Impairment, Functional Mobility, and Gait Kinematic Gains In Response To FNS and Weight Supported Gait Training

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Abstract

After stroke, persistent gait deficits cause debilitating falls and poor functional mobility. The purpose of this study was to test two promising gait training technologies: functional neuromuscular stimulation (FNS) with intramuscular (IM) electrodes (FNS-IM); and body weight supported treadmill training (BWSTT). Sixteen subjects (> 12 months post stroke) were randomized to one of two treatment groups (Group 1, No-FNS; Group 2, FNS-IM). For each treatment session, all subjects received ½ hr BWSTT, ½ hr exercise, and ½ hr over ground gait training, and all received treatment for 12 weeks, 4x's/wk, 1½ hrs/session. The FNS-IM group used FNS for all treatment aspects; whereas, the No-FNS group did not use FNS. Our outcome measures were of volitional motor function (FNS de-activated) including impairment, functional mobility, and gait kinematics. Pre-/post-treatment comparisons were made using the Wilcoxan Rank Sum Test for ordinal measures and small sample size. Both groups had gains in coordination, Tinetti Balance and Gait, and Six Minute Walk Test. The FNS-IM group had significantly greater gains in the Tinetti Gait Scale versus the No-FNS group. The No-FNS group had no gains in gait kinematics. The FNS-IM group had significant gains in two swing phase gait kinematic measures that were maintained for six months.

1 Introduction

1.1 Problem

More than 3 million stroke survivors live with residual disabilities and mobility deficits even after rehabilitation. Persistent gait deficits cause debilitating falls and poor functional mobility. Gait restoration can preclude these outcomes. For successful motor learning, the desired motor task must be practiced in a pattern as closely approximating normal as possible (Wu 2000) and intensive practice must be provided (Butefisch 1995). Often, conventional gait training methods do not provide these motor learning requirements. There is a dearth of studies showing gait kinematic improvements in response to treatment following stroke.

1.2 Purpose

The purpose of this study was to develop and test gait training methods that potentially could provide a practice pattern that was close to normal and afforded multiple repetitions of the desired pattern. Two promising gait training technologies were tested: functional neuromuscular stimulation (FNS) with intramuscular (IM) electrodes (FNS-IM); and body weight supported treadmill training (BWSTT).

2 Methods

2.1 Subjects

Sixteen subjects (> 12 months post stroke) were stratified according to severity of stroke, using the Fugl-Meyer (FM) Coordination Scale, and randomized to one of the two gait training treatment groups. An inclusion criterion was a swing phase gait deficit that was not corrected with up to 30% BWS at walking speeds as slow as 0.1 mph. The swing phase deficit was defined as inability to flex the hip, knee, and ankle, sufficiently to clear the floor normally in the sagittal plane.

2.2 Intervention

Both groups received treatment for 12 weeks, 4 times/wk, 1½ hrs/session, including: ½ hour strengthening and coordination; ½ hour over ground gait training; and ½ hour BWSTT. Group 2 used FNS-IM for all aspects of treatment; whereas, Group 1 did not use FNS.

2.3 Equipment and Technology

BWSTT was implemented using the BIODEX 500 (Biodex; Shirley, New York) treadmill and harness apparatus. For the FNS-IM system, subjects were implanted with up to 8 intramuscular electrodes to treat the following paretic muscles: tibialis anterior; peroneus longus; lateral head of the gastrocnemius; short head of the biceps femoris; semimembranosus; semitendonosus; vastus lateralis; and gluteus medius. The percutaneous, intramuscular (IM) electrodes were constructed of 316, ten-strand, stainless steel wire configured in a double helical coil for flexibility, with a polypropylene filament core for durability. We used the following parameters: frequency, 33Hz; amplitude, 20mamps; and pulse width duration 4 - 150microsecs.

2.4 Outcome Measures and Data Analysis

All outcome measures were made without the use of FNS-IM or BWS or BWSTT. (i.e., volitional motor function). Pre-/post-treatment measures were obtained for impairment, functional walking, and gait kinematics. The following measures were used: Fugl-Meyer Coordination Scale (FM); Ashworth Spasticity Scale (AS), Tinetti Balance and Gait Scales; the Six Minute Walk Test (6Min). Gait kinematics were measured using a 7-camera, Vicon 370 system (Oxford Metrics; UK), a computerized, three-dimensional video data acquisition system. We calculated peak swing hip flexion, peak swing knee flexion, and mid-swing ankle dorsiflexion using Matlab (The MathWorks, Natick MA). Group and pre-/post-treatment comparisons were made using the Wilcoxan Rank Sum Test, a non-parametric model for ordinal scales an/or small sample size.

3 Results

Prior to treatment, there was no significant difference between the two treatment groups regarding age (F (1,14) = 1.001, p = .34); years following stroke (F (1,14) = .044, p = .84); stroke severity (FM score; p = .27) or kinematic gait components (peak swing hip flexion, p = .55; peak swing knee flexion, p = .31; mid-swing ankle dorsiflexion, p = .55). There was subject attrition of 1 subject (from the No-FNS group).

Table 1 and 2 list the pre- and post-treatment mean values and change scores for each treatment group, respectively, regarding impairment and functional gait. For both groups there were significant gains for the FM, TB, TG, and 6Min. In terms of group comparisons, there was no significant difference between the two groups for any of the impairment or disability measures, except the Tinetti Gait Scale, for which the FNS-IM group showed greater gain than the No-FNS group (p = .04).

Table 1. NO FNS

	Pre Mean (Std Dev)	Post Mean (Std Dev)	Pre/Post Change
1. F-M Coordination	19.56 (± 4.48)	22.67 (± 5.27)	3.11 p = .01*
2. Ashworth	5.50 (± 5.68)	3.89 (± 5.21)	-1.61 p = .04*
3. Tinetti Balance	11.11 (±2.89)	12.78 (± 2.73)	1.67 p = .02*
4. Tinetti Gait	5.67 (± 1.94)	6.56 (± 1.97)	0.89 p = .04*
5. Six Minute Walk	466.25 (± 110)	623.5 (± 121.81)	157.25 p = .01*

* Significant gains, p < .05.

Table 2. FNS-IM

	Pre Mean (Std Dev)	Post Mean (Std Dev)	Pre/Post Change
1. F-M Coordination	22.63 (± 4.21)	27.13 (± 3.68)	4.5 p = .01*
2. Tinetti Balance	12.75 (± 2.25)	15.00 (± .93)	2.25 p = .03*
3. Tinetti Gait	6.5 (± 2.78)	8.25 (± 2.49)	1.75 p = .03*
4. Six Minute Walk	583.63 (± 247.30)	814.38 (± 376.74)	230.75 p = .02*

* Significant gains, p < .05.

Tables 3a and 3b show results for gait kinematics. Both groups showed no significant pre-/post treatment gain in peak swing hip flexion. Group 1 (No-FNS) had no significant gains in other gait components at post treatment or at follow-up. In contrast, Group 2 (FNS-IM) had significant gains in peak swing knee flexion and mid-swing ankle dorsiflexion (p < .05) that were maintained for six months (p values ranged .27 - .46; Daly 2004).

Table 3a.
Comparison of Three Month Treatment Response

Gait Components	NO FNS (N =7)		
	Pre (degrees)	Post (degrees)	Change (degrees)
Peak Swing Hip Flexion	31.3 ± 5.1	37.8 ± 7.1	6.5 p = .07
Peak Swing Knee Flexion	31.0 ± 12.1	32.4 ± 11.8	1.4 p = .84
Mid-Swing Ankle Dorsiflexion	1.3 ± 7.3	4.6 ± 6.6	3.3 p = .40
Number of gait components with significant gains			0

★ Significant gains, p < .05.

Table 3b.
Comparison of Three Month Treatment Reponse

Gait Components	FNS-IM (N = 8)		
	Pre (degrees)	Post (degrees)	Change (degrees)
Peak Swing Hip Flexion	24.7 ± 13.0	31.3 ± 10.1	6.6 p = .06
Peak Swing Knee Flexion	23.5 ± 14.6	33.5 ± 15.9	10 p = .02*
Mid-Swing Ankle Dorsiflexion	-1.3 ± 9.0	5.0 ± 3.9	6.3 p = .04*
Number of gait components with significant gains			2

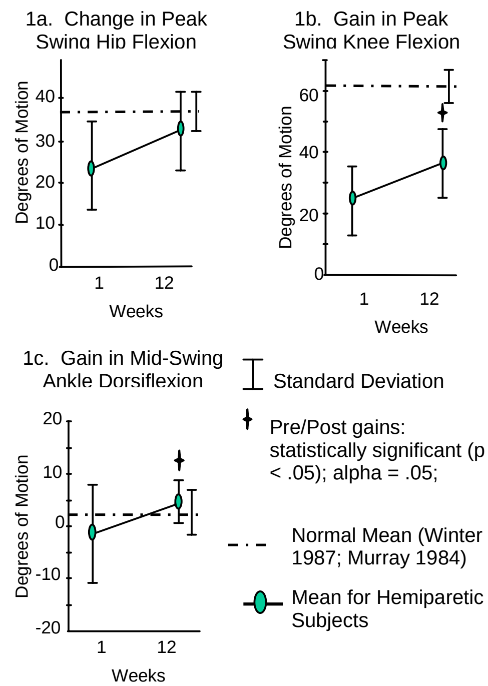
★ Significant gains, p < .05.

4 Discussion and Conclusions

Subjects in both groups had gains in impairment and walking endurance. These gains support the concept that rehabilitation over a year after stroke can have a positive effect. The FNS-IM group had significantly greater gains in the Tinetti Gait Scale versus the No-FNS group. The Tinetti Gait Scale measures the execution of gait components. This single difference between the two groups regarding the Tinetti Gait Scale may indicate that the gains in impairment translated into actual gains in the gait pattern only for the FNS-IM group.

The gait kinematics results also suggest that FNS-IM produced changes in execution of the gait pattern. Before treatment, subjects in the FNS-IM group had gait deficits that had persisted 1 – 15 years, but the group still demonstrated significant gains after FNS-IM regarding volitionally performed swing phase gait components (Figure 1). These gains were maintained for six months after the end of treatment. The No-FNS group did not demonstrate gains in gait kinematics at either post-treatment or follow-up. The unique capabilities of FNS-IM enabled practice of muscle contractions and gait swing phase components that closely approximated normal. The BWSTT provided a safe environment in which to practice repetitions of the gait components. The combination of FNS-IM and BWSTT could have synergistically produced the gains in gait kinematics.

***Figure 1:** Significant Kinematic Changes In Swing Phase Following FNS-IM*



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