Non-invasive interactive neurostimulation in the post-operative recovery of patients with a trochanteric fracture of the femur

A RANDOMISED, CONTROLLED TRIAL

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We undertook a trial on 60 patients with AO 31A2 fractures of the hip who were randomised after stabilisation of the fracture into two equal groups, one of which received post-operative treatment using a non-invasive interactive neurostimulation device and the other with a sham device. All other aspects of their rehabilitation were the same. The treatment was continued for ten days after operation.

Outcome measurements included the use of a visual analogue scale for pain, the brief pain inventory and Ketorolac for post-operative control of pain, and an overall assessment of outcome by the surgeon. There were significantly better results for the patients receiving treatment by active electrical stimulation (repeated measures analysis of variance, $p < 0.001$). The findings of this pilot trial justify a larger study to determine if these results are more generally applicable.

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It is estimated that approximately 1.5 million fractures of the hip occur annually worldwide.[1,2] It has been suggested that this number could quadruple by the middle of this century.[2,3] Trochanteric fractures typically comprise 40% to 50% of all fractures of the proximal femur,[4] and it has been suggested that they will become increasingly prevalent in an ageing population.[3] This trend poses a challenge, since mortality, morbidity and costs have been shown to be greater for trochanteric fractures than for intracapsular fractures.[5,6]

Prompt recovery, with early return of mobility is essential for these patients to achieve the most favourable outcome.[7-10] Pain after stabilisation of the fracture can delay recovery.[11,12] Post-operative protocols which reduce pain and promote mobilisation should improve the outcome.

Electrical stimulation including transcutaneous electrical nerve stimulation and microcurrent, interferential and other techniques have all been used to facilitate recovery and to manage pain.[13] However, a Cochrane Group review[14] of the current literature on electrotherapy found no conclusive evidence for its efficacy, especially for transcutaneous electrical nerve stimulation.

We have evaluated the post-operative pain and function after treatment using a hand-held, non-invasive, interactive neurostimulation device (InterX 5000; Neuro Resource Group, Plano, Texas).[15] Initial reports indicated that a non-invasive, interactive neurostimulation device could be used to control pain without adverse effects in patients recovering from trauma or an orthopaedic procedure.[16-19] Our hypothesis was that this device could reduce pain and the time required to achieve functional independence in older patients recovering from stabilisation of fractures to the trochanteric area of the femur.

Patients and Methods

To be eligible for entry into the study, patients had to be between 60 and 75 years of age and have undergone stabilisation of an A2 femoral trochanteric fracture as classified by the AO system.[20,21] Exclusion criteria included limitations which might have interfered with electrical stimulation including the presence of insulin pumps, pacemakers or neurostimulation implants, a history of epilepsy or seizure, bilateral fractures and fractures of pathological origin, excluding osteoporosis. Changes in the trabecular pattern of the calcaneum were used to grade the presence of osteoporosis using the Singh index.[22,23]

During the period of study, between February and November 2005, 83 patients with A2 trochanteric fractures were admitted, of whom 23 did not meet the inclusion criteria, leaving 60 patients, all of whom completed

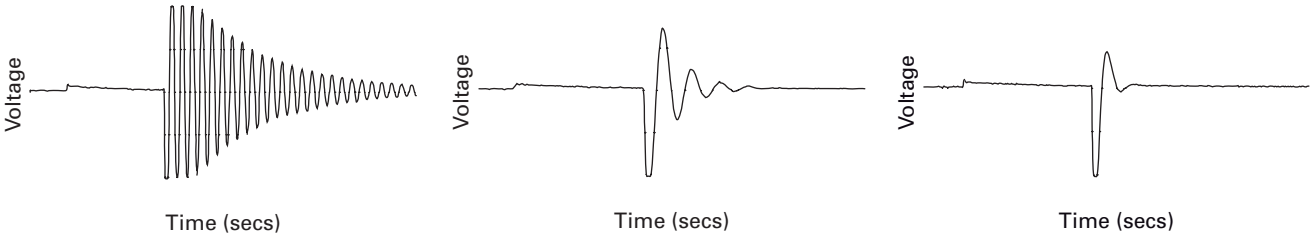

Fig. 1a Fig. 1b Fig. 1c

Diagrams of the waveform of the non-invasive neurostimulation device showing a) no skin contact, b) high-impedance skin contact, and c) low-impedance skin contact. The waveform dynamically adjusts in relation to changes in the skin. This allows localisation of sites of low impedance which are then specifically targeted. Conductive gel is not required.

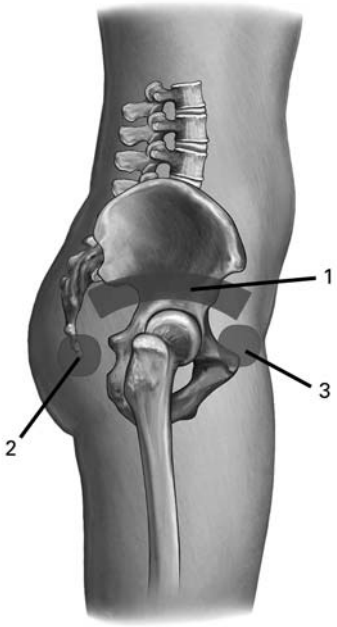

Fig. 2

Diagram of the sites of treatment which include 1) the skin just above the primary surgical incision, 2) the buttock area posterior to the hip, and 3) the skin inferolateral to the anterior superior iliac spine (areas of deeper grey shading).

the study. Of these, 30 were randomised to be treated with the InterX 5000 device, and 30 to the placebo group which used a sham device. All patients gave informed consent and the protocol received formal approval from the institutional review board. The patients were allocated to the study groups using a fixed randomisation scheme with sealed envelopes. The sample size was determined based upon the observed variation in pain scores from two earlier pilot studies,[16,17] and the investigators' opinion and a three-point reduction in reported pain, on a scale of 1 to 10, represented a clinically meaningful result. The study was designed to provide power of 95% with a level of 0.05, and allowed for loss to follow-up of 10%.

Operative technique. All the fractures have been stabilised using a dynamic hip screw (DHS)/dynamic condylar screw (DCS) (Synthes GmBH, Solothur, Switzerland) for non-complex fractures, or the Gorodnichenko (UVI-COM Co. Ltd, Moscow, Russia) external fixation method for complex fractures.[24] The latter produces less bleeding compared with the DHS/DCS method and is quicker to implant. The proportion of patients who received the external fixator was similar in both the non-invasive neurostimulation and sham device groups, with five patients (17%) and three patients (10%), receiving the treatment, respectively. All surgery was performed under general anaesthesia.

The non-invasive neurostimulation treatment protocol. All the patients received standard interdisciplinary post-operative care including routine assessment and daily care by an orthopaedic surgeon supported by a physiotherapist and nurse. A non-steroidal anti-inflammatory agent (Ketorolac tromethamine) was prescribed as needed up to three times daily for analgesia.

Within 24 hours of surgery, all patients began a ten-day course of standard rehabilitation including either the active or sham device. Treatments and physiotherapy were carried out each morning and took approximately 20 to 30 minutes to complete. The therapist who administered treatment was aware of the assignment of the patient to an active or sham device. However, all the assessing surgeons, patients and research personnel involved in determining and recording outcome measurements were blinded to this information. The sham device had an identical appearance and application to the active device with lights, buzzing and beeps, but did not produce interactive neurostimulation.

Patients in the active group received non-invasive neurostimulation therapy daily using the InterX 5000. The device generates a high peak amplitude averaging 17 volts on the skin with a low current of about 6 mA, and damped biphasic electrical impulses which are delivered

Table I. Clinical details of the two groups

	Active NIN* therapy group	Sham group
Male:Female	9:21	11:19
Mean age in yrs (range)	71.5 (67 to 75)	70.8 (63 to 75)
Pre-injury locomotion, complete/modified independence (with or without use of a walker)	30	30
AO classification:[20,21] 31A2	30	30
Method of surgical stabilisation		
Internal fixation	25	27
External fixation	5	3
Singh index of calcaneal osteoporosis[22,23]		
Mild	11	9
Moderate	8	7
Advanced	5	6
None	6	8

* NIN, non-invasive interactive neurostimulation

to the tissue through a pair of concentric electrodes placed in direct contact with the target area. The device is able to adjust its strength and damping of the biphasic stimulus changes in accordance with the impedance of the underlying tissue (Fig. 1), resulting in a highly sensitive and variable voltage in order to maintain constant peak current.[15,25]

The active or sham device was applied once each morning during the same two-hour period for a total of 20 to 30 minutes combined, at the three sites close to the surgical incision, as well as the corresponding areas on the contralateral side (Fig. 2). The device was set to record relative impedance values at each site of treatment. For each, the area was scanned using minimal intensity of stimulation to identify the position of the electrode which correlated with the lowest tissue impedance (Fig. 1).[26,27] The device was then held stationary at this location and the intensity was increased to produce a comfortable sensation for the patient. The duration of treatment was determined by the device in response to changes in impedance over time. The process was repeated at each site. Following this, the area was palpated by the therapist to identify pressure-sensitive sites, each of which was treated as before. Additionally, areas of redness were also treated in the same manner.

The patients were evaluated by the attending surgeon before their first therapy session. The pain score and range of movement were recorded within 30 minutes before and after each treatment. Hip flexion was assessed using a goniometer, with 90° of flexion being the goal during the period of study. Measurements of pain were taken using a standard visual analogue scale (VAS).[28]

The brief pain inventory[28,29] was administered at one, five and ten days after surgery. This is quick and easy to use and has been shown to be useful for a variety of patient populations.[29,30] It consists of a series of questions which address many aspects of pain including intensity, impact on the patient's life, the type and effectiveness of treatment and functional deficits related to pain. These required the patient to complete a VAS on how the pain interfered with their mood, walking ability, sleep and enjoyment of life, where a score of 1 indicated no interference and of 10, absolute interference. The daily intake of Ketorolac was also recorded.

On completion of the ten-day course of treatment, the orthopaedic surgeon (not an author), who was blinded to the group allocation and who had no involvement in treatment or daily monitoring, made an overall assessment of progress using a Likert scale.[31] This consisted of five discrete categories from 'no improvement' (score of 1) to 'full recovery' (score of 5).

Statistical analysis. All continuous variables were analysed using a repeated-measures univariant analysis of variance (ANOVA) to determine significant differences between the two groups as well as treatment-time interactions. Computations were performed with the SPSS version 13.0 for Windows statistical package (SPSS Inc., Chicago, Illinois). The categorical data produced from the surgeon's overall assessment were analysed using a manually calculated chi-squared test. A p-value ≤ 0.05 was considered to be significant.

Results

All the patients were Caucasian, none had dementia and all were functionally independent before their injury. The baseline characteristics of the two groups were similar and are shown in Table I.

Post-operative VAS assessments showed that the patients had comparably high mean levels of pain immediately after surgery of 9.0 (7.5 to 10.0) and 8.8 (7.5 to 10.0) for the

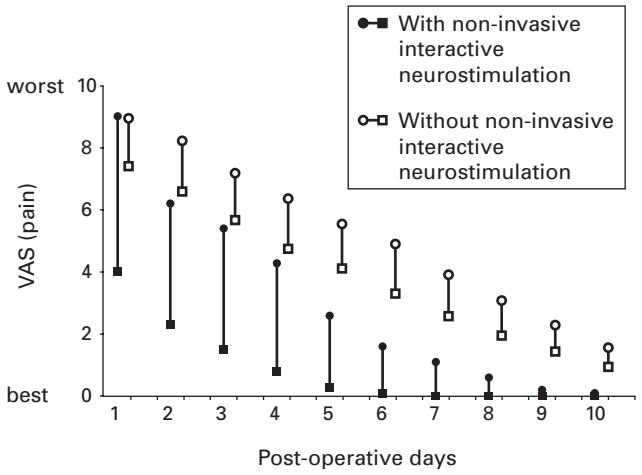

Fig. 3

The mean visual analogue scale (VAS) pain score with and without non-invasive interactive neurostimulation. The bars represent the range of pain reduction. The mean value of the score before treatment is represented by a circle, and after treatment by a square.

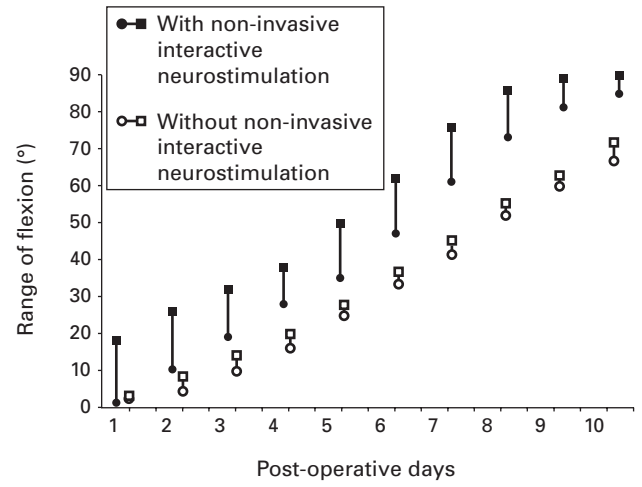

Fig. 4

Mean range of flexion with and without non-invasive interactive neurostimulation. The bars represent the mean range of flexion. The mean range of flexion before treatment is represented by a circle, and after treatment by a square.

non-invasive neurostimulation and the sham groups, respectively. However, on commencement of daily therapy, the non-invasive neurostimulation-treated patients experienced a marked reduction in pain scores. After the first session, they reported a decrease in the mean VAS pain score to 4.0 (3.2 to 5.1). In the sham treatment group, the mean VAS decreased to only 7.3 (5.3 to 10.0) after the first treatment. This difference persisted throughout the ten-day trial with the VAS declining much more rapidly in the non-invasive neurostimulation-treated group (Fig. 3).There was a highly statistically significant difference between the treatment groups, as well as for the effects of treatment over time (ANOVA, $p < 0.001$).

Table II. The mean (range) post-operative intake of Ketorolac in both groups

Day	NIN* group	Sham group
1	3.47 (3 to 4)	4.47 (4 to 5)
2	3.07 (2 to 4)	4.07 (3 to 5)
3	2.63 (2 to 3)	3.77 (3 to 4)
4	2.03 (1 to 3)	3.27 (2 to 4)
5	1.53 (1 to 2)	2.87 (2 to 4)
6	1.07 (0 to 2)	2.57 (2 to 3)
7	0.73 (0 to 1)	2.17 (1 to 3)
8	0.47 (0 to 1)	1.77 (1 to 2)
9	0.13 (0 to 1)	1.33 (1 to 2)
10	0.00 (0 to 0)	0.87 (0 to 1)

* NIN, non-invasive interactive neurostimulation

Evaluation of the range of movement yielded a similar result. The initial range of hip flexion was restricted in both groups, with a mean of 1.3° (0° to 5°) in the active non-invasive neurostimulation arm and of 1.0° (0° to 5°) in the sham group immediately before therapy. After the first session, the non-invasive neurostimulation group showed an improvement in the mean range of movement to 18.2° (0° to 35°), while the sham group had a minimal change, to a mean of 1.8° (0° to 5°). Again, this treatment effect continued throughout the trial (Fig. 4). By the ninth post-operative day, the non-invasive neurostimulation-treated group had achieved a mean range of flexion of 88.7° (80° to 90°), while in the sham group it was 63° (45° to 85°), which was highly significant both between the treatment groups and for the effects of treatment over time (ANOVA, $p < 0.001$).

In addition, the use of Ketorolac was much less in the non-invasive neurostimulation group as shown in Table II. Differences were highly significant (ANOVA, $p < 0.001$) for the treatment group and for the effects of treatment over time.

From the brief pain inventory the impact of pain on functional capacity, particularly walking ability was substantially reduced by daily non-invasive neurostimulation therapy. The mean aggregate scores decreased more sharply in the non-invasive neurostimulation group than in the sham group (Table III). At the end of the study, the non-invasive neurostimulation group reported a mean pain interference score of 1 (0 to 2.5), while the sham group had a mean score of 5.3 (4.3 to 6.5). These differences were statistically significant (ANOVA, $p < 0.001$). In particular, walking ability decreased from a baseline score of ten immediately post-operatively in both groups to a mean of 6.3 (5 to 8) on the fifth post-operative day for the active group as compared with 7.9 (6 to 9) for the sham group. By the tenth day, the active group reported minimal interfer-

Table III. The mean (range) values for pain and functional ability according to the visual analogue scale score for the two groups at days 1, 5 and 10

Score	NIN* group	Sham group
Mean aggregate score		
1	8.3 (7.5 to 9.0)	9.0 (8.0 to 9.5)
5	4.1 (3.3 to 4.5)	7.2 (3.8 to 8.5)
10	1.0 (0.0 to 3.5)	5.3 (4.3 to 6.5)
Ability to walk		
1	10.0 (10 to 10)	10.0 (10 to 10)
5	6.3 (5 to 8)	7.9 (6 to 9)
10	1.6 (0 to 3)	5.5 (4 to 9)
Ability to sleep		
1	6.9 (6 to 9)	8.1 (7 to 9)
5	2.8 (1 to 4)	6.2 (5 to 8)
10	0.6 (0 to 2)	4.2 (3 to 6)
Enjoyment of life		
1	9.0 (8 to 10)	9.4 (8 to 10)
5	3.8 (2 to 5)	7.3 (6 to 9)
10	1.2 (0 to 3)	5.5 (4 to 8)
Mood		
1	7.4 (6 to 8)	8.5 (7 to 9)
5	3.4 (2 to 5)	7.2 (6 to 8)
10	0.6 (0 to 2)	6.2 (4 to 8)

* NIN, non-invasive interactive neurostimulation

Table IV. Overall assessment of outcome by an orthopaedic surgeon for both groups

Improvement in patient status	NIN* group	Sham group
None	0	3
Minimal	0	12
Average	0	15
Substantial	12	0
Full recovery	18	0

* NIN, non-invasive interactive neurostimulation

ence with walking due to pain, yielding a mean score of 1.6 (0 to 3) compared with 5.5 (4 to 7) in the sham group.

Finally, the general therapeutic impact on recovery was assessed by the surgeon's overall evaluation of each patient's status upon completion of the ten-day protocol. All patients treated by the sham device had only 'no improvement', 'minimal', or 'average' improvement with a mean score of 2.4 (1 to 3) according to a 5-point Likert scale,[31] where 1 represents no improvement and 5 represents full recovery. By contrast, all those treated by the active non-invasive neurostimulation device had either 'substantial improvement' or 'full recovery' with a mean score of 4.6 (4 to 5) (chi-squared test, $p < 0.001$; Table IV).

Discussion

In our randomised, controlled study, we hypothesised that active non-invasive neurostimulation therapy in addition to standard post-operative care would improve recovery in elderly patients with a trochanteric fracture of the hip as a result of reduced pain and improved range of movement.

The precise biochemical mechanism of the action for non-invasive neurostimulation is not yet known. Animal experiments have suggested that stimulation releases endogenous opioids.[32-34] Additional theories are that the body may modulate bidirectional communication between the cutaneous system and the nervous and immune systems.[35,36] Further support for this concept was found in a study on rabbits which showed activation of the optic and somatic cerebral cortices as well as the hypothalamus after non-invasive neurostimulation treatment for 15 minutes.[37] We found this therapy produced an accelerated recovery in the range of movement and reduced pain with a mean VAS for pain < 1.0 by the fourth post-operative day. A similar improvement in pain was delayed until the tenth post-operative day in the sham group.

A poor outcome associated with a fracture of the hip in elderly patients has been extensively documented.[38,39] It has been shown that there is a relationship between the extent of mobility during the first few days or months post-operatively and the occurrence of adverse events, including repeated hospitalisation, placement in a nursing facility and death.[7,8] Equally, a positive long-term outcome has been shown to be associated with achieving functional independence within 72 hours of surgery.[40]

Morrison et al[12] found a relationship between the level of post-operative pain and the outcome as well as the longer term outcome after reconstructive surgery for fracture of the hip. They reported that higher levels of post-operative pain were associated with longer hospital stays, poorer adherence to physiotherapy protocols, diminished ability to walk three days after the procedure and at six months after discharge. The relationship between pain and the functional outcome is highlighted in our study.

Furthermore, we identified a potential relationship between non-invasive neurostimulation therapy and length of hospital stay. Based upon the results of the pain scores and range of hip flexion, the patients treated by the non-invasive neurostimulation device could have been discharged from hospital earlier than those treated by a sham device. Additionally, the overall assessment by the surgeon indicated that all active non-invasive neurostimulation-treated patients had substantial improvement or full recovery upon completion of the protocol, while none treated by the sham device reached this degree of recovery during the period of study.

We accept that our study has not established whether any long term benefits will be obtained from non-invasive neurostimulation therapy. This will require investigation over a longer period of time.

We acknowledge the limitations of our pilot study. First, the patients were all Caucasian and were somewhat younger than patients with fracture of the hip worldwide.[3,41] Principally, this is a reflection of the reduced life

expectancy in Russia.[42,43] Further studies are required to confirm whether these results can be generalised to more ethnically diverse and elderly groups of patients. Secondly, our patients were in relatively good health. None had dementia and all were functionally independent before their injury. It has been shown that a poorer outcome tends to occur in those patients with pre-existing mental and/or physical impairment.[44,45] Thus, evaluation of the effectiveness of non-invasive neurostimulation therapy in patients with a much more compromised health status and who are most at risk for unfavourable outcomes is mandatory. Thirdly, the physiotherapist was not blinded to the allocation of active or sham devices and may have inadvertently introduced bias. We attempted to control for this by incorporating an overall surgeon's assessment to increase objectivity, but felt that the design of the study could have been improved if the physiotherapist had been blinded. However, because of the interactive nature of the technology application, this was not possible.

Although improvements in the recovery from fractures of the hip have been reported,[46-48] the treatment of these patients continues to represent one of the major costs in healthcare. The improvement in the rate of recovery after non-invasive neurostimulation therapy suggests that it could play a valuable role in reducing the length of in-patient stay. Our findings justify a larger study to evaluate the role of non-invasive neurostimulation therapy as part of an integrated rehabilitation strategy.

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