (this volume), Dubrovnik

14. Jaeger, R.J., Yarkony, G.M., Roth, E.J.(1988) Standing by acombined orthosis/electrical stimulation system in thoracic paraplegia, Proc ICAART 88, pp 336-337, Montreal, Canada.

15. Lehneis, H.R.(1972) New developments in lower limb orthotics through Bioengineering., Arch. Phys. Med. & Rehabil., 53, (7), pp303.

16. Matsuo, T., Wada, H.(1976) Stabilising operation for paralysed lower limb due to poliomyelitis., J. Jap. Orthop. Assoc., 50:275.

17. Petrofsky, J.S., Phillips, C.A., Larson, P., Douglas, R.(1985) Computer synthesised walking, J.Neurol. & Orthop. Med. & Surg., vol6, Issue 3, October, pp 219-230.

18. Popović, D.,Schwirtlich, L.(1987) Gait restoration by active SFMO, **IFAC Monograph: Control Aspects in Biomedical Robotics**, pp84-94, Pergamon press.

19. Rose G.K.(1979) The principles and practice of hip guidancearticulations, Prosthetics and Orthotics Internat., 3:37-43.

20. Saltiel, J.(1969) A one piece laminated knee locking short leg brace., Orthotics and Prosthetics, June, pp 68-72.

21. Schwirtlich, L.,Popović, D.(1984) Hybrid orthoses for deficient locomotion, in **Advances in External Control of Human Extremities VIII**, Dubrovnik, pp 23-32.

22. Solomonow M.R., Baratta R., Shoji D., D'Ambrosia N., Rightar W., Walker R., Beandette R.(1989) FES powered reciprocating gait orthosis for paraplegic locomotion, Proc 3rd Vienna Int. Workshop on Electrical Stimulation, p81.

23. Tomović, R.,Vukobratović, M.,Vodovnik, L.(1972) Hybridactuators for orthotic systems: Hybrid Assistive Systems., Proc 4th Internat. Symp. on Control of Human Extremities, Dubrovnik, pp 73-79, ETAN Belgrade.

24. Yang, G.W., Chu, D.S., Ahn, J.H., Lehneis, H.R., Conceicaco, R.M.(1986) Floor reaction orthoses: clinical experience., Orthotics and Prosthetics, 40, (1), pp33-37.

11. Harrington E.D., Lin R.S., Gage J.R.(1984) Use of the anterior floor reaction orthosis in patients with cerebral palsy, Orthotics and Prosthetics, vol.37:4, pp34-42.

12. Hausdorf, J.M., Durfee, W.K.(1988) Hybrid FES Gait Orthosisusing controllable damping elements, Proc. ICAART 88, pp 348- 349, Montreal, Canada.

13. Heller B., Granat M.H., Kirkwood C.A., Delargy M., Andrews B.J.(1990) Preliminary studies of swing-through gait using surface FES, in **Advances in external control of human extremities X** (this volume), Dubrovnik

14. Jaeger, R.J., Yarkony, G.M., Roth, E.J.(1988) Standing by acombined orthosis/electrical stimulation system in thoracic paraplegia, Proc ICAART 88, pp 336-337, Montreal, Canada.

15. Lehneis, H.R.(1972) New developments in lower limb orthotics through Bioengineering., Arch. Phys. Med. & Rehabil., 53, (7), pp303.

16. Matsuo, T., Wada, H.(1976) Stabilising operation for paralysed lower limb due to poliomyelitis., J. Jap. Orthop. Assoc., 50:275.

17. Petrofsky, J.S., Phillips, C.A., Larson, P., Douglas, R.(1985) Computer synthesised walking, J.Neurol. & Orthop. Med. & Surg., vol6, Issue 3, October, pp 219-230.

18. Popović, D.,Schwirtlich, L.(1987) Gait restoration by active SFMO, **IFAC Monograph: Control Aspects in Biomedical Robotics**, pp84-94, Pergamon press.

19. Rose G.K.(1979) The principles and practice of hip guidancearticulations, Prosthetics and Orthotics Internat., 3:37-43.

20. Saltiel, J.(1969) A one piece laminated knee locking short leg brace., Orthotics and Prosthetics, June, pp 68-72.

21. Schwirtlich, L.,Popović, D.(1984) Hybrid orthoses for deficient locomotion, in **Advances in External Control of Human Extremities VIII**, Dubrovnik, pp 23-32.

22. Solomonow M.R., Baratta R., Shoji D., D'Ambrosia N., Rightar W., Walker R., Beandette R.(1989) FES powered reciprocating gait orthosis for paraplegic locomotion, Proc 3rd Vienna Int. Workshop on Electrical Stimulation, p81.

23. Tomović, R.,Vukobratović, M.,Vodovnik, L.(1972) Hybridactuators for orthotic systems: Hybrid Assistive Systems., Proc 4th Internat. Symp. on Control of Human Extremities, Dubrovnik, pp 73-79, ETAN Belgrade.

24. Yang, G.W., Chu, D.S., Ahn, J.H., Lehneis, H.R., Conceicaco, R.M.(1986) Floor reaction orthoses: clinical experience., Orthotics and Prosthetics, 40, (1), pp33-37.