PERONEAL NERVE FUNCTIONAL ELECTRICAL STIMULATION: FOR WHOM?

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ABSTRACT

Studies of peroneal nerve FES surface systems were performed on forty-three patients with floor clearance problems in gait associated with upper motor neuron dysfunction. Standard clinical assessments of gait utilizing a scoring method were applied prior to, and following varying intervals of FES use. This gait evaluation recorded observed changes in the affected limb(s) during swing phase of gait, and ankle-foot position at the time of floor contact. Based on the initial gait dysfunctional patterns which interfered with limb clearance, patients were divided into two groups; those with primarily distal joint deviations (A), and those with more complicated patterns of both proximal as well as distal joint deviations (B). There was significant improvement in gait in both groups with FES, in the region of 50%, both during swing phase and in ankle-foot position at the time of floor contact. In Group B, approximately 33% increases in knee and hip flexion scores were observed, with approximately 75% of patients demonstrating improvement in floor clearance as well. Unfortunately, all units proved to be unreliable, with frequent electrical and mechanical failures. When patients with clearance problems related to proximal as well as distal joint deviations are responsive to peroneal nerve stimulation, FES would appear to be the orthotic treatment of choice at this time.

INTRODUCTION

Peroneal nerve functional electrical stimulation was developed almost twenty years ago in order to control ankle motion during ambulation by stimulation of the peroneal nerve which activates the dorsiflexor and evertor musculature (1). Numerous reports indicated positive outcomes and beneficial results when it was applied as a dorsiflexion assist in the hemiplegic population (2, 3, 4, 5, 6). Indeed, the patient with hemiplegia, exhibiting predominantly one-sided weakness and equinovarus posturing during gait, served as the prototype for peroneal nerve FES application.

In the United States, despite its initial promise, FES has failed to achieve broad use in the treatment of abnormal gait patterns associated with hemiplegia or other upper motor neuron syndromes. While there are no

available estimates of current FES use, there is likely to be a diminished interest in external FES systems, as evidenced by reductions in the numbers of commercial units available. The paucity of reports in the clinical literature regarding its clinical efficacy has emphasized the lack of support for continued investigation and dissemination.

Research interest and engineering resources have rather been applied to the development of more sophisticated, multi-channel systems (7, 8). Single channel implant systems have also been developed, and the clinical efficacy of these trials has been reported in the recent literature (9, 10). But these do not preclude appropriate continued development of effective and reliable surface systems which do not require surgical intervention. Their use may yield improved gait for a substantial number of patients in a variety of clinical settings.

Unfortunately, there have been few structured programs for patient evaluation utilizing disciplined and standardized clinical methodologies for FES effects since the evaluation of the Ljubljana Functional Electrical Peroneal Brace (11). The development of an evidential basis for FES application would constitute a valuable resource for objective evaluation, particularly if the methods of assessment could also be transferred to the clinical settings where most patients seek care. This study was undertaken to test the efficacy of FES in patients with upper motor neuron syndromes, and in particular, to test its effect on patients with proximal versus distal gait deviations.

METHODOLOGY

The population consisted of patients referred directly to the Krusen Research Center from Temple University Hospital and Moss Rehabilitation Hospital. Patients were referred due to problems in gait. All were associated with upper motor neuron dysfunction.

A standard assessment protocol for evaluation of each patient was utilized as previously described, including the assessment of gait in a test situation (12). The gait evaluation recorded observed changes in the affected limb(s) during swing phase of gait, and ankle-foot position at the time of floor contact, and utilized a numerical scoring system.

Based on the gait dysfunctional patterns observed at the time of initial evaluation, which interfere with clearance of the limb, patients could be described as exhibiting primarily distal joint deviations (classified as Group A), or more complicated patterns of both proximal as well as distal joint deviations (classified as Group B). In both groups, FES was applied for assistance in foot-floor clearance problems during the swing phase of gait. Following base-line assessment, and gait training, the effects of FES were determined at serial intervals, utilizing the same procedure weekly, and monthly (13). Medtronic, Mensor, and Ljubljana units were used. Each

patient was able to adapt to the device in the supervised, test situation, and trained with FES for at least one week. All patients demonstrated intact peroneal nerve activation. The initial, pre-FES values were tabulated as the baseline determination and the last assessment values with FES were used for comparison. The length of time during which FES was used varied with each patient in the study. The intervals between baseline and final assessment differed.

Swing phase evaluation of gait was measured by clinical observation of five components, as previously defined (14). Effective floor clearance was scored normal (score = 0), inconsistently present (score = 1), or absent (score = 2). Position of the foot during the swing phase was observed for foot drop (none = 0), inconsistently present (score = 1), or present (score = 2). Forefoot position was observed and rated normal (score = 0), everted (score = 1), or inverted (score = 2). Maximum knee flexion during initial swing phase of gait was rated normal (score = 0), moderate (score = 1), excessive (score = 1), slight (score = 2), or none (score = 3). Maximum hip flexion during mid swing was rated normal (score = 0), moderate (score = 1), excessive (score = 1), slight (score = 2), or none (score = 3). Degree of knee extension during terminal swing-initial contact was rated normal (score = 0), limited (score = 2), or exaggerated (score = 2). The sum of swing phase scores was compared for each group for both baseline and after FES assessments. Scores ranged between zero, which reflected no deviations, and fourteen, which reflected maximum deviations.

Stance phase evaluation of gait was measured by clinical observation of two components. Contact of the foot on the floor was measured in terms of presence of heel strike (score = 0), inconsistent heel first response (score = 1), entire sole down (score = 2), or forefoot first contact (score = 3). In addition, foot position from initial contact to mid-stance was graded as normal (score = 0), toe-in, toe-out, eversion (score = 1), inversion or foot slap (score = 2), and heel up (score = 3). The sum of foot floor contact scores was compared for each group for both baseline and after FES assessments. Scores ranged between zero, which reflected no deviations, and six, which reflected maximum deviations.

A composite gait score comprising both swing phase and foot-floor contact values was tabulated for both Group A and Group B. The scoring method reflected increasing deviation with higher scores (0 - 20); the greater the reduction in scores with FES, the greater the improvement in gait deviation. Mean scores were compared utilizing Student's t distribution.

RESULTS

A total of forty-three patients (nineteen males, twenty-four females) were included in this study (Table 1). The mean ages and the sex distributions differed slightly between Group A (20) and Group B (23). There were also

variations in both the mean and range of time since onset of disability. In Group A, the patient sample consisted of ten patients with cerebrovascular disease resulting in hemiparesis, four patients with spinal cord injuries resulting in paraparesis, three patients with brain lesions resulting from head injuries, two patients with multiple sclerosis, and one patient with dystonia. In Group B, there were ten patients with spinal cord injuries resulting in paraparesis, six patients with cerebrovascular disease, resulting in hemiparesis, five patients with multiple sclerosis, and one each with closed head injury and parkinsonism.

Both Group A and Group B demonstrated significant improvement during the swing phase of gait with FES, exceeding 50% improvement for both groups (Table 2). Group B had higher mean scores, indicating greater deviation, at both baseline and with FES determinations.

Both Group A and Group B demonstrated significant improvement in mean scores of ankle-foot position at the time of floor contact with FES (40.5% and 64.0%, respectively). The baseline mean score was lower in Group B than in Group A, and also showed greater improvement in mean score with FES (Table 3).

Examination of the total gait during swing phase, as well as at the time of foot-floor contact revealed significant improvement in mean scores for both groups with FES (Table 4). The level of gait disability was greater in Group B, as compared with Group A, at baseline testing before FES. With FES, both groups demonstrated similar mean scores, reflecting approximately 50% improvement in score, with slightly better results in Group B.

Clinical gait evaluation scores of patients with both proximal as well as distal joint dysfunctional patterns (Group B) were further analyzed by focusing on specific FES-effected changes in knee and hip flexion during the swing phase (Table 5). There was a 30.2% increase in knee flexion, and a 35% increase in hip flexion when FES mean scores were compared with baseline.

When improvement with FES in Group B patients was further analyzed according to non-parametric distributions, results showed that fourteen patients (61%) demonstrated increased knee flexion, and fourteen patients (61%) had increased hip flexion, by at least one grade (Table 6). Eighteen patients in this group (78%) demonstrated increase in both knee and/or hip flexion. Two of these patients demonstrated improvement of two grades in knee flexion with FES. All patients with improvement in the proximal joint functions also exhibited improvement in distal joint functions with FES.

DISCUSSION

The evidence from this study showed significant improvement in gait scores in the range of 50% for all patients. This was true for both Group A

and Group B patients, and was manifested by changes in clearance during swing phase, as well as a more normal heel first floor contact. Statistically significant differences were observed when baseline, pre-FES scores were compared with those tabulated following variable intervals of continuous FES use, ranging in this sample, from one week to over three years.

This sample of forty-three patients was characterized by upper motor neuron lesions with different etiologies and varying functional deficits. The patients were selected for this investigation because they responded to FES with peroneal nerve activation, and with changes of increased dorsiflexion, without experiencing any complications that precluded the testing of therapeutic efficacy in a clinical trial. Accordingly, this group represents the potential population for application of FES as an orthotic appliance.

Is FES the best orthotic application for all patients in this sample, because of its proven efficacy? The study design did not include a comparison of other available orthoses on the same patients. However, seventeen patients who were accepted into the study had previously been fitted with metal or plastic mechanical orthotic systems which had not effectively corrected the problem of floor clearance. Further examination of the problems associated with daily FES use may help to clarify the specific indications and unique effects of the FES system for some of these patients.

The problems related to peroneal FES systems were frequent and frustrating. Every patient was plagued with interruptions in use caused by mechanical and electrical failures requiring technical repair services. No single unit functioned reliably for any sustained interval. The most frequent equipment failures in the external Ljubljana units were broken connector plugs and cables, together with faulty foot switches and broken on-off switches. Patients using Mensor units had most frequent problems with foot switch wire leads and main cable connector plugs. There were also many breakdowns caused by rechargeable batteries that did not hold their charges. In the Medtronic units, broken ratchet and amplitude dials comprised the most frequent breakdowns requiring repair. Defective integrated circuits and resistors were second in frequency of repair. Patients using the Medtronic system needed to replace electrodes frequently because of broken-off connector attachments to the electrode cable plug. These failures tended to undermine patient confidence and compromised both adaptation and tolerance, not to mention the time and expense of service.

The FES system, unlike a more conventional orthosis, requires more time and motivation for success in daily application. Training is required for effective daily use and requires supervision and surveillance. Expensive service facilities with skilled technical staff are a necessity. The FES units are far more expensive than any other existing ankle-foot orthoses, and in the U.S., are not readily available for purchase. If other, less sophisticated orthotic systems are effective for needed distal joint improvement, should they not be preferred?

Patients who exhibit swing phase floor clearance problems which are associated with complex deviation patterns, such as inadequate hip and/or knee flexion and/or inadequate ankle dorsiflexion, may experience failure with mechanical orthotic systems that mainly affect foot-ankle changes. For example twenty-one of twenty-three patients in Group B characterized by these complex deviation patterns, had floor clearance problems, despite the fact that most had already been fitted with mechanical systems. Seventeen of twenty-one showed improvement in this category. Of these seventeen patients, seven improved from no floor clearance to clinically acceptable and consistently present floor clearance; six improved from no floor clearance to the category of inconsistent floor clearance; four improved from inconsistent floor clearance to consistently present floor clearance. It is difficult to attribute a cause and effect relationship between floor clearance and improvement in joint deviations. Improvement in floor clearance was observed in thirteen of eighteen patients in Group B who demonstrated proximal joint changes. But it was also observed in four of the remaining five patients in Group B who experienced neither increased hip or knee flexion with FES. These tabulations were based on small sample sizes, and additional studies of inter-related joint changes are indicated (see Table 6). However, it seems fair to say that improvement of gait with FES probably resulted from changes in a number of clinical parameters (some as yet unidentified), and not from any single joint change alone.

In addition to the specific problem of clearance, other manifestations of improvement in gait patterns were noted. There was increased symmetry of right-left step length and swing-stance ratios in thirteen patients (57%), and reports of increased endurance in gait in twelve patients (52%) in Group B with FES. Six of seven patients with both improved symmetry and increased endurance also showed improvement in both knee and hip flexion, as well as improved distal joint function. This group, representing approximately one in four of the Group B patients, and one in seven of the total sample of forty-three patients, achieved optimal effects with an external peroneal nerve stimulating system.

Patients who exhibit changes in proximal as well as distal limb movement with FES, effecting clearance, increased symmetry and endurance, justify continued FES application, and the development of more reliable systems. It appears that no other distally applied orthotic system exists to date with similar clinical applicability. Therefore, at the present time, when clearance problems related to deviations at the hip and knee, as well as at the ankle, are responsive to peroneal nerve stimulation, FES would be the orthotic treatment of choice.

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Table 1

Description of Patient Sample for FES

Characteristic	Group A * n = 20	Group B ** n = 23
Sex:		
Males	10 (50%)	9 (40%)
Females	10 (50%)	14 (60%)
Age:		
Males (mean, years)	40.5	45.4
Females (mean, years)	36.7	50.9
Time since Onset:		
Range (years)	0.5 to 28.0	1.0 to 34.0
Mean (years)	4.5	8.7
Duration of FES Trial:		
Range (weeks)	1 to 60	1 to 157
Mean (weeks)	9.2	21.8

* Patients with Primarily Foot-Ankle Disabilities

** Patients with Hip, Knee, and Ankle Disabilities

Table 2

FES Effects During Swing Phase in Group A (Primarily Foot-Ankle Disabilities) and Group B (Hip, Knee, and Ankle Disabilities).

(Range = 0 - 14)

Group	No.	Baseline Pre-FES (Mean Score)	With FES * (Mean Score)	Percent Difference (Improvement)
Group A	20	6.05	2.70	55.4% **
Group B	23	8.35	3.83	54.1% **

* Final assessment of multiple evaluations (intermediate values not included): time intervals from initial to final assessments vary.

** p = less than .001

Table 3

FES Effects on Ankle-Foot Position at Time of Floor Contact in Group A (Primarily Foot-Ankle Disabilities) and Group B (Hip, Knee, and Ankle Disabilities).

(Range = 0 - 6)

Group	No.	Baseline Pre-FES (Mean Score)	With FES * (Mean Score)	Percent Difference (Improvement)
Group A	20	3.70	2.20	40.5% **
Group B	23	2.78	1.00	64.0% **

* Final assessment of multiple evaluations (intermediate values not included): time intervals from initial to final assessments vary.

** p = less than .001

Table 4

Total Effects of FES During Gait (Swing Phase and Foot-Floor Contact) in Group A (Primarily Foot-Ankle Disabilities) and Group B (Hip, Knee, and Ankle Disabilities).

(Range = 0 - 20)

Group	No.	Baseline Pre-FES (Mean Score)	With FES * (Mean Score)	Percent Difference (Improvement)
Group A	20	9.75	4.90	49.7% **
Group B	23	11.13	4.83	56.6% **

* Final assessment of multiple evaluations (intermediate values not included): time intervals from initial to final assessments vary.

** p = less than .001

Table 5

Changes in Knee and Hip Flexion During Swing Phase for Group B (Hip, Knee, and Ankle Disabilities): N = 23.

(Range = 0 - 3)

Joint	Baseline Pre-FES (Mean Score)	With FES * (Mean Score)	Percent Difference (Improvement)
Knee	2.30	1.61	30.2 **
Hip	1.74	1.13	35.0 **

* Final assessment of multiple evaluations (intermediate values not included): time intervals from initial to final assessements vary.

** p = less than .001

Table 6

Analysis of Group B Patients (Hip, Knee, and Ankle Disabilities) for Improvement Rates in Knee and in Hip Flexion with FES During Swing Phase.

Changes with FES	Knee		Hip		Both Knee and/or Hip	
	No.	%	No.	%	No.	%
No Change	9	39	9	39	5	22
Increased Flexion (1 or more scores)	14	61	14	61	18	78
Total	23	100	23	100	23	100