Functional Neuromuscular Stimulation for Mobility in People with Spinal Cord Injuries. The Parastep® I System

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Although Kantrowitz[1] reported over 35 years ago using electrical stimuli to enable people with paraplegia to take steps,[2] it has only been in the past several years that the use of functional neuromuscular stimulation (FNS) for people with spinal cord injuries has become more than a laboratory curiosity in this country.[2-14] The Parastep® I system, which is now FDA approved and commercially available, has been used in over 23 centers in this country and a number of centers in Europe as well. This report provides a brief overview of the outcome of a cohort of the first 100 people to use the device.

The Parastep® System is produced by Sigmedics, Northfield, IL. The system is an open loop design and was originally developed and tested by Daniel Graupe, Ph.D. and Kate Kohn, M.D. at the University of Illinois Medical School and Michael Reese Medical Center in Chicago, now Columbia/HCA - Michael Reese (Figure 1). The system includes a battery pack (containing 8 AA batteries) which provides 2-1/2 hours of continual use under normal conditions, a microprocessor with either four or six channels, surface electrodes with connecting cables and a modified front-wheeled walker (Figure 2). A single cable with a modular plug connects the microprocessor to the front wheeled walker and patients control the stimulation sequence by manipulating switches mounted on its upper anterior portion. The microprocessor and the battery pack can clip onto the user's belt, be placed in a pants pocket or in a specifically designed waist pack (Parapack™) (Figure 3). With four channel units, two sets of electrodes are placed over the quadriceps to promote sit to stand, standing and standing to sitting and two sets of electrodes are placed over the
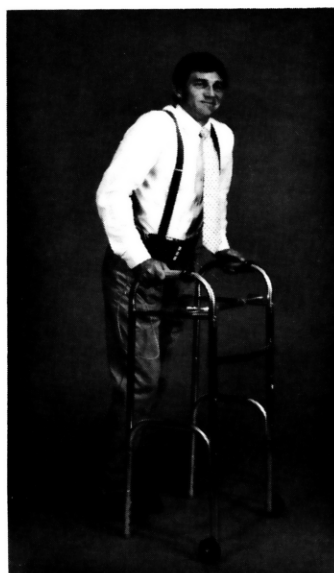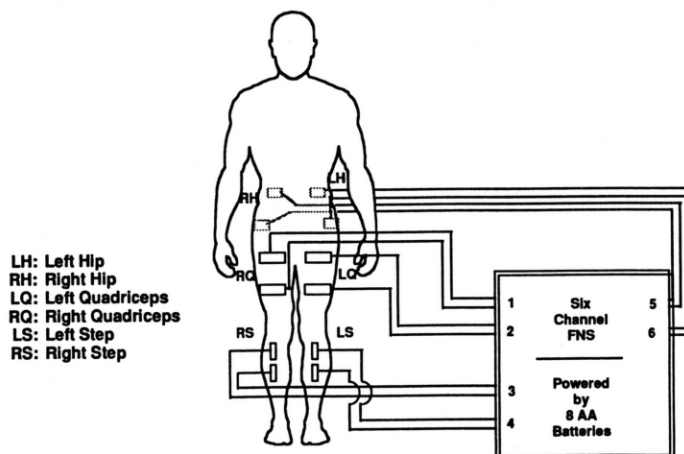

LH: Left Hip
RH: Right Hip
LQ: Left Quadriceps
RQ: Right Quadriceps
LS: Left Step
RS: Right Step

Figure 1. (Above) A schematic of the six-channel Parastep®System. Two sets of electrodes are placed over the quadriceps to promote sitting to standing and standing activities, two sets of electrodes are placed over the perineal nerve to stimulate triple flexion responses used in stepping and two sets of electrodes are placed over the gluteus region to promote extension.

Figure 2. (Left) Someone using the system to stand. The battery and microprocessor are in the Parapack.

Figure 3. (Below) The system including microprocessor, battery pack leader and surface electrodes.

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peroneal nerve, usually across the head of the fibula, to elicit a triple flexion response for stepping. With the six channel unit, two additional sets of electrodes are placed over the glutei and/or paraspinus muscles to promote extension of the lower spine and hips.

All 100 participants were more than 14 years old and were seen a minimum of six months after spinal cord injury and restorative surgery. They had sustained complete and incomplete injury to the spinal cord at T12 or higher in the thoracic area or had incomplete injuries in the cervical region. A screening evaluation was conducted for all participants to insure the absence of orthopedic, neurologic or metabolic problems, the presence of intact lower motor
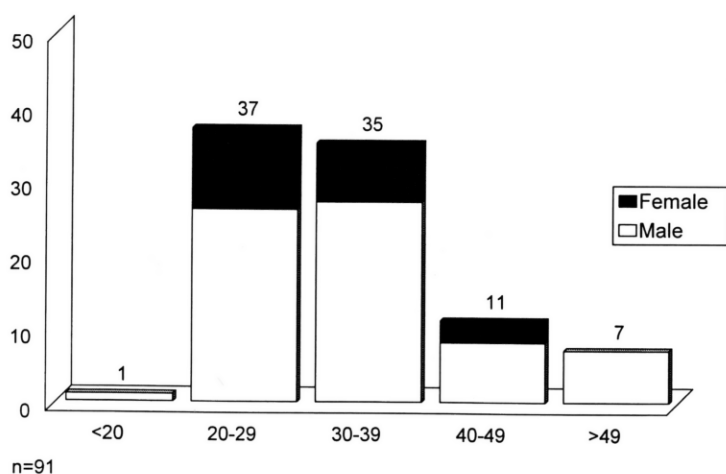

Figure 4. Age at Entry. Distribution of age and sex at the time of injury.

neuron activity (L1 and below), the absence of a history of fractures of long bones secondary to osteoporosis and the absence of joint disease in the lower extremities. The physical examination also assured that joint stability was sufficient for weight bearing in both lower extremities. A good range of motion, absence of contractures about the hips, knees and ankles and absence of spasticity which might preclude standing in the upright position were necessary. Subjects had to demonstrate the cognitive ability to employ the system, had to be independent in transfers and had to have adequate finger function to manipulate the system controls. Finally, electrical stimulation must produce muscle contraction of the quadriceps.

Before formal training in the program, participants were required to demonstrate standing balance for greater than three minutes without symptomatic orthostasis, upper body strength sufficient to lift the body out of the chair and into a standing walker,

muscle power generated by FNS sufficient to maintain locked knees while weight bearing in the standing position (grade 3+ with FNS muscle strength testing) and the ability to maintain standing posture with less than 20 percent of the body weight borne by upper extremities. If subjects were not able to meet these criteria or they had limitation in range of motion, they were requested to enroll in a physical therapy program designed to increase range of motion, standing tolerance, FNS muscle strength and endurance. Subjects with active cardiac disease, pulmonary insufficiency, epilepsy, pregnancy, severe scoliosis, severe symptomatic osteoporosis, active skin disease at the stimulation sites, irreversible contractures, morbid obesity, visual or hearing impairments which would interfere with training or symptomatic autonomic dysreflexia were excluded.

The training program for the Parastep® was designed to promote safe and effective standing and walking within 32 physical therapy training sessions. Training was aimed at increasing strength and endurance in the quadriceps muscles, magnitude and reproducibility of triple flexion responses, overall cardiovascular endurance and the ability to remain in the upright position and take steps using FNS stimulation in the lower extremities. Participants were given a specifically modified four-channel unit to perform quadriceps muscle exercises and to elicit triple flexion responses as part of a home exercise program. Almost all participants were fitted with bilateral ankle-foot orthoses for ankle stabilization to facilitate toe clearing during stepping.

Of the first 100 people seeking to use the system, 91 were judged to be possible candidates and nine were judged not to be appropriate candidates. These 91 participants ranged in age from 15 to 69 years (Figure 4) with a median age of 33.7 years. Approximately 76 percent were male and 24 percent female. Of 91 participants, all but three had sustained traumatic injuries to the spinal cord. The remaining three had a diagnosis of multiple sclerosis, transverse myelitis or spinal cord infarction following meningitis. Sixty-four percent of the traumatic injuries were secondary to motor vehicle accidents, 12 percent from falls, 10 percent from violence and the remaining 14 percent included occupational injuries, diving injuries and a bicycle injury (Figure 5). Level of injuries ranged between C6 and T12 (Figure 6). Two were
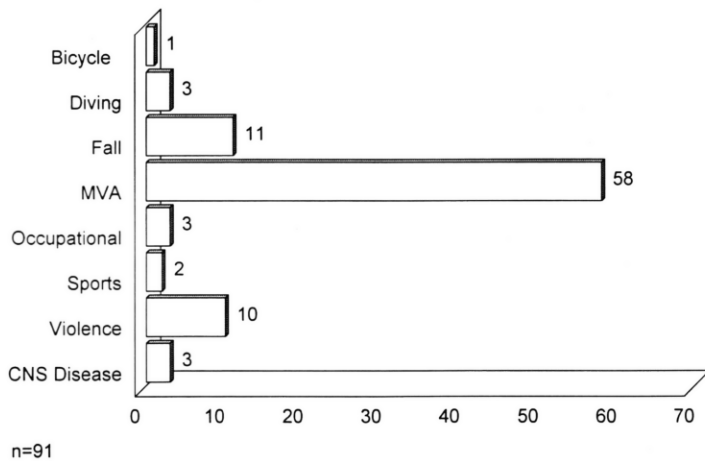
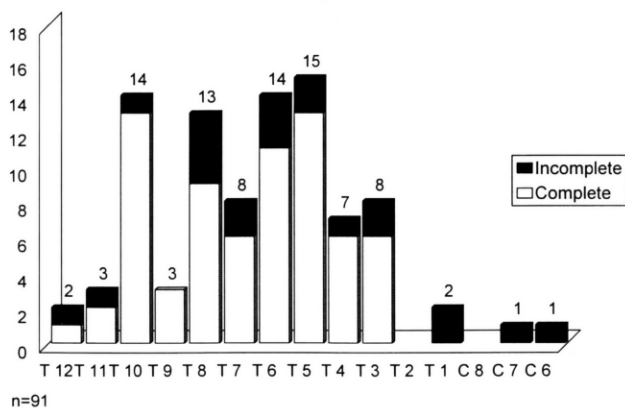Figure 5. Types and frequencies of injuries to the spinal cord.

Figure 6. Level and completeness of spinal cord injury.

incomplete cervical injuries. The remaining participants had injuries ranging from T1 through T12. Seventy-eight percent of these were complete injuries and 22 percent incomplete thoracic injuries (Figure 6).

From an overall outcome perspective, all 91 people demonstrated the ability to stand using the Parastep® System and 84 (92 percent) were able to stand and take steps using the system. Thirty-one or 34 percent were eventually able to ambulate using the system without the assistance of another person (Figure 7). Fifty of the 91 participants completed training and 41 did not. All participants who completed the program were able to stand and take steps; 27 (54 percent) independently, eight (16.6 percent) with verbal cueing and 15 (30 percent) required some hands-on assis-

tance. The program is designed to generate independent use in 32 sessions; however, the actual median number of therapy sessions for the group that completed the program and were independent upon completion was 34.

Completing or not completing the training program did not appear to be related to the level of injury (Figure 8). There was no statistical correlation between level of injury and achieving independence (x^2 p = 0.34) nor between complete or incomplete injury and reaching independence (x^2 p - 0.664). However, none of the participants in this cohort whose level of injury was above T4 reached an independent status (Figure 9). All four of the participants with injuries at T3 who completed the program still required some physical, contact guard assistance as did the person with an incomplete C7 injury.

For the group of 31 participants who completed training or who did not complete training but still reached an independent level of function with the system, 75 percent were able to ambulate for distances of 80 to 625 feet at any time without pausing to rest. The average post-ambulation heart rate for the group was 124 and the median 126. The average distance this group could ambulate was 324 feet and the median distance was 226 feet (Figure 10). The average total distance walked during a full training session was 1460 feet and the median 1250 feet. The overall range for the group was as low as 25 feet to as high as 1560 feet. For comparison, modified independence on the Functional Independence Measure (FIM = 6) includes the ability to ambulate 150 feet using an assistive device. This is generally adequate to be household ambulatory. In contrast, functional ambulation in the community is held to require ambulation greater than 150 feet. Twenty-one of the 31 used the system for both mobility in home and mobility in community.

Reasons given for not completing the training program in the 37 participants who did not complete it prior to reaching an independent level of function are outlined in Table 1. Not complying with the protocol and time conflicts were the most common reasons. Seven did not complete the program because of medical conditions shown in Table 2. One was noted to have excessive knee laxity soon after admission to the
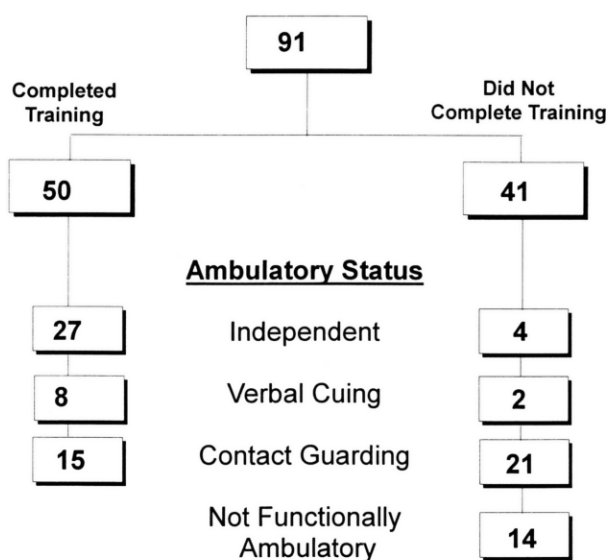
Figure 7. Functional outcome and completion or non-completion of training of 91 subjects who entered the program.

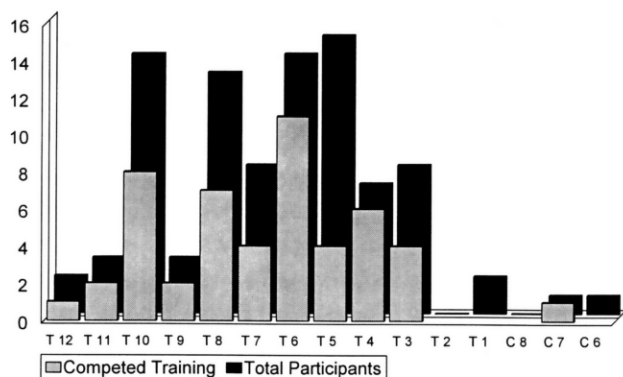**Those Completing Training vs Total Entrants as Level Of Injury**

Figure 8. Subjects who completed training versus total number of subjects.

Table 1. Reasons for failure to complete training before reaching independence.

(n = 37)	
Reasons Given	**Number**
Non compliant with protocol	9
Time conflicts	7
Moved	4
Returned to work or school	3
Failure to progress	2
Family emergencies	1
Transportation problems	2
Program suspended	2
Medical conditions	7

Table 2. Medical conditions.

(n = 7)	
Diagnosis	**Number**
Knee laxity	1
Post-use fatigue	1
Belching	1
Motor vehicle accident	1
Fractured great toe	1
Fractured tibia	1
Avascular necrosis of hip	1

program. One patient with transverse myelitis had persistent post-use fatigue. He eventually received a diagnosis of multiple sclerosis. One experienced recurrent belching when standing, one sustained a fracture of the great toe, one a fracture of the tibia, one avascular necrosis of a hip and one experienced injuries from a motor vehicle accident. Overall, three of 91 participants (3.3 percent) sustained a bony injury. Not all of these could be attributed directly to specific use of the Parastep®. However, they did occur during a time period when the Parastep® was being intermittently used. Fractures are not uncommon in this population. For example, published reports on bony injuries from the Model SCI Program claim 14 percent of people with SCI sustained fractures over the first five-year period post-injury, 28 percent over 10 years, or an approximate average of 2.8 percent per year.[15] When lower extremity fractures are adequately reduced, healing of the bony injuries almost always occurs with conservative measures.[16] In over 4,000 hours of direct observation in training and in many more hours of home and community use, there have been no injuries attributable to failure of the system's electronics.

Many arguments have been put forth concerning demonstrated or potential benefits of ambulation and activity in people with spinal cord injuries. These arguments will not be repeated here. In the long run, whether such benefits are achieved or not will likely depend upon the ease of use and the benefit or utility of the system employed. Earlier surveys of people with SCI and their use of other ambulation orthotics indicated use is related to cosmetic factors, ease of donning and doffing and overall energy requirements.[17-20] Until now there seems to be an inverse relationship between cosmetic factors and ease of donning and doffing versus stability and bracing. The greater the emphasis on stability, the more awkward and less cosmetically desirable the orthosis. Given the rate of bony injuries in this population, bracing is not likely to prove a fail-safe way of totally preventing them. The more bracing, the more stability provided;
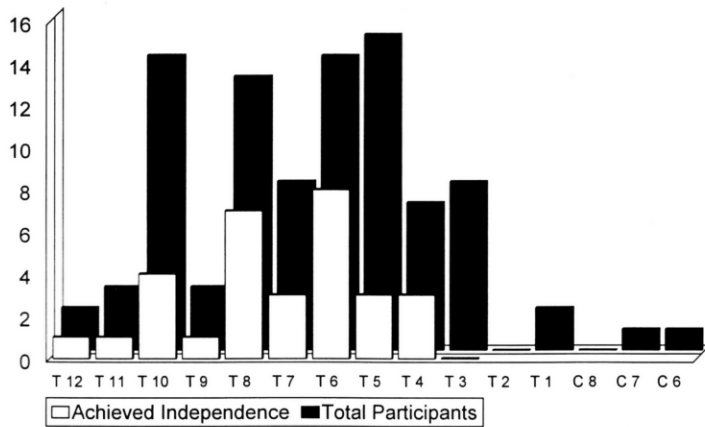
Figure 9. Diagram of subjects who became independent versus total number of entrants into the program as a function of level of injury.

the more cumbersome, the less "natural" the gait pattern. In the long run, the balance and tradeoffs between cosmetics, ease of donning and doffing, energy requirements and safety are likely to be determined not by the medical profession but by the end users of the system and the payors for the system. Preliminary follow-up studies on people (N=48) who
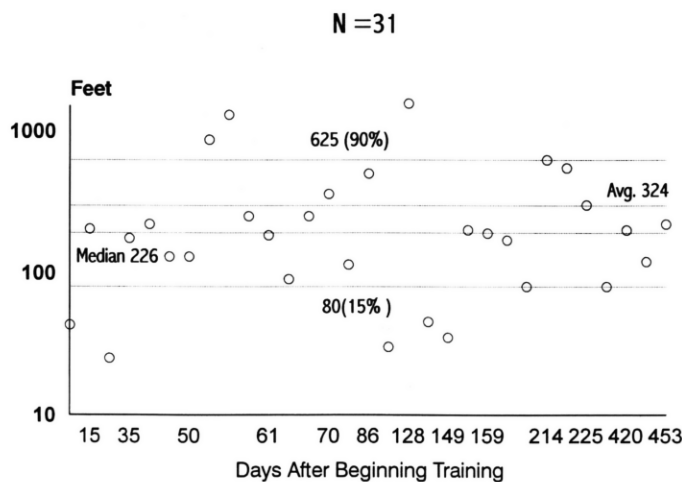

N =31

Figure 10. Distance ambulated for a group of 31 subjects who reached independence. The data is plotted as a log function of distance versus the number of days after entering the training program.

have obtained the Parastep® device suggest 82 percent use the system regularly and 3/4 use it three or more times per week which is more than orthotics such as long leg braces are used.[18-21]

The Parastep® System was designed to be as inobtrusive as possible. A recent article also cited difficulty of getting from sitting to standing and standing to sitting positions as reasons for not using standard reciprocating gait orthosis (RGO) systems. It is far simpler to go from sitting to standing or from standing to sitting with the Parastep® System than with long leg braces or RGO systems. In addition to cosmetics, ease of donning and doffing, energy requirements and self esteem, the utility of these devices is likely to be a very important factor determining use versus non-use. Their overall value, and changes in quality of life that these devices bring to people with spinal cord injuries, will determine whether they are used or not. The overall cost versus objective benefits is likely to influence insurers.

To date, good comparative studies of energy consumption and work among the various options for mobility in spinal cord injured people are lacking. There is the temptation to take various small reports and make sweeping claims. For example, consider the study of Bowker et al.[22] which reported a Physiological Cost Index (PCI) of 5.6 ± 2.4 beats/m using RGOs alone and the study of Winchester et al.[21] which reported a PCI of 4.81 ± 1.78 beats/m for the Parastep®. Comparing the means (formula below) might suggest that Parastep® users experience 16 percent less energy cost in terms of this index.

$$PCI = \frac{HR_W - HR_R}{V}$$

where,
PCI = Physiological Cost Index
HR_R = Heart Rate at Rest
HR_W = Heart Rate Walking
V = Velocity Walking

However, such a conclusion might be incorrect because of errors in logic and lack of adequate controls. First, the numbers are small and if the data is plotted out, there is overlap in the population (Figure 11). Second, distances traveled may be different from report to report. Third, as studies of Winchester et al.[23] report, the PCI is highly correlated with frequency of use and longevity of use of the system, i.e. training (Figure 12). Therefore, although a PCI of 2.53 beats/m for an RGO system as cited by Isakov et al.[24] is much lower than the average reported by Bowker et al.,[22] the difference

ENERGY CONSUMPTION ESTIMATES
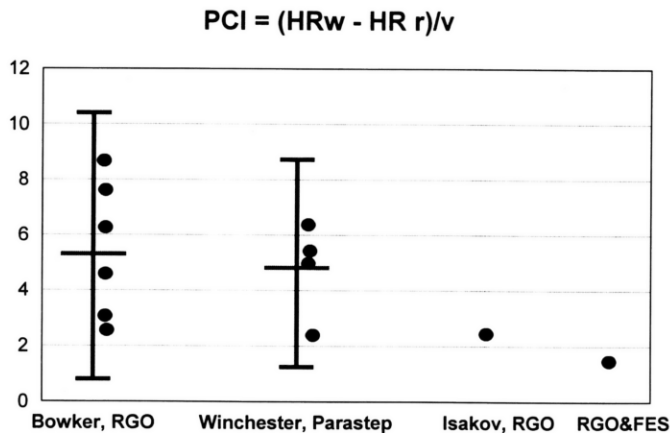
$$PCI = (HRw - HR\ r)/v$$

Figure 11. Average, mean and individual data points are plotted from previously published reports including that of Bowker[22] using an RGO system alone, Winchester et al.[23] using the Parastep® System and Isakov et al.'s[24] single subject using an RGO and an RGO with FES.
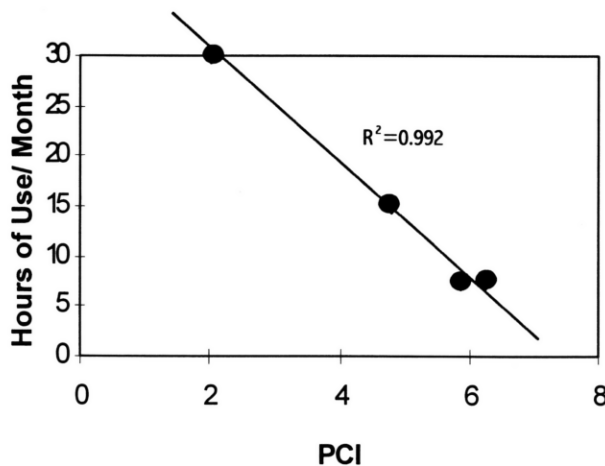

Figure 12. The PCI (physiological cost index) is highly inversely correlated (R^2 0.992) with hours of use per month. (This data was supplied by Patty Winchester, Ph.D.[23])

could very well relate to underlying conditioning, i.e. training of the subjects, and not efficiencies of the devices and orthotics. Clearly, there is less energy cost reduction when FNS is added to the RGO.[25] These latter studies have been carried out in the same subjects making direct comparisons possible. Until similar comparisons are made between devices in the same individual or in very large populations, comparisons of energy consumption are not really valid.

The current cost for the Parastep® System, which includes the system and therapy training, is $14,990 for the 4-channel system and $15,980 for the 6-channel system.

In summary, all subjects reported here were able to stand and 92 percent were able to take steps using the Parastep® System. Thirty-four percent of all subjects who entered the program and 54 percent of subjects who completed the training program reached the point where they were able to use the device independently and 91 percent used the system for mobility in the community. Neither the Parastep® System nor the other ambulatory orthotic systems presented here are replacements for the wheelchair. Extrapolating and then projecting data published from Waters et al.,[26] it is easy to see that the efficiency and energy cost of RGOs alone, RGOs with FNS and FNS with minimal bracing must still be improved to reach the efficiency of the wheelchair. As noted earlier, almost all participants presented here were fitted with lightweight ankle-foot orthoses (AFOs). More recently, users are being fitted with ground loading, knee stabilizing AFOs (sometimes referred to as knee level KAFOs). These provide stability across the knee and will allow the stimulus intensity and rate of stimulation to quadriceps during standing and ambulating to be lessened, reducing overall energy consumption during use.

These results indicate that computer-generated FNS to aid standing and reciprocal stepping is a clinically viable mobility orthotic in appropriately selected and trained individuals with spinal cord injury. "Appropriately selected" is the key phrase. Patient motivation, pre-injury activity habits and general health status appear to be predictors of successful ambulation. Many health care professionals who worked with the subjects reported here noted distinct improvements in their mood and affect as the issue of "whether I am ever going to walk again" was confronted. There were many reports of subjects who had become withdrawn and passive post-injury and who became more outgoing and social after being able to stand and take steps. A number began actively planning for their futures and participating in other aspects of day-to-day living. Changes in self-esteem and disposition toward life were the most noteworthy benefits. As with any ambulation program in SCI patients, risks, especially the results of a

sedentary life style (i.e., osteoporosis), must be communicated to potential system users.

REFERENCES

1. Kantrowitz A. Electronic physiologic aids. Report of the Maimonides Hospital. Brooklyn, New York, 1960.

2. Kralj A, Grobelnik S. Functional electrical stimulation of paraplegic patients - a new hope for paraplegic patients. Bull Prosth Res 1973;75:10-20.

3. Stanic U, Acimovic-Janezic R, Gros N, Trnkoczy T, Bajd T, Kljajic M. Multichannel electrical stimulation for correction of hemiplegic gait. Methodology and preliminary results. Scand J Rehab Med 1978;10:75-92.

4. Brindley GS, Polkey EG, Rushton DN. Electrical splinting of the knee in paraplegia. Paraplegia 1979;16:428-37.

5. Kralj A, Bajd T, Turk R. Electrical stimulation providing functional use of paraplegic patient muscles. Med Prog Technol 1980;7:3-9.

6. Turk R, Kralj A, Bajd T, Stefancic M, Benko H. The alteration of paraplegic patients muscle properties due to electrical stimulation exercising. Paraplegia 1980;18:386-91.

7. Bajd T, Kralj A, Turk R, Benko H, Sega J. The use of a four-channel electrical stimulator as an ambulatory aid for paraplegic patients. Phys Therap 1983;63:1116-20.

8. Kralj A, Bajd T, Turk R, Krajnik J, Benko H. Gait restoration in paraplegic patients: a feasibility demonstration using multichannel surface electrode FES. J Rehab R and D 1983;20:3-20.

9. Marsolais EB, Kobetic R. Functional walking in paralyzed patients by means of electrical stimulation. Clin Orthop Rel Res 1983;175:30-6.

10. Petrofsky JS, Philips CA. Computer controlled walking in the paralyzed individual. J Neurol Orthop Surg 1983;4:153-64.

11. Jaeger RJ, Kralj A. Studies in functional electrical stimulation for standing and forward progression. In; Proceedings of the 5th Annual Conference on Rehabilitation Engineering, San Diego, CA, 1983.

12. Cybulski GR, Penn RD, Jaeger RJ. Lower extremity functional neuromuscular stimulation in cases of spinal cord injury. Neurosurg 1984;15:132-46.

13. Petrofsky JS, Philips CA, Heaton HH 3d. Feedback control system for walking in man. Comput Biol Med 1984;14:135-49.

14. Holle J, Frey M, Gruber H, Kern H, Stohr H, Thomas H. Functional electrostimulation of paraplegics. Experimental investigations and first clinical experience with an implantable stimulation device. Orthoped 1984;7:1145-55.

15. Maynard FM, Karvnas RS, Adkins RH, Richards JS, Worring WP. Management of neuromusculoskeletal systems in spinal cord injury. In; Stover SL, DeLisa JA, Whiteneck GG, eds. Clinical outcomes from the model systems. New York; Aspen Publishers, Inc., 1995.

16. Ragnarsson KT, Sell GH. Lower extremity fractures after spinal cord injury: a retrospective study. Arch Phys Med Rehab 1981;62:418-23.

17. Cerny K, Waters R, Hislop H, Perry J. Walking and wheelchair energetics in persons with paraplegia. Phys Therap 1980;60:1133-9.

18. Heinemann AW, Magiera-Planey R, Schiro-Giest C, Gimines G. Mobility for persons with spinal cord injury: an evaluation of two systems. Arch Phys Med Rehab 1987;68:90-3.

19. Mikelberg R, Reid S. Spinal cord lesions and lower extremeity bracing: an overview and follow-up study. Paraplegia 1981;19:379-85.

20. Coghlan JK, Robinson CE, Newmarch B, Jackson G. Lower extremity bracing in paraplegia — a follow-up study. Paraplegia 1980;18:25-32.

21. Sykes L, Edwards J, Powell ES, Ross ER. The reciprocating gait orthosis: long-term usage patterns. Arch Phys Med Rehab 1995;76:779-83.

22. Bowker P, Messenger N, Ogilvie C, Rowley DI. Energetics of paraplegic walking. J Biomed Eng 1992;14:344-50.

23. Winchester P, Carollo JJ, Habasevich R. Physiologic costs of reciprocal gait in FES assisted walking. Paraplegia 1994;32:680-6.

24. Isakov E, Douglas R, Berns P. Ambulation using the reciprocating gait orthosis and functional electrical stimulation. Paraplegia 1992;30:239-45.

25. Hirokawa S, Grimm M, Le T, et al. Energy consumption in paraplegic ambulation using the reciprocal gait orthosis and electrical stimulation of the thigh muscles. Arch Phys Med Rehab 1990;71:687-94.

26. Waters RL, Lunsford BR. Energy cost of paraplegic locomotion: J Bone Joint Surg 1985;67:1245-50.