Randomised controlled trial of electrical stimulation of the quadriceps after proximal femoral fracture

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ABSTRACT. ***Background and aims:*** *Proximal femoral fracture is often associated with long-term residual disability. Quadriceps weakness may be a factor in poor outcome. This study aimed to determine whether training of the quadriceps using electrical stimulation (ES) increases leg extensor power and decreases disability in elderly subjects rehabilitating after fracture.* ***Methods:*** *A single-blind randomized controlled trial of elderly post-surgical proximal femoral fracture patients, comparing 6 weeks of supplementary electrical stimulation of the quadriceps (15 patients) to usual physiotherapy alone (11 patients). The electrical stimulation on:off duty cycle was 7:23 seconds, with 36 cycles per session, given daily as an in-patient and twice weekly after discharge. The primary outcome measure was change in leg extensor power (Nottingham Power Rig). Functional mobility (Elderly Mobility Scale), disability (Barthel Index) and health status (Nottingham Health Profile) were also measured.* ***Results:*** *There was no significant difference in change in leg extensor power, or any other outcome measure, in the ES group compared to usual-care controls. Fractured leg extensor power increased by 10.9 (standard error of the mean 2.1) Watts at 6 weeks in the ES group compared to 15.3 (5.5) in the controls (mean adjusted difference -3.1, 95% CI -7.8, 1.6 Watts). Only 3 (20%) of the intervention patients tolerated sufficient stimulation intensity to produce repetitive knee extension, while 11 (73%) sustained palpable or visible contractions with no leg movement.* ***Conclusion:*** *A 6-week program of electrical stimulation of the quadriceps did not increase leg extensor power, or reduce disability, in elderly patients rehabilitating after surgical fixation of proximal femoral fracture. In many patients local discomfort limited the intensity of electrical stimulation that could be delivered.*
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INTRODUCTION

Persisting disability is a common long-term problem in older survivors of proximal femoral fracture. Of those who could previously walk independently, 60% require aids or assistance to walk at 1 year after fracture (1). Muscle weakness may be an important contributor to this disability (2). After femoral fracture there is a reduction in fast-twitch muscle fibre size in the quadriceps (3). These fibres are particularly important in generating leg extensor power. Fractured leg extensor power one week after femoral fracture fixation is a key determinant of walking speed and stair climbing time (4). Voluntary high intensity quadriceps training may improve muscle weakness and improve mobility in these patients, however even with such approaches residual disability is common (5).

Cyclic electrical stimulation of skeletal muscle could be a useful tool in rehabilitation. In young subjects it can produce powerful muscle contraction and give training effects as good as, or better than, voluntary isometric exercise (6). Cyclic electrical stimulation can produce skeletal muscle contraction independent of volition. This could be particularly beneficial in frail subjects who may lack motivation for prolonged programs of regular voluntary exercise. In a pilot case-control study we found that subjects who received electrical stimulation of the quadriceps after proximal femoral fracture had greater improvements in leg extensor power than those who had usual care (7). One small randomized controlled trial has reported faster recovery of mobility in elderly patients who receive electrical stimulation of quadriceps after femoral fracture (8).

Our hypothesis was that supplemental cyclic electrical stimulation applied to the quadriceps of the fractured leg would improve muscle function and reduce disability in elderly patients rehabilitating after proximal femoral fracture.

This study aimed to determine whether 6 weeks of supplementary cyclic electrical stimulation applied to the

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quadriceps of the fractured leg increases leg extensor power and decreases disability in elderly patients rehabilitating after proximal femoral fracture.

METHODS

This was a single-blinded, parallel group, randomized controlled trial comparing electrical stimulation of quadriceps (plus standard physiotherapy) to standard physiotherapy alone. Randomization was by computer-generated random numbers, with individual patient codes held in opaque sealed envelopes by an administrator independent from the study. Patients were recruited from consecutive admissions to hospital wards on two sites (Fig. 1). Inclusion criteria were age ≥65 years and proximal femoral fracture treated surgically (up to 21 days previously). Exclusion criteria included terminal disease, abbreviated mental test score of <7/10, previous inability to walk, profound deafness, permanent implanted cardiac pacemaker and unstable medical condition (e.g. pneumonia, heart failure). Written informed consent was obtained from all patients. All subjects were given usual-care physiotherapy while inpatients. This included supervised strengthening and range of motion exercises, balance training, work on transfers and progressive gait re-education.

Electrical stimulation was delivered via a small battery powered device, using two large self-adhesive electrodes positioned proximally and distally over the quadriceps muscle. Patients were seated with their fractured leg in 60° of free knee flexion resting on a customized foam support (Fig. 2).

Optimal current frequency and intensity were established individually using a standardized procedure and a range of phasic motor stimulation frequencies (40, 60, 80 or 100 Hz). Adjustment was made to achieve maximal quadriceps contraction without causing significant local discomfort. Assessment was undertaken by an expert physiotherapist to establish the optimum electrical stimulation set up for each individual patient within one working day after completing the baseline outcome measures assessment, but prior to randomisation. Three variables were adjusted following a set protocol. These were electrode site, current frequency and current intensity. Electrode placement was established first: the dispersive electrode was placed distally, then the active electrode was placed either proximally over the femoral nerve (pre-branch) or over the motor point of the vastus lateralis depending on which placement produced the best contraction. The electrode site was marked with indelible pen. The comfort of different frequencies varies between individuals (9, 10), and therefore

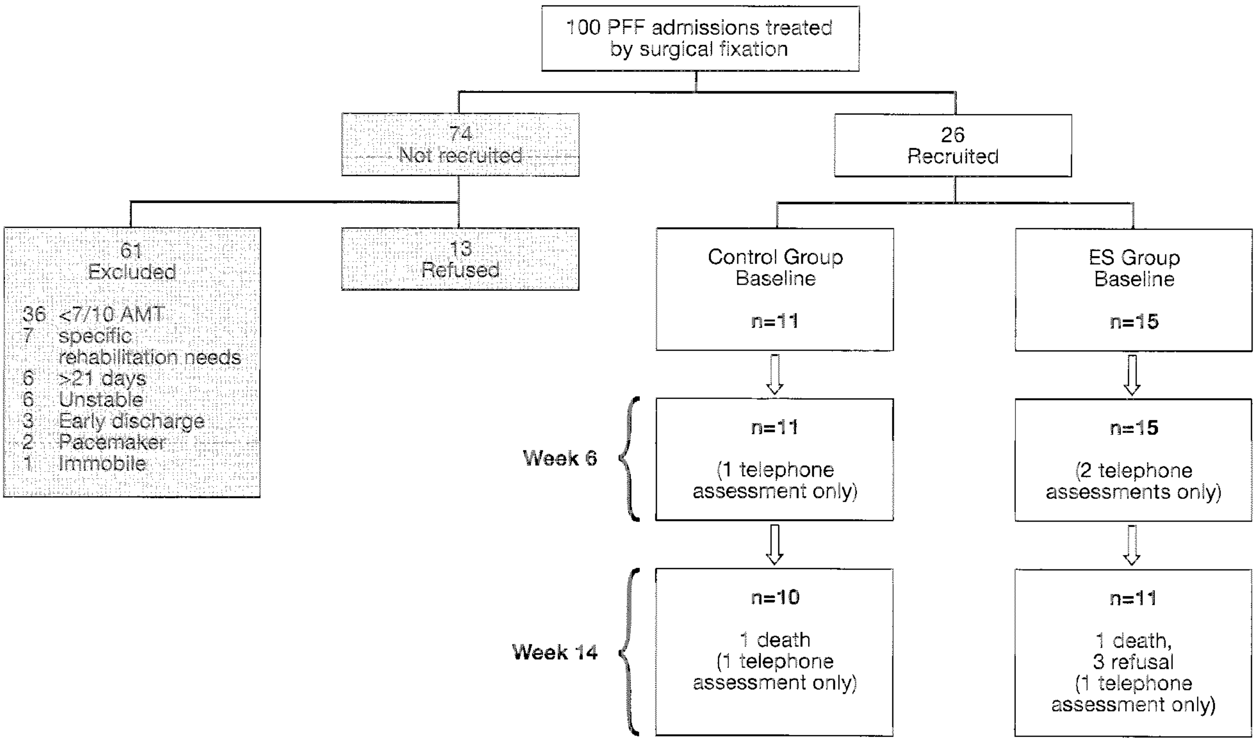

Fig. 1 - *Flowchart of patients from recruitment to final follow-up. PFF= proximal femoral fracture; AMT= Abbreviated Mental Test; ES=Electrical stimulation of quadriceps.*

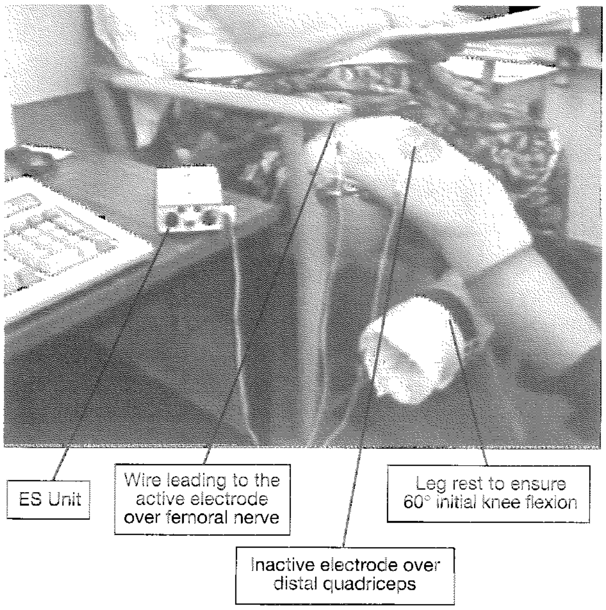

Fig. 2 - *Electrical stimulation of quadriceps; electrode and leg position.*

maximum intensity was established for ascending frequencies (40, 60, 80 or 100 Hz). The resultant contraction effect was recorded using a simple observational scale (no contraction, palpable contraction, visible contraction, partial knee extension, and full knee extension). The aim was to select the electrode site, and current frequency and intensity that gave maximal muscle contraction intensity without generating significant local discomfort. During the course of the subsequent intervention, which was delivered by a physiotherapist assistant, electrical stimulation intensity was increased in every session, and also as sessions progressed, according to patient tolerance. The assistant checked that the level of contraction matched the intensity of that achieved during initial set up, using the scale outlined above.

We aimed to give electrical stimulation 5 days per week as an in-patient and twice weekly once discharged, for a total of 6 weeks. Each session contained 36 repetitions of a 7 seconds 'on' (including a 2-second ramp-up period) and 23 seconds 'off' cycle; each session lasted 18 minutes. The protocol for electrical stimulation was used previously in a case control study (7).

The primary outcome was change in leg extensor power measured using the Nottingham Power Rig (11); each patient recorded 10 efforts with a 30 second gap between each one, and the mean of the last 5 attempts was used in the analysis. Functional mobility (Elderly Mobility Scale) (12), disability (20-point Barthel Index) (13) and health status (Nottingham Health Profile) were also recorded. Measurements were made at baseline, at 6 weeks (the end of the intervention) and 14 weeks by a single, blinded assessor. Where patients declined to attend for follow-up, data on activities of daily living (Barthel score) and quality of life (Nottingham Health profile) were gathered by telephone interview by the blinded assessor. The study was approved by the local hospitals research ethics committee.

Statistical analysis was performed using SPSS for Windows (version 14.0). Results are expressed as mean (standard error) unless otherwise stated. Data were analyzed according to intention to treat. Comparisons between the two groups were made using the unpaired *t*-test or Mann Whitney U-test. Further statistical analyses of change in key outcome variables were performed with ANCOVA using the baseline measure of the respective variable as a covariate. Statistical significance was accepted as $p \leq 0.05$. Power calculations indicated that with 20 patients per group we would have 80% power at $p=0.05$ (2-tailed) to detect a between-group difference of 7 Watts in change in leg extensor power in the fractured leg from baseline to 6 weeks, assuming a standard deviation of 8.0 of change in leg extensor power. Our final sample size had 80% power to demonstrate a between-group difference in change in leg extensor power of 9 Watts ($p=0.05$, 2-tailed).

RESULTS

Twenty-six subjects were recruited from 100 consecutive admissions to the rehabilitation units. Reasons for exclusion are shown in Figure 1. The shortfall in recruitment was due to the combination of the high number of exclusions, slower than expected recruitment rate and time limitation to the grant funding.

The control group (n=11) and the electrical stimulation group (n=15) had similar baseline characteristics in terms of age, gender split, days post surgery (Table 1), and frac-

Table 1 - *Comparison of baseline characteristics of the study population. All results are expressed as mean (standard error) unless otherwise stated.*

Characteristic	Control group (n=11)	Electrical Stimulation group (n=15)
Age (yrs)	80 (2)	81 (2)
Males : females	0:11	2:13
BMI (kg/m^2)	23 (2)	23 (1)
Intra : extracapsular	5:6	5:9
Baseline gait		
Independent : dependent	6:5	4:11
Days post-operation to baseline	10 (1)	11 (1)

LEP= Leg extensor power; EMS= Elderly Mobility Scale.
Intra : extracapsular= ratio of intra- to extracapsular proximal femoral fractures; Independent gait= requiring no personal assistance to walk; Dependent gait=requiring assistance from 1 or more persons or unable to walk.

tured leg extensor power (Table 2) with no statistically significant differences between groups. However, there was a non-significant trend for the control group to have greater unfractured leg extensor power and higher Barthel scores at study entry (Table 2). One patient died in the control group, and 1 in the electrical stimulation group, both after the active intervention period of the study during follow-up (Fig. 1).

Three (20%) of the intervention group patients tolerated sufficient electrical stimulation intensity on initial set up to produce visible knee extension, 11 (73%) produced palpable or visible contractions but no leg movement and 1 (6%) produced no contraction. A median of 10 (IQR 6, 17) sessions of electrical stimulation were given to the 13 (87%) subjects in this group who returned for the 6 week assessment. By week 14 there were 4 refusals to attend assessment (1 control, 3 in the electrical stimulation group) and 2 deaths (1 in each group) (Fig. 1).

There was no significant difference in improvement of leg extensor power, or any of the other outcome measures, in the electrical stimulation group compared to the controls. Table 2 presents baseline values for each measure and the subsequent change.

Fractured leg extensor power increased by 10.9 (standard error of the mean 2.1) Watts at 6 weeks in the ES group compared to 15.3 (5.5) in the controls. Correction for baseline levels of outcome variables was calculated by ANCOVA, using baseline measure of the respective outcome variable and study group as covariates. For leg extensor power (fractured side) the adjusted difference in change between electrical stimulation and control groups from baseline to 6 weeks was -3.1 (4.7) Watts [-0.013 (0.096) Watts per kilogram body weight]; for the unfractured leg adjusted differences were -0.3 (5.4) Watts [+0.06 (0.115) Watts/Kg]. For the Elderly Mobility Scale adjusted differences at 6 weeks were -0.6 (1.4), and for the 20-point Barthel Index -0.9 (1.3). There were no statistically significant differences in leg extensor power, Elderly Mobility Scale or Barthel index at 14 weeks.

DISCUSSION

We found that 6 weeks of supplementary electrical stimulation of quadriceps did not improve leg extensor power or disability in elderly patients rehabilitating after surgical fixation of proximal femoral fracture. The most likely reason for this apparent lack of effect is the low levels of muscle contraction produced by electrical stimulation in our sample; this was primarily due to low tolerance of stimulation intensity. It was beyond the scope of this study to objectively measure the intensity of muscle contraction achieved under electrical stimulation. Nonetheless, using a simple observational scale (no contraction, palpable contraction, visible contraction, partial knee extension, full knee extension) the contraction effect was disappointing. Healthy elderly males tolerate sufficient current to quadriceps to produce 40% of their maximal voluntary isometric contraction (6), however it seems that our frail, hospitalised elderly group had lower tolerance. This treatment may be less effective in women (who predominate in our study) because of increased electrical impedance associated with adipose tissue around the thigh. Post-operative tissue oedema of the thigh may also be a factor.

The number of sessions of treatment and repetitions of stimulation may also have been insufficient to promote improved muscle function. The median of 10 treatment ses-

Table 2 - *Changes in leg extensor power and disability measures in electrical stimulation of quadriceps and control groups at 6 weeks (end of electrical stimulation) and 14 weeks (end of follow-up) compared to baseline. Results are expressed as mean (standard error) unless otherwise stated (IQR=Interquartile range).*

		LEP Fractured leg (Watts)	LEP Unfractured leg (Watts)	EMS Median (IQR)	Barthel Median (IQR)	NHP Median (IQR)
	Baseline	21.5 (4.4) n=15	41.2 (5.6) n=15	9 (4, 13) n=15	12 (9, 15) n=15	179 (150, 263) n=15
Electrical Stimulation	Change to week 6	+10.9 (2.1) n=13	+7.6 (4.1) n=13	+7 (3.75, 10) n=13	+5 (4, 7) n=15	-98 (-144, -44) n=14
	Change to week 14	+14.7 (1.6) n=9	+10.2 (5.0) n=9	+8 (4.75, 10.5) n=9	+6 (3, 7) n=13	-100 (-149, -24) n=13
	Baseline	20.8 (3.1) n=11	44.3 (6.7) n=11	9 (6, 17) n=11	14 (10, 17) n=11	167 (104, 327) n=11
Control	Change to week 6	+15.3 (5.5) n=10	+8.6 (3.1) n=10	+7 (2, 9) n=10	+4 (2, 7) n=10	-63 (-99, -6) n=11
	Change to week 14	+26.1 (7.7) n=9	+13.6 (4.9) n=9	+4 (1.75, 9.25) n=9	+3 (2, 5) n=10	-77 (-150, -5) n=10

LEP= Leg Extensor Power; EMS=Elderly Mobility Scale; NHP=Nottingham Health Profile.

sions delivered over 6 weeks was low, however the number of repetitions per session was much higher than the standard 10 repetitions per session from studies training healthy quadriceps with phasic type stimulation (4). Thus, had electrical stimulation delivered a sufficient intensity of contraction, the 'dose' received might have been expected to have some beneficial effect.

Our results contrast to those of Lamb et al. (8). In a randomized controlled trial of 24 women rehabilitating after femoral fracture, they found 3 hours per day of electrical stimulation improved walking speed. However, improvements were delayed and only seen 6 weeks after electrical stimulation had finished, with no significant benefits at the end of the training program. No data are provided on improvements in muscle strength or power to support the above findings. It is, therefore, not certain than the improvement in function was directly due to the electrical stimulation.

Our patients were a genuinely frail elderly group, with poor muscle function. Independent older people have a mean leg extensor power of around 2 watts/Kg, while those with mild disability around 1.3 watts/Kg (14). This contrasts with a mean leg extensor power in the unfractured leg of 0.8 at baseline and 0.96 watts/Kg at end of follow-up in our cohort.

There are a number of limitations and potential confounders in our study. There was a trend for the control group to be stronger and less disabled at study entry, which could have been a cause of bias. However, correction for baseline values also showed no significant independent effect of electrical stimulation on change in leg extensor power. This was a small study and it is possible we may have missed a small beneficial effect from electrical stimulation. However, from the confidence intervals it can be seen that the study has sufficient power to exclude a moderate or large beneficial effect on the primary outcome of leg extensor power.

There are a variety of ways that electrical stimulation might be made more effective. Initial use of a hand-held electrode to explore optimal site of stimulation might allow greater muscle stimulation without causing excessive discomfort. A third electrode might increase the current delivery to quadriceps allowing greater stimulation at a lower intensity. Other protocols, such as using chronic low frequency electrical stimulation might be more effective (5). Alternatively a combination of cyclic electrical stimulation and voluntary contraction could be used; asking patients to actively extend their knee against resistance with each pulse of electrical stimulation.

In conclusion, a 6-week course of electrical stimulation of the quadriceps did not increase leg extensor power or reduce disability in elderly patients rehabilitating following surgical fixation of proximal femoral fracture. Poor electrical stimulation-induced muscle contractions associated with low stimulation tolerance levels may explain this lack of effect.

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