Table I. NMES Case Series Studies for Use of Parastep®I System

Author/Year	Objectives	Patient Characteristics	Methods	Results/Conclusions
Brissot/2000	To investigate the motor performances of Parastep device regarding energy expenditure, and to evaluate its advantages and limitations.	15 patients with paraplegia (11 M & 4 F; range 16-47, with mean 28+/-9). Affected levels from T3 to T11, with Frankel A in 13 patients and incomplete in remaining 2 (one B and one C). All with moderate spasticity (Ashworth scores 2 and 3). Mean time since spinal cord injury (SCI) 53+/-59 months, with range 6-240. Traumatic cause in 14/15, with infection in remaining patient. INCLUSION CRITERIA: 1. Intact lower motor neurons (T12-L1 and below). 2. Appropriate contractile response to NMES. 3. Sensory tolerance to stimulus. 4. Adequate upper limb function. 5. Intact cardiorespiratory function. 6. Good standing tolerance. 7. Sufficient motivation. 8. At least 6 months since injury and/or restorative surgery. EXCLUSION CRITERIA: 1. Severe spasticity. 2. Limited range of motion of hip, knee or ankle. 3. Joint laxity or instability. 4. History of fracture. 5. Severe scoliosis. 6. Skin conditions at electrode site.	Standing up was permitted as soon as quadriceps strength reached 3-4 kg under surface electrostimulation. Upright mobility was taught first by using parallel bars. Gait with the walker began as soon as the patient had acquired the basic principles of this ambulation and handling of the device. Activities of daily life studied during clinical visits and by questionnaire. Training in most patients was under one month.	13/15 patients acquired independent ambulation, and the other two withdrew, one of whom had significant pain induced by electrostimulation, in spite of rapid progress during early gait training. Mean walking distance without interruption was 52.8+/-69 m (range 2-350 m). Average speed was 0.15+/-0.14 m/sec (maximum 0.4 m/sec). 10/13 patients had evaluation for long-term use, but this duration was not specified. 5 still using it at home. Significant improvement in self-concept scores, but modest increase in social rehabilitation scores. Study concludes, however, that high ratio of energy cost to effectiveness (speed) is likely to account for its limited use in daily activities.
Gallien/1995	Similar to Brissot above.	Significant overlap in patients used in above Brissot study.	See Brissot above.	4/8 patients who possessed their own device used it regularly for walking at home with one patient using it up to 2.5 years (mean follow-up 15 mo.).
Winchester/1994	To report the velocity and physiologic cost index (PCI) of ambulation using Parastep in paraplegic SCI subjects.	Five subjects (4 M, 1 F), with age range 20-37 and complete SCI between T4 and T12 (subjects above T3 excluded from study consideration). Times since injury ranged from 21-84 months.	Each subject was instructed to walk at a self-selected velocity down a 5 m gait lane while being videotaped from the front and side. Average time using the system was 16.8+/-5.0 months.	Velocity range: 4.60-24.28 m/min Cadence range: 14.1-45.0 steps/min PCI range: 2.30-6.26 beats/min Distance walked range: 10.97-61.87 m Parastep users perform at significantly different levels, with even the best users being slower and less energy efficient than normal walkers.
Klose/1997	To describe performance parameters in SCI subjects with the Parastep 1 system.	16 subjects (13 M & 3 F, mean age 28.4 +/- 6.6 years). All subjects with complete injuries between T4-T11, and mean duration of injury 4.0 +/- 3.5 years. Exclusionary criteria included history of fractures or degenerative joint disease, skin breakdown, cardiovascular disease, lower motor neuron injury, restricted range of motion in lower extremities and severe spasticity.	Weekly means and standard deviations were calculated for (1) distance; (2) duration of standing and walking; and (3) pace (i.e., distance divided by duration) across 11-week study period.	Repeated measures ANOVA revealed statistically significant overall differences across the 11 weeks for distance, duration and pace. Tukey "A" pairwise test comparisons indicated that means for weeks 8-11 did not differ significantly, but were different from weeks 1-4. Most peak values occurred in weeks 10 or 11.

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Chaplin/1996	Brief overview of the outcome of a cohort of the first 100 people to use the device.	100 participants expressed desire to use the system, and had the following selection (screening) criteria - INCLUSION: 1. Minimum of six months after spinal cord injury and restorative surgery. 2. Incomplete cervical injuries, with complete or incomplete thoracic injuries. 3. Absence of orthopedic, neurologic or metabolic problems. 4. Presence of LMN activity (L1 and below). 5. Absence of long bone fractures secondary to osteoporosis and absence of lower extremity joint disease. 6. Sufficient joint stability for weight bearing in both lower extremities. 7. Good range of motion, absence of contractures about the hips, knees and ankles, and absence of spasticity which might preclude standing in upright position. 8. Cognitive ability to employ the system, independent in transfers and adequate finger function to manipulate system controls. 9. Stimulation must contract quadriceps. EXCLUSIONS: Active cardiac disease, pulmonary insufficiency, epilepsy, pregnancy, severe scoliosis, severe symptomatic osteoporosis, active skin disease at the stimulation sites, irreversible contractures, morbid obesity, and visual hearing which would interfere with training or symptomatic automatic autonomic dysreflexia. Of these 100 subjects, 91 were judged to be appropriate candidates: Mean age 33.7 (range 15-69), 76% M and 24% F. 3/91 had non-traumatic injuries: Multiple sclerosis, transverse myelitis, and infarction following meningitis. Two injuries at C6-7 and remaining from T1-12, with 78% complete and 22% incomplete. Indeterminate overlap of subjects with FDA Summary of Safety and Effectiveness Data. No mention of number of centers used to recruit subjects.	Training program was designed to promote safe and effective standing and walking within 32 physical therapy training sessions. Almost all participants were fitted with bilateral ankle-foot orthoses.	All 91 subjects demonstrated the ability to stand, 84 (92%) were able to stand and take steps and 31 (34%) were eventually able to ambulate without the assistance of another person (with mean ambulation distance = 324 feet and median distance = 226 feet). 21/31 used the system for mobility both in the home and in the community. 50/91 completed training and completion rate did not appear to be correlated with level of injury. Three most common reasons for failure to complete training before reaching independence: Non-compliance with protocol, time conflicts and miscellaneous medical conditions. Preliminary follow-up on 48 subjects suggested 82% used system regularly and 75% used it three or more times per week.

Table II. NMES Case Series Studies for Use of Non-Parastep®I Systems

Author/Year	Objectives	Patient Characteristics	Methods	Results/Conclusions
Solomonow/1997	Evaluation of Reciprocating Gait Orthosis powered with NMES (RGO II) across a broad cross-section of the paraplegic population.	70 patients (50 M, 20 F) who voluntarily sought treatment with RGO II. 66 with T1-T12 injury level and 4 with C-6/7. 63/70 with gunshot wounds, motor vehicle accident or other injury and remaining 7 with medical complications (not specified). 30 patients recruited within 2 years of injury, 30 others between year 2-10 and remaining 10 greater than 10 years. Largest age cohort (27 patients) from 26-35, with 3 patients over age 50. Please note that variability in extent of SCI was not specified.	Surface system. Patient was considered successful if able to do each of the following independently: Don and doff the RGO II, stand up and sit down, walk on grass, gravel, ramps and up and down curbs and to walk at least 180 m. Six months after the last of the 70 patients concluded their training and were discharged, each patient was contacted to obtain information on further use, utility and impact of RGO on their lives.	Overall 75.7% success rate, and 24.3% failure rate, with diverse causes of failure: Medical problems unrelated to RGO II device, lack of motivation & miscellaneous personal problems. Diminishing success:failure ratios by ascending level of injury, with 4.25:1 at T-11/12 and 1:1 at C-6/7. 41 patients participated in post-discharge assessment: 22% used it >3/wk., 26.8 1-3/wk., 12.2% at least once/mo., and 19.5% were non-users. 65.9% used it for exercise, and 14.6% in daily life activities (e.g., shopping, social occasions, and housework).
Granat/1992	Gait reproduction in patients with SCI. Comparison between orthoses and NMES.	Six patients with incomplete SCI (only considered for participation if at or above T-12). 3 M and 3 F, with age range 18-40, and periods varying from 2-19 years post-injury. Two patients had mid-cervical lesions, one a mid-thoracic lesion, and three had lower thoracic lesions. Three patients depended entirely upon a wheelchair for mobility, one could ambulate at home with bilateral ankle-foot orthoses, and two patients usually walked with the aid of a unilateral ankle-foot orthosis.	Muscles were activated using a Strathclyde programmable stimulator linked to a microcomputer. Surface system. Walking tests were initially performed with a rollator and recorded on videotape. Time taken to complete the program ranged from 9-12 months.	Significant increase in strength of voluntary contractions of the quadriceps ($p < 0.05$). Differences not significant among the speeds of gait using orthoses (types unknown) and NMES, noting that speeds comparable with normal walking (1.7 m/sec) not obtained. At a mean period of 12 months after completion of the program, three patients continued to use the system at home (two of whom were totally wheelchair-bound at the beginning of the study), and no longer used their original orthoses. The other three discontinued use, citing impracticality.
Wieler/1999	To test the long-term benefits of several non-invasive systems during walking.	40 subjects, from 4 Canadian centers, 31 of whom had an incomplete SCI, 8 with cerebral impairment from stroke and one with head injury. The latter nine presented with motor deficits similar to SCI group. All subjects could stand and, with one exception, could walk to some extent without NMES. SCI lesions distributed along all levels, but excluding lumbosacral injury. All subjects older than 17, with SCI group mean age 36+/-2 and cerebral impairment group 57+/-4. EXCLUSIONS: Pressure sores, extreme spasticity or symptomatic cardiovascular disease.	Surface system. Stimulation via 1-4 channels, using either the Unistim or WalkAide (1-channel) devices or the Quadstim (4-channel) device. Gait analyzed using a video camera. At end of test period, subjects were given option of continuing with NMES.	SCI group walking speed increased by 55% vs. 19% for cerebral impairment group ($p < 0.01$), with a significant training effect in total and SCI groups, but not in cerebral impairment group. Increased stride length ($p < 0.01$), with no significant change in cycle time among 31 patients (noting that subgroup was not specified). 23/40 regularly (i.e., frequency not specified) continued with NMES use, when given the option.

Table II. NMES Case Series Studies for Use of Non-Parastep®I Systems

Author/Year	Objectives	Patient Characteristics	Methods	Results/Conclusions
Bonaroti/1999	To prospectively compare NMES to long leg braces (LLB) as a means of upright mobility for children with complete thoracic level spinal injuries.	5 subjects, 4 M & 1 F, 9-18 years. Levels of motor complete paraplegia ranging from C8/T1-T8, and times post-injury ranging from 1.5-9 years. INCLUSION CRITERIA: 1. Intact lower motor neurons to innervate lower extremity muscles. 2. No outstanding orthopedic deformities such as heterotopic ossification. 3. Flexion contractures less than 15 deg for hip and knee and less than 10 deg for ankle. 4. No ankle or knee joint abnormalities by X-ray. 5. At least one year post SCI or not demonstrating change in neurologic function over previous 6 months. 6. Spasticity which does not interfere with standing. 7. Age between 6-18. 8. Motor complete injury between T1-T8. 9. Ability to attain erect standing posture with bracing. 10. Functional independence in ADL and basic wheelchair management. 11. Perform straight leg raise of at least 90 deg. 12. Minimum of six dips on parallel bars with legs supported in long sit position. 13. No fast range of motion limitations.	LLB consisted of knee-ankle-foot orthoses (KAFO) in four subjects and RGO in the other. NMES system consisted of fine-wire intramuscular electrodes.	Using Functional Independence Measure (FIM) scoring, in 35/37 (94%) of comparisons, NMES required equal (70%) or less (24%) assistance relative to that of previous LLB. For two activities (floor to stand in one subject and 6-meter walk in another), LLB provided greater independence. 2/8 activities (stand and reach, high transfer) were performed significantly faster ($p < 0.05$) with NMES, as measured by group average time-to-completion. 6/8 activities failed to show significant differences: Donning, toilet transfer, floor-to-stand, 6-meter walk, stair ascent and stair descent. For the 37 instances (seven mobility activities and donning), NMES was preferred in 62% of the cases.
Heller/1996	Using NMES to assist in ambulating with a swing-through gait pattern.	3 subjects, 2 M & 1 F, ages 22-28, with 2 having complete T11 lesions and the other with complete T6 lesion. INCLUSION CRITERIA: 1. Mid-to-low thoracic, motor-complete lesion. 2. At least 2 years post-injury. 3. Lack of joint contracture. 4. Previous NMES strengthening program for quadriceps group, and was able to stand using NMES and a walking aid for 5 min. 5. Intact flexion reflexes. 6. Trained in use of knee-ankle-foot orthoses for swing-to or swing-through gait (but did not necessarily have to walk regularly). 7. Able to attend weekly training sessions.	Surface system. Stimulator was an eight channel, current regulated programmable device and controlled by an IBM PC compatible computer. Hip/knee extensors/flexors were used for production of swing-through gait. Gait trials took place along a long, straight corridor with a level floor.	Distance walked: range 43.3-55.5 m Speed: range 0.30-0.40 m/s Stride length: range 1.08-1.26m Stride time: range 2.97-3.60 sec
Stein/1993	Assessing improved locomotion after incomplete SCI.	10 subjects with incomplete SCI at levels ranging from C2-T10. All could stand unassisted, and had a range of walking abilities from being unable to walk without NMES (i.e., 4/10 subjects) to walking with canes at 50 m/min. Only included subjects with more than 2.5 years post-injury.	Used 1-4 channel systems with either surface, percutaneous or implanted electrodes.	Stimulation increased the speed in all subjects studied. The mean difference was 4 m/min independent of the speed at which the subject could walk without NMES.

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Author/Year	Objectives	Patient Characteristics	Methods	Results/Conclusions
Thoumie/1995	Clinical evaluation of RGO-II hybrid orthosis, such that performance could be compared with and without NMES.	26 patients (23 M & 3 F), with mean age 31 (20-53) and mean delay from onset of paraplegia was 32 months (9-144). All met selection criteria for RGO-II orthosis: Complete spastic paraplegia without hip, knee or foot contracture greater than 5 deg. Levels of injury from C8-T11.	Surface system. Four-channel stimulator, with thumb switches mounted on a rollator. Hybrid orthosis being NMES + RGO II. Follow-up patient data were available.	Maximum walking distance ranges: 1. Without NMES, 150-400m 2. With NMES, 200-1400 m (Comparative statistics N/A) No significant differences in walking speeds, with and without NMES, and both with approximately 15-20% of normal walking speed, explaining less than full acceptance of NMES. 15/26 patients used the hybrid orthosis for more than 2 months: 4 in the rehabilitation center and 11 in/around the home. 6 stopped using it as soon as they returned home.
Sykes/1996	To measure home use of the RGO and the electrically augmented (hybrid) RGO.	Five subjects, ages 29-37. Using the ASIA impairment scale, neurological level of lesions ranged from C2 (C) to T6 (A). 4/5 with traumatic lesions (8-14 years post-injury), with remaining subject having myelitic illness. All subjects successfully using RGO at the start of the study, with only one subject able to walk in the community (i.e., using crutches, as opposed to others using rollators).	Each subject was supplied with stimulation equipment after a period of muscle conditioning and gait training with the hybrid system. Four channel stimulator with signals to both quadriceps and hamstrings, using surface system. Electronic step counters/patient diaries used to record data over 18 months.	Using the step counter data, overall use of the RGO, whether with or without stimulation, was low, and there was no trend to demonstrate increased use following supply of the hybrid system. Statistical analysis was not available. Diary data showed similar low use (i.e., often less than one hour/day), as well as no increase with NMES.
Marsolais/2000	Comparison of custom-built RGO with and without NMES.	Six paraplegic subjects, 5 M & 1 F, age range 22-50. Injury levels ranging from C7-T12/L1, without specification of completeness, and times post-injury 2.5-20.6 years. Profile of subjects' prior (baseline) device use: 1. RGO with crutches. 2. NMES-only walking (10 years). 3. RGO with standard walker. 4. RGO. 5. No experience with braces. 6. NMES-only walking (6 years). At baseline, 4/6 subjects could transfer, 5/6 could stand, 5/6 could walk in some capacity (see above devices), and 2/6 could stair climb, noting that both of these individuals (#2 and #6) had NMES assistance.	Used prototype Case Western Reserve University (CWRU) hybrid gait orthosis system comprised of either surface or implanted NMES in combination with modified isocentric reciprocal gait orthosis (ISO-RGO). Following activities noted prior to, and with NMES: Transfer, standing, walking, distance with speed and stair climb.	Results reported for each subject: 1. Walking improvement beyond parallel bars only, going from 90 m to 200 m. Use at home for walking and occasional functional activity (e.g., wash dishes). 2. Distance from 70 to 350m. 3. Walking from contact assist to use of crutches, and distance from 3 to 350 m. Independent use at home for exercise and some household chores. 4. Could now do transfer activity. Walking from parallel bars to large base quad canes with maximal assistance. 5. From no walking to walking with parallel bars. 6. No distances/speeds noted.

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Author/Year	Objectives	Patient Characteristics	Methods	Results/Conclusions
Moynahan/2000	To assess home use patterns of NMES among adolescent subjects.	5 subjects (2 M & 3 F, range 17-20), with motor complete (ASIA "A") lesions ranging from T4-T11. Orthotics used with NMES: Molded shoe inserts in 4/5 and molded ankle foot orthosis in remaining subject. Assistive device used with NMES: Rolling walker in 4/5 and forearm crutches in remaining subject. INCLUSION CRITERIA: 1. 13-18 years old. 2. Motor complete SCI between T1-T12. 3. Intact LMN innervating hip and lower extremity muscles, as confirmed by strength-duration test. 4. No outstanding orthopedic deformities, such as heterotopic ossification, history of spontaneous fractures or history of joint dislocation. 5. No psychosocial problems to limit participation. 6. Hip and/or knee flexion contractures less than 20 deg. 7. No ankle or knee joint abnormalities via MRI. 8. Brisk, isolated responses to surface NMES. 9. Ability to attain erect standing posture with KAFO's. 10. At least one-year post-injury and demonstrating functional independence in ADL's, wheelchair management and transfers.	Intramuscular electrodes, exiting from anterior thigh, with custom 16-channel stimulator worn around waist. Training sessions conducted 2-3 days per week in the hospital and in simulated home environments. Number of months of home follow-up ranging from 12-38 months (3 for 12 months, 1 at 19 months and 1 at 38 months). Post-discharge, subjects were questioned every 1-4 weeks about different facets of use, with periodic readmissions at 3, 6, 12, 18 months, and annually thereafter, to confirm such data.	Daily frequency of donning the system was 23-34% (or once every 3-4 days), with main reason cited for donning being exercise (51-84% of time). Standing was another key motivator for NMES use, with fatigue not identified as a limiting factor for this use. Subjects overwhelmingly declined to wear the system all day, and subjects rarely used NMES to maneuver around their homes. Frequency data of days used for exercise during longitudinal 50-day blocks showed 4/5 patients with at least some use after 300 survey days. By having to respond to regular questioning about their use of the NMES system, subjects admitted that they sometimes felt compelled to increase what they perceived as an infrequent pattern of use.
Davis/2001	Exploring development and initial application of NMES for exercise, standing and assisted transfers.	12 subjects (11 M & 1 F, mean age at implant 35), with injuries ranging from C5-T9. 9 ASIA class A, 2 class B and 1 class C. Months post-injury ranging from 13-202. INCLUSION CRITERIA: 1. Intact LMN. 2. Skeletal maturity (>18 years). 3. Neurologic/emotional stability (>1 yr post-injury). 4. Normal ROM, joint integrity and acetabular coverage. 5. No history of spontaneous fractures. 6. No orthopedic or medical conditions contraindicating electrical stimulation or surgery (pacemakers, diabetes, colostomy, pregnancy, etc.) 7. Good skin integrity and controlled spasticity. 8. No seizure disorders or immunological compromises. 9. Ability to complete follow-up evaluations and travel.	CWRU/VA standing neuroprosthesis, consisting of an 8-channel implanted receiver-stimulator. Follow-up evaluations performed at 3, 6 and 12 months post-discharge. Usability and preference scale was developed to assess user perceptions of effort and assistance during transfers with NMES.	Only a brief qualitative description of ADL's, from which no conclusions could be drawn. With respect to level transfers, both NMES and conventional transfers were equal in difficulty, but subjects preferred conventional transfers. High transfers were deemed easier with NMES. All users refused to attempt non-NMES transfers from low to high surfaces and preferred using NMES. Please note that actual usability/preference scale data was not available.

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Author/Year	Objectives	Patient Characteristics	Methods	Results/Conclusions
Maxwell/1999	Survey the use of and demand for NMES and conventional orthoses among the SCI population	Mean age of respondents was 47 years, and average age at time of injury was 31 years. Complete paraplegic 43%, incomplete paraplegic 19%, complete tetraplegic 25% and incomplete tetraplegic 13%.	4,840 questionnaires were mailed to SCI subjects living in the United Kingdom. 1,122 completed replies were received for a 23% response rate.	19% of respondents had used some type of NMES, 59% of which used for muscle re-strengthening and only 2% for walking. 41% of NMES users were able to walk independently vs. 76% of AFO users, noting, however, that AFO users included relatively higher proportion of incomplete vs. complete SCI individuals. Other types of orthotics users (KAFO and HKAFO) showed similar-to-less walking independence than NMES, with percentages being 34% and 15% respectively. Unclear adjustments for injury severity make direct comparisons between orthotics and NMES indeterminate, and there are also potential biases from self-reported questionnaire data.
Ladouceur/2000	Measuring various mobility parameters	14 incomplete SCI subjects who were a "sample of convenience." Mean age 33 (range 25-48.9), with range of time between injury and start of NMES program 1.8-19.1 years. Injuries between C5-L1, and using International Medical Society of Paraplegia classification, 5 in category C and 9 in category D. At baseline, 6 used walkers, 4 forearm crutches and 4 canes.	Surface system. Variable stimulators used, including Quadstim, Unistim and MikroFES. Functional mobility scale used but not described in any detail.	Significant increase in functional mobility, but such results not able to be interpreted in any meaningful way. During at least 23 weeks (of one year), increases in maximal over-ground walking speed ranged from 0.00-0.69 m/sec, demonstrating statistical significance over baseline.

Table III. NMES Studies on Muscle Atrophy/Limb Blood Flow/Bone Mineral Density (BMD)

Author/Year	Objectives	Patient Characteristics	Methods	Results/Conclusions
Baldi/1998	To assess effects of NMES upon acute SCI patients with respect to muscle atrophy.	Randomized controlled trial with 26 subjects recruited from an acute SCI unit who were within 15 weeks of incurring a Frankel A or B traumatic thoracic or cervical injury. Mean ages of different groups in 25-28 year range, with mean weeks post-injury ranging from 8-10.	Assignment into cycle ergometry (CE) group (using ERGYS 1 system), isometric exercise group and control group. Lean body (or muscle) mass (LBM) was measured via DEXA. Measurements were conducted both at 3 and at 6 months.	In the CE group, lower limb LBM and gluteal LBM loss were prevented both at 3 and 6 months, and total body LBM was prevented at 6 months. In the isometric exercise group, only 6-month gluteal LBM loss was significantly attenuated relative to controls. With respect to increased muscle mass, CE significantly increased gluteal LBM and lower limb LBM after 6 months of training.
Nash/1997	Measure multiple blood flow parameters in SCI patients.	(12 subjects similar to those reported by Klose in Table I)	Exercise conditioning on the Parastep®I system performed three times per week for a total of 32 sessions. Conducted baseline and post-training quantitative Doppler ultrasound examinations of the common femoral artery (CFA).	There were significant effects of training (at least $p<0.05$) upon the cross-sectional area, flow velocity integral, computed pulse volume and computed arterial inflow volume of the CFA. The study concluded "improved post-training blood flow is attributable both to vascular structural changes and upregulation of vascular flow control mechanisms."
Leeds/1990	To evaluate effects of NMES cycle ergometry on BMD in SCI patients.	6 quadriplegic men (traumatic injuries between C4-C6) ranging in age from 18-27 and post-injury years ranging from 2-9.	Exercise training on REGYS I Clinical Rehabilitation System (surface electrodes).for 3 times per week X 6 months. Dual photon absorptiometry used for BMD.	No significant quantitative changes in BMD at the following proximal femoral sites: Femoral neck, Ward's triangle and trochanteric region.
DeBell/1996	To evaluate effects of NMES cycle ergometry on BMD in SCI patients.	12 male volunteers (mean age 34, range 23-46) with lesions ranging from C5-T12, and mean time post-injury 9.7 years (range 2-19).	Exercise training on REGYS I ergometer with surface electrodes, with variable completion of different performance-based protocols. All 12 subjects completed Phase 3a training in 34+/-8 weeks, with 8 completing Phase 3b training in 25+/-9 weeks. DEXA used to measure BMD.	BMD measurements at L2-4, bilateral trochanters, Ward's triangles and femoral necks only showed L2-4 with nearly significant Phase 3a training effect ($p=0.056$). Other sites with positive trends only. Further Phase 3b training did not show any increases in BMD. Univariate analysis was performed to evaluate other variables, such as number of exercise sessions and weeks of exercise, and no correlations with BMD were found.
Needham-Shropshire/1997	To evaluate a training program on BMD among SCI patients.	(Please refer to patient descriptions from Klose in Table I)	Parastep®I system-based training for 32 sessions (approximately 12 weeks) with 14/16 completing an additional 8 weeks of exercise. BMD measured via dual-photon densitometer.	No statistically significant increases were found at any of the three BMD sites as a result of either the 32 sessions or after an additional 8 weeks of training: Femoral neck, Ward's triangle and greater trochanter.

Table III. NMES Studies on Muscle Atrophy/Limb Blood Flow/Bone Mineral Density (BMD)

Author/Year	Objectives	Patient Characteristics	Methods	Results/Conclusions
Bloomfield/1996	To investigate whether NMES exercise training can produce increases in bone mass in SCI individuals with established disuse osteopenia.	Non-randomized case-control design with 9 experimental subjects, mean age 28.2+/-1.8 and minimum of 3 years post-injury. Frankel Class A or B SCI ranging from C5-T7. 8 control subjects with mean age 34.4+/-2.5. Exclusion criteria included independent factors affecting bone metabolism such as recent fracture and prolonged steroid use.	9-month protocol involving REGYS I Clinical Rehabilitation System and ERGYS Home Rehabilitation System (using surface electrodes). Measured BMD using DEXA at lumbar spine, femoral neck, distal femur and proximal tibia.	Statistically significant ($p<0.05$) increase in group mean BMD at lumbar spine but not at other sites tested. When stratifying NMES by power outputs, high power subgroup (at least 18 watts) experienced a statistically significant 17.8% increase at the distal femur.
Belanger/2000	To investigate whether NMES exercise training can increase muscle strength and reverse osteopenia among patients with SCI.	Non-randomized case-control design with 14 test subjects (11M & 3F, mean age 32.4+/-5.9). 12 complete SCI injuries ranging from C5-T6, and 2 incomplete injuries at C5-C6. Years post-lesion 9.6+/-6.6. 14 age- and sex-matched controls with no known neurologic lesions were also recruited.	Surface electrode system applied for 5 days per week X 24 weeks. BMD measured via DEXA at distal femur, proximal tibia and mid-tibia.	Pre-training BMD values of the SCI subjects for all three regions were lower than those of control subjects. Post-training values represented a recovery of the lost BMD equal to 28.7% in the distal femur and 28.0% in the proximal tibia. The mid-tibia showed no recovery.
Sloan/1994	To evaluate musculoskeletal effects of an NMES induced cycling program.	12 patients (7 M, 5 F), 15-54 years, with incomplete SCI ranging from C5-L1, and one patient with complete T4 SCI. All patients at least 2 months post-injury. Only two patients with BMD: Incomplete injuries at C6 and C7.	Cycling program three times per week for three months. Surface NMES system, with BMD measured via dual X-ray absorptiometry (DEXA).	No increase in BMD for each of two subjects. With sample size of two, this study is nearly a case report. (Muscle evaluation data not pertinent to this current evaluation.)