

# FNS For Gait Component Restoration Post Stroke

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## Abstract

Purpose. A multi-channel functional neuromuscular stimulation (FNS) system using intramuscular (IM) electrodes (FNS-IM) and an externally worn stimulator were tested for suitability in patients with stroke; feasibility in acute stroke; and efficacy in restoration of gait in chronic stroke. Methods. First, mechanical and physiological performance and subject response were quantified for 124 electrodes in 17 subjects. Second, we tested a seven-channel system for acute stroke (3 weeks to 3 months from stroke onset). Third, we studied the efficacy of FNS-IM for gait restoration for chronic stroke. Outcome measures included impairment, disability, and function. Results. There were 1,413.8 total electrode-months of use, free of mechanical failure. There was a 99.6% chance of electrode survival at 21 months and no infections. FNS-IM proved feasible for subjects with acute stroke, who improved in pre-/post-treatment measures ( $p \leq .014$ ). After FNS-IM treatment, subjects with chronic stroke demonstrated gains in strength, coordination, and gait components beyond those achieved following surface stimulation ( $p < .05$ ). Conclusion. These results justify further studies of this technology for stroke gait training.

## Introduction/Background

Common and disabling gait deficits following stroke include the inability to achieve normal floor clearance of the limb during the swing phase of gait and inability to maintain balance control during stance phase. These gait deficits can result in an inefficient gait and debilitating falls. Inefficient gait results in high energy cost and poor walking endurance [1], which in turn can require costly care and reduced quality of life. Falls can result in broken bones, other injuries, and fear of ambulation, which can in turn cause a downward spiraling sequelae of events including greater dependence, costly care, and reduced quality of life. The therapeutic results obtained from single channel implanted and multi-channel surface systems for patients with stroke are well documented and included: improving muscle strength [e.g., 2,3]; passive range of joint motion [4], active range of joint movement [5]; muscle spasticity [6]; muscle reeducation [7, 8]; and gait [9, 10, 11, 12, 13]. Shortcomings of these systems included: poor muscle selectivity; pain with surface electrodes; poor repeatability in muscle response on different days; patient inability to don the surface-stim system; impractical setup time for the therapist; skin irritation; inadequate number of channels; and lack of

portability of the system [8, 12, 13, 14, 15]. In addressing these shortcomings, the use of multi-channel, implanted technology has been investigated for patients with stroke. For restoration of the swing and stance phase of gait, one promising treatment system is a multi-channel functional neuromuscular stimulation (FNS) system using intramuscular electrodes (FNS-IM) and an externally worn stimulator. The hypotheses for testing this system were: (1) the FNS-IM system with the intramuscular electrodes is suitable for gait training in patients with stroke; (2) the FNS-IM system is feasible for gait training in patients with acute stroke; and (3) the FNS-IM system is efficacious in restoration of swing and stance phase gait components in patients with chronic stroke.

## Methods

Hypothesis 1. We studied the performance of 124 electrodes in 17 acute and chronic subjects with stroke, measuring mechanical and physiological performance and biocompatibility [16]. The electrodes were constructed with a double helical coil for flexibility and a polypropylene core for durability. The electrodes and stimulus parameters were tested extensively for safety of charge density within the tissue [17]. Outcome measures were mechanical and electrical performance of the electrode and response of the subject to the electrodes.

Hypothesis 2. Eight subjects with acute stroke (3 weeks to 3 months from stroke onset) were provided with twice weekly gait training using FNS-IM for six months. Stimulus parameters were 30 Hz, 1-150 $\mu$ sec, 20mA, 3 sec on, 3 sec off). Outcome measures were subject toleration of treatment, subject satisfaction, system performance and use, gains in muscle strength (manual muscle test), coordination (Fugl-Meyer Scale; [18]), balance (Tinetti Scale; [19]), and gait (Tinetti Scale; [19]), all measured with the FNS deactivated. Pre/post treatment comparisons were made through analysis of ANOVA models ( $\alpha = .05$ ).

Hypothesis 3. Six subjects with chronic stroke were enrolled in a single case design pilot protocol for comparing response to sequential treatments of surface FNS followed by FNS-IM. The subjects had a stroke from one to four years prior to enrolling. All subjects had participated in rehabilitation immediately following the stroke. They received surface stimulation for knee and ankle flexors and extensors twice weekly for 3 months using a commercially available system. The stimulus parameters were optimized within the

limitations of the commercial system (30 Hz; 300  $\mu$ sec; 1-6mV, and 3 sec on, 3 sec off). The second in the series of treatments was FNS-IM which was provided according to the same treatment schedule and the following stimulus parameters: 30Hz; 0-150  $\mu$ sec; 20mA. Outcome measures were lower limb muscle strength (manual muscle test) and coordination and gait components (video-based motion analysis data acquisition system). Pre/post treatment comparisons were made through analysis of ANOVA models ( $\alpha = .05$ ).

## Results

Hypothesis 1. Overall, there were 1,413.8 total electrode-months of use, free of mechanical failure. There was a 99.6% chance of electrode survival at 21 months of use. There were 6 electrodes exhibiting high impedance, and assumed breakage (Table 1 [16]). There were no infections and 100% patient satisfaction. Therapists used the system for strengthening, endurance, coordination and gait training.

**TABLE 1. Mechanical Performance of Electrodes**

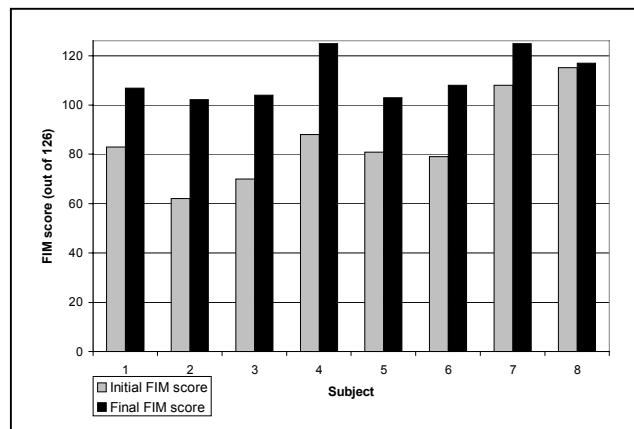
	A.	B.	C.	D.
Subjects	Total Elect.	Normal Imp. (no. of elect.)	Abnormal Imp. (no. of elect.)	Total Elect-Months Free of Failure
Acute	55	55	0	484.9
Chronic	69	63	6	928.9
Totals	124	118	6	1413.8

Hypothesis 2. The day after implantation, all acute subjects had the same ambulatory status, as prior to the procedure and lost no days of rehabilitation or normal activity except the day of the electrode implantation. The majority of subjects reported thigh discomfort for less than 24 hours following electrode placement. They tolerated the treatment well and were able to receive FNS-IM in addition to their prescribed conventional therapy. As a result of the FNS-IM, they did not worsen. Subjects improved for these pre-/post-treatment measures: FIM score ( $p = .0159$ ; Fig. 1); muscle strength (77% of treated muscles improved); Fugl-Meyer Coordination Scale ( $p = 0.014$ ); Tinetti Balance ( $p = 0.022$ ) and Gait Scales ( $p = 0.029$ ).

Hypothesis 3. During the conventional treatment for chronic subjects, there were gains; however, gains generally plateaued below normal performance. During the FNS-IM treatment, there were additional gains in muscle strength, coordination (Table 2), and volitional gait (Table 3) achieved beyond those obtained in the conventional phase of treatment. All six subjects

**Fig. 1. FIM Score Pre/post Treatment for Each Subject**

improved in dorsiflexion at heel strike. Five improved in knee flexion at toe-off, peak swing knee flexion, and



**TABLE 2. Gains of Strength And Coordination For Chronic Stroke Patients Following FNS-IM, Beyond Gains Attained With Three Months Of Conventional Treatment**

Strength Measure <sup>1</sup>	Number of Patients with Gains (N=6)
Ankle Dorsiflexion	3 / 6
Knee Flexors	4 / 6
Knee Extensors	3 / 6
Coordination Measure <sup>2</sup>	
Ankle Flexion Coordination	5 / 6
Knee Flexion Coordination	5 / 6
Knee Extension Coordination	5 / 6

<sup>1</sup> Gains in strength = change in one whole number (e.g. 2 to 3); or change from partial to full movement within normal range; or change from zero to partial movement

<sup>2</sup> Gains in Fugl-Meyer score = change from partial to full motion within a category; or change from movement within synergy to isolated movement outside of synergy control.

**TABLE 3. Gains of Volitional Gait For Chronic Stroke Patients Following FNS-IM, Beyond Gains Attained With Three Months Of Conventional Treatment**

Gait Component	Number of Patients with Gains
Dorsiflexion at Heel Strike	6 / 6 *
Peak Swing Dorsiflexion	5 / 6 *
Knee Flexion at Toe Off	5 / 6 *
Peak Swing Knee Flexion	5 / 6 *
Knee Angle at Heel Strike	4 / 5 **
Knee Angle at Midstance	4 / 5 **

\* Significant pre/post treatment gains ( $p < .05$ ).

\*\* One patient was normal throughout.

peak swing dorsiflexion. Gait pattern improvements enhanced quality of life in terms of personal care capability and leisure and social activity levels.

## Discussion/Conclusions

The electrode design for the FNS-IM system was successful in functioning for patients with stroke during gait training within an environment which required long lead wires, large muscle forces, tissue shear forces, joint

crossings, and large excursions of movement. The design features of the single and double helical coil of the lead wire and electrode were sufficiently flexible to withstand the relatively large excursions of muscle and joint movement without dislodging the electrode from the initial motor point. The reported comfortable stimulus resulted in muscle contractions sufficient to support body weight and lift a limb segment against gravity which could have then produced gains in volitional coordination and gait. The absence of infection indicates a suitably safe technology.

The technology was tolerated well by patients within 3 weeks to 3 months following stroke. This finding supports performance of a larger study using randomized assignment to FNS-IM or conventional therapy. Pilot data from patients with chronic stroke suggests that the treatment was efficacious. The findings support the need for a study with a larger sample size so as to enable generalization of findings.

## References

- [1] Perry J. Gait Analysis: Normal and Pathological Function. Thorofare, NJ: Slack Inc., 1992.
- [2] Vodovnik L., Kralj A., Stanic U., et. al.: Recent Applications of Functional Electrical Stimulation to Stroke Patients in Ljubljana. *Clin Orthop*, 131:64-70, 1978..
- [3] Winchester, P. Montogmery P., Bowman B., Hislop H.: Effects of Feedback Stimulation Training and Cyclical Electrical Stimulation on Knee Extension in Hemiparetic Patients, *Phys Ther*, 678(7):1096-1103, 1983.
- [4] Baker L.L., Yeh C., Wilson D., et. al.: Electrical Stimulation of Wrist and Fingers for Hemiplegic Patients. *Phys Ther*, 59:1495-1499, 1979.
- [5] Bowman B.R., Baker L.L., Waters R.: Positional Feedback and Electrical Stimulation: An Automated Treatment for the Hemiplegic Wrist. *Arch Phys Med Rehab* 60:497-502, 1979.
- [6] Lagasse P.P.: (Human Motor Performance Lab, Laval University, Ste-Fog, Quebec, Canada), Campney H.K., Steinberg G.S., Knoll W.P., Patterned Electrical Stimulation and Treatment of Spastic Hemiparesis, *Arch Phys Med Rehab*, 66:530, 1985.
- [7] Benton L.A., Baker L.L., Bowman B.R., et. al.: Functional Electrical Stimulation: A Practical Clinical Guide. Rancho Los Amigos Rehab Eng Center, Downey, CA, 1980.
- [8] Stanic, R., Acimovic-Janezic, R., Gros, N., Trnkoczy, Bajd, T. & Kljajic, M. Multichannel electrical stimulation for correction of hemiplegic gait. *Scand J Rehab Med*, 10, 15-92, 1978.
- [9] Meadows, P., Winstein, C and Bowman B. (1985) Weight Transfer Using Biofeedback and Electrical and Electrical Stimulation. In Proceedings of RESNA 8th Annual Conference (Memphis, 1985), pp. 117-118.
- [10] Kralj A, Trynkoczy A, Acimovic R. Hemiplegic gait improvement by means of three-channel functional electrical stimulator. *Elektrotehniki Vestnik*, Ljubljana, 1971 pp a12-a15, 1971.
- [11] Malezic, M., Hesse, S., Schewe, H., Mauritz, K.H.: Restoration of standing, weight-shift and gait by multichannel electrical stimulation in hemiparetic patients. *International Journal of Rehabilitation Research*, 17:169-79, 1994.
- [12] Bogataj U., Gros N., Malezic M., Kelij B., Kljajic M., Acimovic R.: Restoration of Gait During Two of Three Weeks of Therapy with Multichannel Electrical Stimulation. *Phys Ther* 69(5):319-326, 1989.
- [13] Bogataj, U., Gros, N., Kljajic, M., Acimovic, R., Malezic, M.: The rehabilitation of gait in patients with hemiplegia: a comparison between conventional therapy and multichannel functional electrical stimulation therapy. *Phys Ther*, 75:38-52, 1995.
- [14] Petrofsky J.S., Phillips C.A.: Closed-loop Control of Movement of Skeletal Muscle. CRC Critical Reviews in BME, 13(1):35-75, 1985.
- [15] Brandell, B.: The Study and Correction of Human Gait by Electrical Stimulation. *American Surgeon*, 52, pp. 257-263, 1986.
- [16] Daly JJ, Debogorski A, Strasshofer B, Scheiner A, Kollar K, Marsolais EB, Ruff RL, Snyder S. Percutaneous electrode performance and use for restoration of gait in patients with stroke. *J Rehab Res Dev*, accepted, 2001.
- [17] Scheiner A, Polando G, Marsolais EB. Design and clinical application of double helix electrode for functional electrical stimulation. *IEEE Trans Biomed Eng* 1994;41(5):425-431.
- [18] Fugl-Meyer AR, Jaasko L, Layman I, Olssen S, Steglind S. Post stroke hemiplegic patient. *Scand J Rehab Med*. 1975;2:13-31.
- [19] Tinetti ME. Performance-oriented assessment of mobility problems in elderly patients. *JAGS* 1986;38:119-126.

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