Neuromuscular Stimulation of the Quadriceps Muscle After Hip Fracture: A Randomized Controlled Trial

Sarah E. Lamb, DPhil, Jacqueline A. Oldham, PhD, Rhian E. Morse, MD, John Grimley Evans, MD

ABSTRACT. Lamb SE, Oldham JA, Morse RE, Evans JG. Neuromuscular stimulation of the quadriceps muscle after hip fracture: a randomized controlled trial. Arch Phys Med Rehabil 2002;83;1087-92.

Objective: To study the feasibility and effect of neuromuscular stimulation on recovery of mobility after surgical fixation for hip fracture.

Design: Double-blind study with stratified randomization.

Setting: Home-based rehabilitation program.

Participants: Twenty-four women over the age of 75 years with hip fracture.

Interventions: Neuromuscular or placebo stimulation of the quadriceps muscle of the fractured leg, applied for 3 hours a day, for 6 weeks, commencing 1 week after surgery.

Main Outcome Measures: Recovery of walking speed and ability, postural stability, lower-limb muscle power, and pain at 7 and 13 weeks after surgery.

Results: Women in the neuromuscular stimulation group showed faster recovery of mobility. Of the women receiving stimulation, 9 of 12 recovered their prior levels of indoor mobility ability by 13 weeks compared with 3 of 12 in the placebo group (Fisher exact test, $P=.046$). There were no differences in recovery of walking speed in the first 7 weeks, but women in the stimulation group had greater recovery between 7 and 13 weeks (mean difference$=-.13$m/s; 95% confidence interval, $-.23$ to $-.01$).

Conclusions: Neuromuscular stimulation at home is feasible and may be effective in speeding recovery of mobility after surgical fixation of hip fracture.

Key Words: Electric stimulation; Hip fractures; Randomized controlled trial; Rehabilitation.

RECOVERING ONE'S mobility within 4 to 5 days after surgical fixation of hip fracture is critical in regaining independence.[1] Mobility after hip fracture is impaired by deficits of lower-limb muscular power associated with premorbid frailty, pain, and the effects of the injury.[2]

There is little randomized evidence to guide the composition, timing, and duration of rehabilitation that will ensure optimal recovery of mobility after hip fracture.[3] In a large trial,[4] a multicomponent rehabilitation package given after discharge from the hospital was no more effective in promoting recovery than was usual care. In studies that have reported absolute levels of mobility, there is some evidence that functional,[5] isometric strength,[6] and treadmill gait training[7] improve mobility, but these gains may be insufficient to restore preinjury levels of ability. The potential benefits of rehabilitation applied within the first week of recovery have not been studied.

Neuromuscular stimulation is an attractive option to improve lower-limb muscle power and mobility because it can be applied during the earliest, critical stages of recovery. Applications of lower-frequency stimulation ($<$30Hz) within 1 week of knee replacement surgery have shown improvements in mobility,[8,9] and stimulation appears to be well tolerated. The efficacy and acceptability of stimulation in the management of hip fracture is unknown. The purpose of this study was to investigate whether a variable low-frequency chronic stimulation of the quadriceps muscle of the injured leg, initiated in the first week after surgery, is effective in promoting recovery of mobility after hip fracture. The study was intended to test the feasibility of stimulation and the experimental protocol and to gain an estimate of potential treatment effect for larger trials.

METHODS

Design

The study was an exploratory trial with stratified randomization and double blinding. It was conducted at the John Radcliffe Hospital Trauma Service, Oxford, UK, and was approved by the local research ethics committee. Informed, written consent was obtained from all participants.

Eligibility. Women 75 years of age or older who had surgical fixation for hip fracture were eligible, provided they had been living in their own or a relative's home or in sheltered housing before their injury. Women were excluded if they had a history of stroke or Parkinson's disease, clinical depression or acute mental illness, or scored 6 or lower on the Hodkinson Mental Test Score.[10] The Hodkinson Mental Test Score was chosen because it is the recommended tool for UK clinical practice.[11] Also excluded were women who had sustained other fractures at the time of the injury, had respiratory or cardiac failure sufficient to prevent their walking 15.25m (50ft), had systolic blood pressure more than 200mmHg or diastolic more than 100mmHg, or had surgical complications, treatment with total hip replacement, or a pathologic fracture. Previous lower-limb fractures and/or arthroplasties were not reasons for exclusion. An assessment of medications was made on postoperative day 6. Women who were taking hypnotics, sedatives, muscle relaxant, or other medications likely to affect muscular function during the postoperative period were excluded. The potential effect of drugs was determined by reference to the British National Formulary.[12] Anti-inflammatory medications, paracetamol, and combined paracetamol-codeine agents were not exclusion criteria.

From the Interdisciplinary Research Centre in Health, Coventry University, Coventry (Lamb); Centre for Primary Health Care Studies, University of Warwick, Warwick (Lamb); Centre for Rehabilitation Sciences, University of Manchester, Manchester (Oldham); Department of Medicine, University Hospital of Wales, Cardiff (Morse); and Clinical Geratology, Radcliffe Infirmary, Oxford (Evans), UK.

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Reprint requests to Sarah E. Lamb, DPhil, Schl of Health and Social Sciences, Coventry University, Priory St, Coventry CV1 5FB, UK, e-mail: *s.lamb@coventry.ac.uk.*

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Interventions

Participants were randomized to receive either patterned neuromuscular stimulation (PNMS) or placebo stimulation. PNMS is a variable frequency stimulus (mean frequency, 8.9Hz) derived from the discharge of a fatiguing motor unit of the quadriceps.[13,14] The output was a constant, balanced, asymmetric biphasic pulsed current with a pulse width of 300μs and a maximum output intensity of 100mA. The amplitude of current was 66 to 70V on load (resistance, 560Ω). The duty cycle of the PNMS was 66%; each cycle was comprised of 30 seconds on and 15 seconds off, and there was no output intensity ramp. The stimulus intensity was the minimum required for a visible muscle contraction. The stimulators were worn for 3 hours every day for 6 weeks. The total duration of PNMS (ie, excluding off time during stimulation) was 84 hours. Each stimulus delivered 0.3μC of charge. Placebo stimulation was a single 300-μs pulse delivered every 3 minutes, which produced a strong sensory stimulus but negligible muscle activation.[15] The placebo stimulators were identical to the PNMS stimulators in appearance and digital display.

The stimulators were designed for home use. They were portable, being small (100mm wide, 190mm long, 32mm deep), light weight (<0.5kg), and powered by a 9V battery.[a] The current was delivered transcutaneously through large (76×127mm) self-adhesive electrodes.[b] The anode was placed over the superior anterolateral aspect of the thigh, and the cathode was placed just above the patella. A trained assistant, who was independent of the study, showed participants how to apply the stimulator. Care was taken not to place electrodes within 3in (7.62cm) of the surgical incision so not to cause irritation and infection. The stimulators were operated by a simple on-off button, with arrows to increase or decrease the current output. To avoid accidental increases in current, the output intensity was blocked at a predetermined level. The stimulation switched off automatically after 3 hours, and the cumulative time that the stimulator was used was recorded in an accessible memory.

Both groups received routine physical therapy as inpatients, with the therapy consisting of deep breathing exercises, instruction in the use of walking aids, and supervised walking practice confined to small distances. The walking aids provided to patients were, in the first instance, a 4-point walking frame, with progression to crutches or canes depending on a physical therapist's assessment. Pain management was guided by a standard protocol based on 4 hourly assessments and medications, as required. On discharge, all participants were given a standard exercise advice sheet. The exercise intensity was low to ensure that all subjects could complete the exercises safely on their own; it focused on regular walking and chair-rising practice within the limits of pain and fatigue. The exercise recommendations focused on functional activities and did not include specific quadriceps drills.

Study Procedure

Potential participants were identified from a daily review of hospital admission lists and were reviewed for eligibility by the operating surgeon and a physician.

Randomization. A stratified block randomization was used.[16] Participants were stratified by whether they needed a walking aid for indoor mobility or not before the fracture. Randomization lists were prepared in advance of the study with a random number table. Assignments were placed in sealed, numbered, opaque envelopes that were opened in a strict sequence after eligibility had been established and consent obtained.

Blinding. The investigator responsible for measuring outcomes and all participants were blind to the treatment assignment. Participants were told that they would receive electric stimulation of the quadriceps and that they would feel the stimulus, but they were not told which type of stimulation they were receiving. This departure from usual informed consent had ethics committee approval.

Assessment intervals. Baseline assessments were undertaken at 6 and 7 days after fixation, and stimulation commenced the following day. Assessments were repeated at the end of the 6-week period of stimulation (7wk after surgical fixation). The women then stopped stimulating the muscle and were reassessed 6 weeks later (13wk after surgical fixation).

Measures

Preinjury mobility was measured by recall though a short, validated questionnaire.[2] Previous indoor walking ability was recorded as 0, unable to walk, or only with the assistance of another person; 1, able to walk with walking aid (stick, crutch, frame); or 2, completely independent (no aid, no assistance). Comorbidities were ascertained from a review of the medical notes and physician examination by using a checklist validated by Buchner et al.[17] Fractures were classified from radiologic films as intracapsular fractures, 2-part extracapsular fractures, or comminuted extracapsular fractures (ie, >2 parts).[18]

Usual gait speed was assessed over 2 distances, 3.05m (10ft) and 15.25m (50ft), selected to represent the minimum and maximum distances needed to walk around a house. The test was performed in a wide corridor with a nonslip floor surface. The start line and 3.05-m and 15.25-m finish lines of the course were marked on the floor with a thick red line. The ability and time required to complete the distances were recorded. Participants were asked to walk at a comfortable and safe speed to minimize the risk of falling or fatigue. An assistant walked at arm's length from the participant in case of unexpected loss of balance. Timing began when the patient crossed the start line and ended when they stepped onto or over the finish line. Walking aids were permitted, with the women choosing the one with which they felt most confident. If they were at a period of transition, for example, from walking frame to cane, the aid with which they walked the fastest was selected for the test. Ability to walk independently was recorded as (1) with no aid; (2) with a stick or sticks; (3) with crutches; (4) with a walking frame; or (5) unable, including any hands-on assistance or being unable to complete the distance. The test-retest reliability of the timed walking tests (95% limits of agreement) were 2.7 and 12.6 seconds for 3.05-m and 15.25-m walks, respectively (coefficient of variation [CV]=9.5%).

Postural stability was tested by using the tandem stand test[19] timed to 10 seconds by using a hand-held digital stopwatch. Women who were unable to hold the position for 4 seconds were coded as unable to tandem stand and those who could hold for more than 4 seconds were coded as able to tandem stand.[19,20] The test-retest reliability of the tandem stand tests was good (κ>.61).[21]

Leg extensor power (LEP) was measured by using a Nottingham LEP rig,[22] which measures the power generated by a single-leg extension in the seated position. The rig was adjusted to accommodate the leg, and the contralateral leg was positioned so that it could not contribute to power generation. With arms folded across the chest, the participants were encouraged to push the leg into extension with maximal effort. A maximum of 10 tests was performed, with a minimum rest period of 30 seconds between each push. The output was the product of the force and the rate of force generation during a single-leg extension. The maximum power (W) was recorded

Table 1: Baseline Characteristics of Women by Experimental Group

	Placebo Stimulation (n=12)	PNMS (n=12)	All Women (N=24)
Mean age ± 1 SD (y)	83.9±2.9	83.4±4.4	83.7±3.7
Mean preinjury mobility score (max score, 12)	9.9±3.3	10.1±2.7	10±2.9
No. needing a walking aid for indoor mobility before injury	5	4	9
No. (range) of comorbid conditions	1 (0–2)	1 (0–3)	1 (0–3)
No. of comminuted fracture patterns	3	3	6
No. of 2-part extracapsular fractures	5	3	8
No. of intracapsular fractures	4	6	10

Abbreviations: SD, standard deviation; max, maximum.

for the injured and uninjured leg and normalized by body weight (kg). Weight was measured by using a calibrated bathroom-type digital scale placed on a firm surface. Participants were weighed in the standing position while wearing light indoor clothing and shoes but no jewelery or heavy clothing items. The 95% limit of agreement for LEP was 7.7W (CV=6%).

Pain was measured on a 6-point scale: 1, no pain; 2, occasional or slight pain; 3, pain on initiation of exercise; 4, pain with exercise but not at rest; 5, constant yet bearable pain; or 6, constant severe pain for the 24-hour period before the assessment.[18]

Statistical Analysis

The distribution of data was tested by using the Shapiro-Wilk W test.[16] Data were normally distributed, and parametric methods were used. Baseline characteristics of the women in the 2 experimental groups were scrutinized for clinical differences and for statistically significant differences by using an independent sample *t* test or the Fisher exact test.[16] Recovery of mobility at 7 and 13 weeks after fixation was assessed in comparison with self-reported preinjury levels of indoor mobility, coded as recovered or not recovered, and tested with the Fisher exact test. The recovery of LEP, pain, and timed tests of mobility were calculated as the difference between values recorded at 7 weeks and 1 week after fixation (stimulation period), and 13 and 7 weeks, and tested for statistical significance by using an independent sampled *t* test. Statistical significance was defined at the *P* less than .05 level. The statistical package SPSS, version 7,[c] for Windows was used.

RESULTS

Participants

Three women did not complete the study. One developed myasthenia gravis and another had a severe chest infection. Both required hospitalization, which prevented re-examination in our study. Another woman withdrew her consent to participate a few days after commencing stimulation. Twenty-four women completed the study and were included in the analysis.

The women's characteristics are shown in table 1. Before injury, all could walk inside without the assistance of another person, but some required walking aids. The distribution of fracture patterns was similar in each group. Intracapsular fractures were surgically fixed by using hemiarthroplasty, with the exception of 2 women who had AO screws. All extracapsular fractures were repaired with AO dynamic hip screws and plating. There were no statistically or clinically significant differences in mobility, LEP, or pain between the 2 groups at baseline. All of the women used their stimulators for more than 75% of the cumulative time requested and were discharged from the trauma service between 10 and 14 days after surgery. There were no burns, irritation, or other side effects from the stimulation.

Recovery of Mobility

Although there were trends to suggest better recovery of mobility in the PNMS group by 7 weeks after fixation, this difference was not statistically significant (data in table 2; Fisher exact test, $P=.089$). By 13 weeks, 9 women in the PNMS group recovered compared with 3 women in the placebo stimulation group (Fisher exact test, $P=.046$; table 2).

Timed Tests of Mobility

As expected, walking speed improved significantly in both groups during the recovery period. After 6 weeks of stimulation, there were no statistically significant differences in recovery between the 2 groups. When stimulation was ceased, recovery of walking speed was greater in women in the PNMS compared with the placebo group (independent sampled *t* test, $P=.05$).

Postural Stability

Seven weeks after stimulation, 8 women in the PNMS group could tandem stand compared with 3 in the placebo stimulation group (Fisher exact test, $P=.03$). At 13 weeks after fixation, near equal numbers of women in both groups were able to tandem stand.

Leg Extensor Power

Data for LEP are shown in table 3. LEP increased significantly during the recovery period in both the injured and uninjured limbs. There were no statistically significant differences in the recovery of LEP during or after the stimulation period. However, comparison of the ratio of power between the injured and uninjured legs suggests that women in the PNMS group had a more even distribution of power between the injured and noninjured legs (results in fig 1). The difference in the ratio of power was statistically significant at 6 weeks after stimulation (independent sampled *t* test, $P=.05$) but not at 13 weeks.

Pain

Pain data are shown in table 3. There were no statistically or clinically significant differences in pain scores at any of the assessment intervals.

DISCUSSION

Improving the safety and efficiency of mobility is the primary goal of physical therapy in the postoperative management of patients with hip fracture. Our results suggest that neuromuscular stimulation is a feasible home intervention and is potentially an effective method of speeding up the early restoration of mobility after hip fracture. Although gait speed at 13 weeks was significantly lower than would be expected in healthy women of similar age (.97m/s[23]), the improvements in walking speed appear clinically worthwhile.

Table 2: Recovery of Walking Ability, Speed, and Postural Stability

	Placebo (n=12)	PNMS (n=12)	Mean Difference (95% CI)
3.05-m walking speed (m/s)			
Week 1	.17±.13	.14±.08	
Week 7	.40±.22	.41±.25	
Week 13	.43±.23	.54±.36	
Difference week 7 − week 1	.26±.19	.28±.22	−.02 (−.207 to .166)
Difference week 13 − week 7	.02±.09	.14±.16	−.13 (−.232 to −.009)*
15.25-m walking speed (m/s)			
Week 1	.18±.13	.16±.07	
Week 7	.41±.20	.41±.29	
Week 13	.43±.23	.54±.34	
Difference week 7 − week 1	.28±.18	.33±.26	.05 (−.27 to .16)
Difference week 13 − week 7	.02±.08	.13±.12	−.11 (−.19 to −.02)*
Recovery of indoor walking (n)			
Week 7 recovered	2	7	
Week 13 recovered	3	9†	
Tandem stand (n)			
Able after week 1	3	0	
Able after week 7	3	8†	
Able after week 13	7	8	

NOTE. Values are mean ± 1 SD.
Abbreviation: CI, confidence interval.
* $P<.05$, independent sampled t test.
† $P<.05$, Fisher exact test.

The patterns of recovery of impairments suggest the mechanism by which stimulation affects mobility. PNMS resulted in a more even balance of power between the legs, less reliance on the uninjured leg, better postural stability, and reduced need for a walking aid. Not being encumbered by a walking aid is likely to have contributed significantly to speedier recovery of mobility.[23] It is unlikely that the effects reported are attributable to factors other than the stimulation. Pain-relieving medications were administered according to the standard ward protocol, and the pain scores at baseline were similar in both groups. Women were discharged soon after the stimulation was begun. None of the women were acquainted with each other, and it is highly unlikely that blinding was compromised by the women talking among themselves, either in the ward setting or after discharge. Placebo stimulators were used as an attention control, but there was no no treatment component to the trial, and therefore we cannot conclude that the placebo did not affect mobility or lower-limb muscular function.

The lack of congruence between changes in LEP and walking speed are most likely the result of well-documented nonlinear associations between these variables.[24,25] Other studies of older women have shown a strong relation between knee extensor and hip flexor strength and the ability to balance in the tandem stand position.[24] Previous reports[8,9] of quadriceps stimulation after knee replacement surgery showed earlier recovery of gait. Improvements in LEP in the uninjured leg are most

Table 3: Recovery of LEP and Changes in Pain

	Placebo (n=12)	PNMS (n=12)	Mean Difference (95% CI)
LEP injured (W/kg)			
Week 1	.32±.23	.36±.14	
Week 7	.58±.28	.75±.39	
Week 13	.63±.32	.83±.42	
Difference week 7 − week 1	.26±.20	.38±.35	.12 (−.37 to .12)
Difference week 13 − week 7	.05±.18	.09±.21	.04 (−.21 to .13)
LEP uninjured (W/kg)			
Week 1	.80±.21	.87±.52	
Week 7	.96±.34	.95±.47	
Week 13	1.02±.42	1.06±.52	
Difference week 7 − week 1	.17±.24	.08±.26	−.09 (−.119 to .310)
Difference week 13 − week 7	.06±.26	.12±.12	.06 (−.24 to .112)
Pain (max score, 6)			
Week 1	2.67±1.15	2.33±.98	
Week 7	2.17±.83	2.17±.94	
Week 13	1.67±.65	1.92±.51	
Difference week 7 − week 1	−.50±1.31	−.16±1.11	−.33 (−1.37 to .69)
Difference week 13 − week 7	−.50±1.00	−.25±.75	−.25 (−.99 to −.49)

NOTE. Values are mean ± 1 SD.

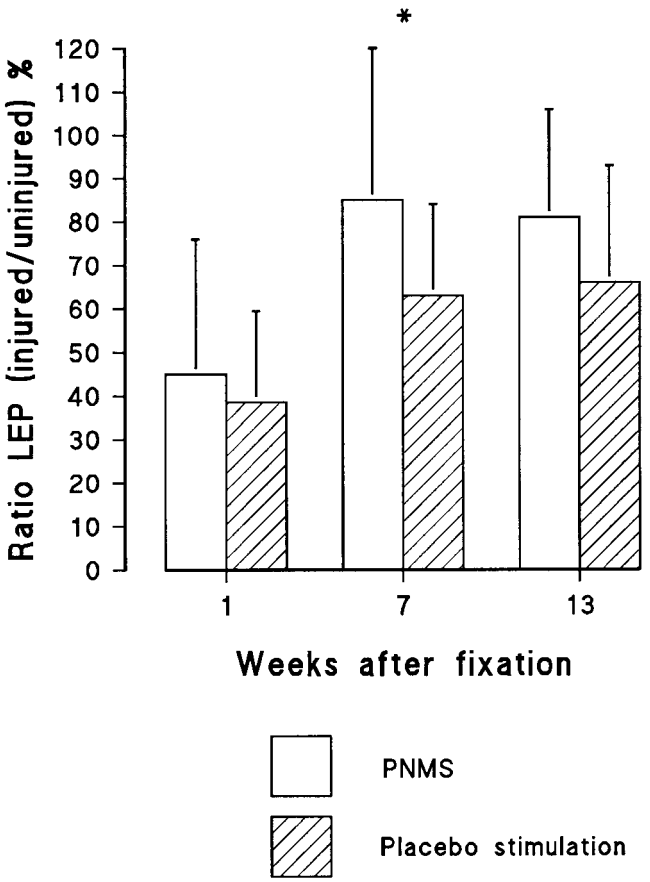

Fig 1. The ratio of power (injured/uninjured) in women in the placebo and PNMS stimulation groups (N=24). Data are the mean and SD. *$P<.05$.

likely attributable to increased reliance on that leg during the recovery period, providing a strong training stimulus. Alternatively, a cross-training effect resulting from the stimulation may have increased power in the uninjured leg.

The mechanism by which stimulation improves muscular performance remains unclear. In animals, low-frequency stimulation results in changes in both the contractile and bioenergetic properties of the muscle and, after prolonged stimulation, alterations in gene expression.[26] After PNMS is applied for 7 weeks for 3 hours a day at an intensity of 30% maximal voluntary contraction, the human hand muscle shows improvements in buffer and glycolytic capacity.[27] The effect of PNMS on peripheral or central activation has not been investigated, but recent research[28] has suggested that similar forms of electric stimulation improve central facilitation of muscle contraction via the motor cortex. It is also possible that the stimulation enhanced the ability to perform home exercise through a proprioceptive neuromuscular mechanism. PNMS did not appear to have any additional effect on pain control.

There was no evidence of PNMS having a detrimental effect on muscle power, as has been noted in studies of 10-Hz stimulation on power-related characteristics of chronically stimulated rabbit muscle.[29] In our study, 2 independent senior physicians reviewed the case history of the woman who developed myasthenia and concluded that the stimulation was not related to the onset of symptoms. Some forms of electric stimulation, notably, uniform 10-Hz stimulation and supramaximal high frequency stimulation (100Hz), can damage muscle in the following ways: reduction in muscle bulk, loss of muscle cells, and metabolic profile.[30] Manipulation of the stimulus characteristics, including reduction of the frequency of stimulation and introduction of variable frequency trains, can negate these effects.[31-33] PNMS uses a variable frequency train of low-mean frequency, and although it was not specifically designed to reduce physiologic stress associated with stimulation, in vivo studies of human muscle suggest no adverse effect.[22] Previous studies of the PNMS technique have shown it to be more effective than 10-Hz stimulation[33]; however, further developments and testing should be tempered by the need for studies to optimize stimulation parameters.

The limitations of our study must be recognized. The recovery reference was a comparison between the participants' reports of their usual needs for indoor mobility before the injury and abilities at each of the reassessment intervals. This is a crude measurement, unlikely to capture all aspects of recovery, but identifying a more robust recovery indicator remains a challenge. Improvements should be made to the stimulators to facilitate their use with older people. Improvements would include increasing the size and improving the contrast of the digital display, using a rechargeable battery and a low-voltage output indicator, and making electrode connections larger. An unanticipated problem was the difficulty women had in changing the stimulator's batteries. This necessitated weekly visits from the study personnel during the follow-up period; to ensure equal attention, all women in the treatment and placebo groups were visited. The personnel who performed home visits were blind to the treatment allocation of the participants who were instructed not to discuss the treatment during visits. Although we were able to record the cumulative amount of time that the stimulator was used during the 6 weeks, it was not possible to ascertain whether the stimulators had been applied daily.

The study was an exploratory trial. The eligibility criteria excluded women who may have had insufficient motivation to undertake the stimulation because of depression or cognitive impairment. Women with clinically evident neurologic conditions were excluded because the combination of neurologic disease and hip fracture is known to result in excessively high levels of disability, the mechanisms of which are not understood.[34] Other exclusions were necessitated by the test protocol, which was considered unsafe for patients with unstable fixation or pathologic fractures. The LEP rig generates forces down the long axis of the femur in a volitional functional movement that minimizes risk to the fracture site. All mobility tests were performed within the limits of pain tolerance and weight bearing. Despite these exclusions, the participants were frail and some had significant levels of comorbidity.

The inadequacy of small trials is now well accepted. There is little published information about the expected treatment difference in a trial of this nature, and this was one of the purposes of this study. By using α equal to 95% with a 2-sample t test, the study had an 80% power to detect a one-third difference in recovery of walking speed between the 2 groups. Previous work suggested that stratifying women by their need for a walking aid indoors would result in a balance of important predictors across the groups,[2] and this was true in this study. The groups were well matched in the distribution of important predictors of outcome, namely, comminuted fracture patterns and preinjury levels of mobility,[2] improving the efficiency of the experimental design.

Larger, pragmatic studies are needed with 1-year follow-up to establish whether the short-term gains in mobility translate into long-term benefits and to compare the effects of stimulation alongside strength training and other rehabilitation inter-

ventions, including pharmacologic optimization of pain control. Further studies should also examine whether the timing of rehabilitation is a significant variable in determining effectiveness.

CONCLUSION

This study suggests that it is possible to speed the early recovery of mobility, but it is premature to suggest that PNMS is the optimal method and should be adopted for routine clinical use. Although we found statistically significant faster recovery rates, the confidence intervals for the treatment effect were wide.

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Suppliers

a. PS1 model; DMI Ltd, Unit 1, Rosebridge Ct, Wigan WN1 3DP, UK.
b. Chattanooga, 100 Shaw Rd, Oldham OL1 4AY, UK.
c. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.