

A Systems Approach to Medically Prescribed Functional Electrical Stimulation. Ambulation After Spinal Cord Injury

C. A. Phillips, MD, PE, D. M. Hendershot, MS

Department of Biomedical and Human Factors Engineering, Wright State University, Dayton, Ohio 45435, USA.

Summary

A functional electrical stimulation (FES) system for ambulation of spinal cord injured patients has been described to consist of physician prescribable, commercially available components. The system components are: electrical muscle stimulators, a reciprocating gait orthosis and the electrode delivery system. A systems approach to medically prescribed FES ambulation requires the interfacing of these basic components, each of which has the flexibility to adjust to the optimal configuration for each individual patient. The electrode delivery system is of central importance in interfacing the basic components. This report describes the electrode delivery system, a transcutaneous transducer garment, which allows a variety of electrode configurations and stimulation patterns. The system has been successfully employed on a C7 level tetraplegic patient and a T9 level paraplegic patient.

Key words: *Electrical muscle stimulation, 'Spinal cord injury', Gait orthosis, Electrode garment, Gait restoration.*

Interest in electrical stimulation for ambulation of spinal cord injury (SCI) individuals occurred with the report by Brindley, *et al.*, (1978) of 'electrical splinting' of a paraplegic patient. However, a number of problems associated with developing a practical electrical stimulation system for SCI have been defined (Stallard *et al.*, 1989). The most practical approach to date appears to combine electrical stimulation of paralysed muscles with a lower extremity reciprocating gait orthosis as first proposed by investigators from two universities (Petrofsky *et al.*, 1985).

A medically prescribed system has been reported to produce stand-up and sit-down (from a wheelchair or other chair) as well as forward and backward ambulation. This has been described for a paraplegic subject (Phillips, 1989b) who sustained a motor complete (but sensory incomplete) lesion and was Frankel class B. This system has also been described for a tetraplegic subject (Phillips, 1989a)

who sustained a motor incomplete (but functionally useless) lesion and was Frankel class C.

As experience has been obtained with the medically prescribed functional electrical stimulation (FES) ambulation system (Phillips, 1989c), it has also become apparent that various electrode configurations and alternative stimulation patterns are necessary for the optimal patient performance when using the system. The goal of this research is to define such a system that is physician prescriptable and consists of commercially available components.

Methods

System components

Four to six small and portable electrical muscle stimulators (EMS) (NTRON, undated) are worn on a belt (Fig. 1) and are connected to EMS override switches (NTRON) (attached to the walker) which allows the patient manual control of the EMS units. Each EMS unit has two channels of stimulation. The frequency, pulse-width, rise time, fall time and amplitude of the stimulation current can be varied for the desired effect. Each EMS unit weighs approximately 6 ounces and is powered with a 9-volt battery.

A commercially available reciprocating gait orthosis (LSU, undated) is applied to the paralysed lower extremities (Fig. 2). This is a bilateral hip-knee-ankle-foot-orthosis (HKAFO) which has an interconnecting (reciprocating) cable at the hips. With weight shifted to the ipsilateral leg, stimulation is applied to the ipsilateral hip extensors (gluteal and hamstring muscles). Through the action of the cables, this results in hip flexion (leg forward) of the contralateral (non-weight bearing) leg.

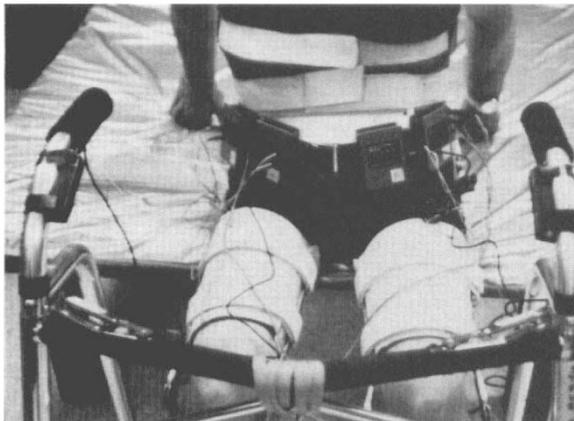


Figure 1 EMS units worn on a belt.



Figure 2 Side view of the RGO.



Figure 3 Individual carbon rubber electrodes on the lower extremities.



Figure 4 Subject seated and wearing the TTG (front view).

From 14 to 16 surface electrodes (Medtronic, undated) are applied bilaterally over the following lower extremity muscle groups: quadriceps, gluteal and hamstring (Fig. 3). Three or four 2"×4" carbon rubber electrodes are applied to each quadriceps muscle group and one 1½"×1½" and one 2"×4" carbon rubber electrode are applied to each gluteal group and to each hamstring group. Liqui-Cor gel is first applied and then followed by both adhesive patches and adhesive tape in order to secure the electrodes to the skin.

One problem with the above system lies in the complexity of the electrode placement. To make the system more efficient, cosmetic, and easier to put on and to remove, electrically conductive clothing with embedded electrodes was reported (Petrofsky *et al.*, 1985). These transcutaneous transducer garments (TTG's), as shown in Figure 4, were developed by Bio-Stimu Trend Corporation* and offer the advantage of ease of use, no exposed wires, and machine washability. They have snap connectors that interface to the EMS for control of movement of major muscle groups of the leg necessary for walking (Granek and Granek, 1989).

The subjects

Two spinal cord injured patients were evaluated in this study. One was a tetraplegic individual and the other was a paraplegic individual. The patient characteristics are summarised in Table I.

Table I Patient characteristics

Sex	Age	Weight ¹	Height ²	Date of injury	Injury level	Frankel class
M	30	64	188	1-11-83	C-7	C
M	44	82	178	8-07-67	T-9	A

¹Weight (kg)

²Height (cms)

*Bio-Stimu Trend Corp., 14851 NW 27th Ave., Opa Locka, FL 33054, USA.

Table II 6 unit, Walk 1 system

EMS unit	Channel	Electrodes
1	A	R. quad
1	B	R. quad
2	A	R. quad
2	B	R. quad
3	A	L. quad
3	B	L. quad
4	A	L. quad
4	B	L. quad
5	A	L. glut
5	B	L. ham
6	A	R. glut
6	B	R. ham

System configurations

The system reported for a tetraplegic subject (Phillips, 1989a) was evaluated and consists of 6 EMS units, each with 2 channels (A and B) as per Table II. This is the Walk 1 mode in which an ipsilateral (non-weight bearing) leg forward is obtained by stimulating the gluteal and hamstring muscle groups of the contralateral (weight bearing) stationary leg.

Another system we have evaluated for an SCI (tetraplegic) subject also consists of 6 EMS units, each with 2 channels (A and B) as shown in Table III. This is the Walk 2 mode in which an ipsilateral (non-weight bearing) leg forward is obtained by simultaneously stimulating the quadriceps muscle group of the ipsilateral (moving) leg and the gluteal and hamstring muscle groups of the contralateral (weight bearing) stationary leg.

The interconnection between the EMS units and the TTG for the 6 EMS unit application (Tables II and III) are shown in Figures 5 to 7. Figure 5 indicates the interconnection of EMS units 1, 2, 3 and 4 on the anterior (quadriceps) aspect of the

Table III 6 unit, Walk 2 system

EMS unit	Channel	Electrodes
1	A	R. quad
1	B	R. quad
2	A	L. quad
2	B	L. quad
3	A	R. quad
3	B	R. quad
4	A	L. quad
4	B	L. quad
5	A	L. glut
5	B	L. ham
6	A	R. glut
6	B	R. ham

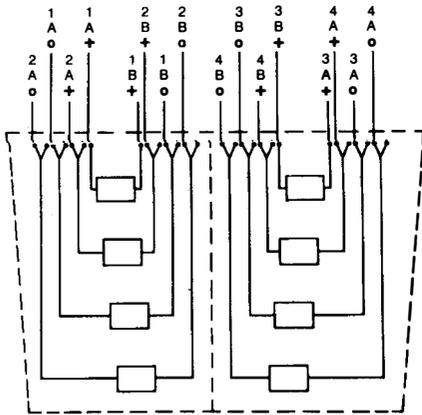


Figure 5 6 unit, Walk 1, quadriceps.

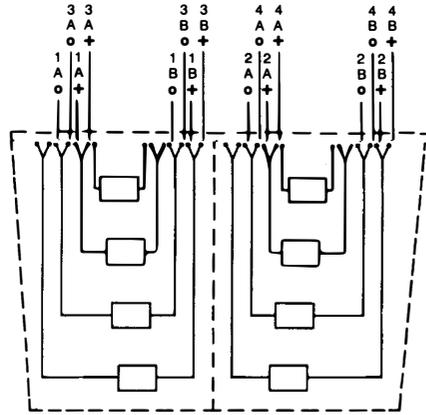


Figure 6 6 unit, Walk 2, quadriceps.

TTG for the configurations given in Table II. Each EMS unit channel (A and B) has a separate anode (+) and cathode (○). Figure 6 indicates the interconnection of EMS units 1 to 4 on the anterior (quadriceps) aspect of the TTG for the configuration as shown in Table III.

Figure 7 indicates the interconnections of EMS units 5 and 6 on the posterior (gluteal hamstring) aspect of the TTG for the configuration given in Tables II and III. EMS units 5 and 6 are independently activated on the posterior (gluteal/hamstring) aspect of the TTG for the configuration given in Table II. EMS units 5 and 6 are co-activated with EMS units 3 and 4, respectively, for the configuration given in Table III.

Furthermore, we have determined that a paraplegic subject can adequately walk with 4 EMS units connected as shown in Table IV. The interconnection between the EMS units and the TTG for the 4 EMS unit applications (Table IV) is shown in Figures 8 and 9. Figure 8 indicates the interconnection of EMS units 1 and 2 on the anterior (quadriceps) aspect of the TTG for the configuration shown in Table IV. Each EMS unit channel (A and B) has a separate anode (+) and cathode (○). Figure 9 indicates the interconnection of EMS units 3 and 4 on the posterior (gluteal/hamstring) aspect of the TTG for the configuration shown in Table IV.

Table IV 4 unit, paraplegic system

EMS unit	Channel	Electrodes
1	A	R. quad
1	B	R. quad
2	A	L. quad
2	B	L. quad
3	A	R. glut
3	B	R. ham
4	A	L. glut
4	B	L. ham

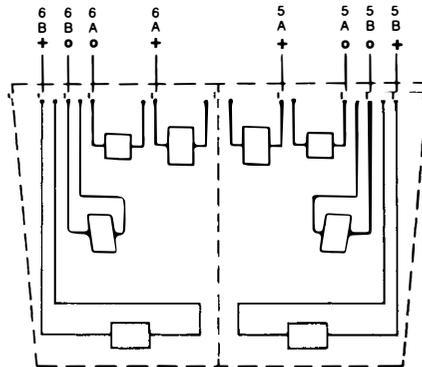


Figure 7 6 unit, Walk 1/2, gluteal/hamstring.

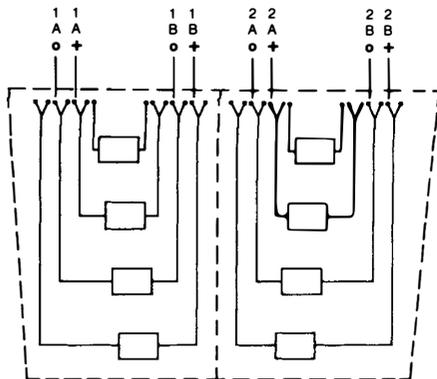


Figure 8 4 unit, paraplegic, quadricep.

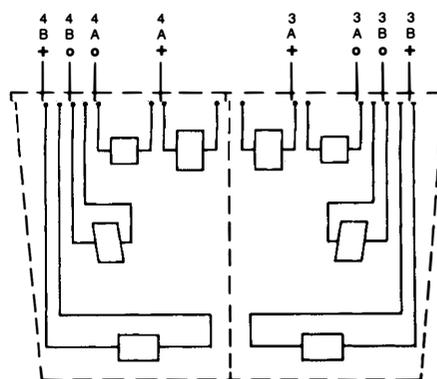


Figure 9 4 unit, paraplegic, gluteal/hamstring

Results

Our research group was initially impressed that the tetraplegic patient was able to pre-gel his TTG without any assistance (Fig. 10). Furthermore, the subject was also able to put on and take off his TTG again without assistance (Fig. 11). This means that functionally, the subject was able to prepare and position all 6 electrodes (and remove them after the testing session). This task would have been virtually impossible with 16 individual carbon rubber electrodes, gel, patches and paper tape.

The system previously described (see Methods) for this tetraplegic subject consists of 6 EMS units, each with 2 channels (A and B) as per Table II. This is the Walk 1 mode which was described above. This system, with the TTG replacing the individual carbon rubber electrodes, has been successfully utilised on the C-7 level tetraplegic subject (Fig. 12). Functional equivalency between the two different electrode delivery systems was obtained.

Another system that has also been evaluated on the tetraplegic subject and consists of 6 EMS units, each with two channels (A and B) and was shown in Table III (see Methods). This is the Walk 2 mode which has been described. This



Figure 10 Tetraplegic subject pre-gelling the TTG electrode garment prior to wearing garment.



Figure 11 Tetraplegic subject wearing TTG and positioned in the RGO.

system, with the TTG replacing the individual carbon rubber electrodes, has been successfully utilised on the C7 level quadriplegic subject (Fig. 13). Functional equivalency between the two different electrode delivery systems has been obtained.

A final system has been evaluated on the paraplegic patient and consists of 4 EMS units, each with two channels (A and B) and was shown in Table IV of the Methods section. This system, with the TTG replacing the individual carbon rubber electrodes, has been successfully utilised on the T9 paraplegic patient. Functional equivalency between the two different electrode delivery systems has also been obtained.



Figure 12 Tetraplegic subject utilising the TTG in Walk 1 mode (see text).



Figure 13 Tetraplegic subject utilising the TTG in Walk 2 mode (see text).

Discussion

Various problems occur when developing a practical electrical stimulation system for ambulation after SCI (Stallard *et al.*, 1989). In particular, these are system reliability, energy loss, safe failure mode for patients, cosmesis of walking, and cost. These and other problems have limited the application of FES technology for ambulation of SCI patients (Gruner, 1986). There is the high energy cost associated with movement induced by FES, and the result is rapid muscular fatigue (Marsolais and Edward, 1988). Another serious problem is that the individual is not protected from falling; postural instability results from stimulation of only a few muscle groups out of the entire population of paralysed muscles. Furthermore, electronic components can fail resulting in partial or total loss of tonic electric activity needed to maintain the patient upright.

The reciprocating gait orthosis (RGO) has been utilised to solve most of these problems (Douglas and Larson, 1983) by combining it with FES (Petrofsky *et al.*, 1985). A major direction of our activity during the past year has been to make this technology available to the medical community and apply it to the general SCI population. By utilising commercially available EMS in combination with a physician prescribed gait orthosis, the system has the advantages of being portable, lightweight and efficient. For example, the power pack is reduced to a single 9-volt alkaline battery within each EMS unit. A total of either 4 or 6 EMS units, each weighing less than 6 ounces, provide complete stand up, sit down and walking functions.

Patient compliance may be a problem in a system where so many electrodes need to be applied to the surface of the body. The application of these electrodes is a somewhat tedious and cumbersome task. Also, good positioning over appropriate motor units is important for optimal performance of the system. New stimulation delivery technology, such as the TTG, resolves this problem by allowing stimulation delivery at multiple sites by means of a customised garment. The actual electrical conduction surfaces are interwoven into the fabric of this garment. The patient now simply puts on the garment and could (in the future) interface with the EMS units via a single universal connector.

A systems approach to medically prescribed FES ambulation requires the interfacing of basic components, each of which has the flexibility to adjust to the optimal configuration for each individual patient. The electrode delivery system is of central importance in interfacing the basic components. The TTG appears to allow such system flexibility.

In conclusion, a systems approach to medically prescribed FES ambulation consisting of EMS units, an RGO and a TTG have reduced most of the problems associated with FES application for ambulation after SCI. Furthermore, the system may be obtained by medical prescription and consists entirely of commercially available components.

References

- BRINDLEY GS, POLKEY CE, RUSHTON DN 1978 Electrical splinting of the knee in paraplegia. *Paraplegia* **16**:428–435.
- DOUGLAS R, LARSON P 1983 Reciprocating gait orthosis. *Orthopaedics* **6**:834–839.
- GRANEK H, GRANEK M 1989 Transcutaneous Transducer Garments: An Advancement in Transcutaneous Delivery and End User Compliance. *Automedica (Lond.)*, **11**:19–23.
- GRUNER J 1986 Considerations in Designing Acceptable Neuromuscular Stimulation Systems for Restoring Function in Paralyzed Limbs. *CNS Trauma Journal* **3**:37–47.
- LSU Reciprocating Gait Orthosis: A Pictorial Description and Applications Manual. Durr-Fillauer Medical, Inc., Chattanooga, TN, USA.
- MARSOLAIS EB, EDWARD BJ 1988 Energy cost of walking and standing with function electric stimulation and long leg braces. *Archives of Physical Medicine and Rehabilitation* **69**:243–249.
- Medtronic® Model 3793 and Model 3795, Neuro Division, 6951 Central Avenue, Northeast, P.O. Box 1250, Minneapolis, MN 55440.
- NTRON Electronic EMS-8100: Patient Instruction Booklet. NTRON, Inc. 104 Industrial Blvd., Sugar Land, TX 77478.
- NTRON PART No. 473D (OP. CIT.).
- PETROFSKY JS, PHILLIPS CA, LARSON P, DOUGLAS R 1985 Computer synthesized walking: Application of orthosis and functional electrical stimulation (FES). *J Neuro Ortho Med Surg* **6**:219–230.
- PHILLIPS CA 1989a A Medically prescribed system of functional electrical stimulation and lower extremity bracing for ambulation exercise of the spinal cord injured individual. *Physical Therapy* **69**:56–63.
- PHILLIPS CA 1989b Electrical muscle stimulation in combination with a reciprocating gait orthosis for ambulation by paraplegics. *Journal of Biomedical Engineering* **11**:338–344.
- PHILLIPS CA 1989c Electrical stimulation for ambulation of selected paraplegics and quadriplegics. *J Neuro Ortho Med Surg* **10**:109–110.
- STALLARD J, MAJOR R, PATRICK J 1989 A Review of the fundamental design problems of providing ambulation for paraplegic patients. *Paraplegia* **27**:70–75.