The Effects of Non-Invasive Interactive Neurostimulation Therapy on Pain and Oedema during Post Surgical Rehabilitation following Internal Fixation of Unstable Bimalleolar Ankle Fractures

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Introduction:

Ankle fractures represent a diverse set of traumatic injuries and account for one of the most common categories of fractures seen by orthopedic surgeons. Epidemiological studies in North America and Europe suggest more than 60,000 cases occur annually in a country the size of the United Kingdom and document an increasing number of reported ankle fractures over the past half century. Surgical correction of bimalleolar and trimalleolar fractures involving both tibia and fibula is widely accepted within the orthopedic community as a necessary procedure in order to regain stability. Less agreement exists on the most appropriate post-operative care and practically, post surgical therapy is based largely on the physicians personal preference along with patient-specific considerations.

Electrical modalities have previously shown to be effective in the reduction and management of pain,[3,4,7] to reduce inflammation and facilitate recovery from traumatic conditions.[2,5] Non-invasive interactive neurostimulation using an InterX device was recently shown to produce beneficial results in the post-operative treatment of patients suffering trans-trochanteric fractures of the femur. Results of treatment using non-invasive interactive neurostimulation showed a sustained decrease in pain (p<0.001) in the active group compared to the control group and statistically significant results all other parameters measured. *(J Bone Joint Surg [Br] 2007;89-B: 1488-94)*

Hypothesis:

This study hypothesises that that Non-invasive, Interactive Neurostimulation Therapy will provide enhanced benefits for patients immediately post-operative following restoration and fixation of unstable bimalleolar ankle fractures. Interactive Neurostimulation, when used alongside standard post-operative care in the Active group will show reductions in pain and oedema as well as an increase in range of motion (ROM) compared to the Sham group. Achieving such outcomes, can aid early rehabilitation and allow the patient to return to full function within an opitmal time frame.

Materials and Methods:

Eligible patients were selected between the ages of 20 and 60 years old following operativerestoration and fixation of bimalleolar, AO type B2 ankle fractures. Requirements for participation included the ability to begin specified post-surgical therapy within 24 hours of the initial procedure and compliance with ongoing care; exclusion criteria included neurostimulation implants, history of epilepsy or seizure, pregnancy or active malignancies. The completed trial included 60 patients, 30 were assigned to active treatment with an InterX device and 30 were assigned to control for treatment with a Sham device that had been modified to be asthetically idenitical to the active device but the ability to deliver interactive neurostimulation was removed. Patients were blinded and randomly allocated to each group and received standard medical care alongside Active or Sham treatment. (Fig.1)

Treatment Groups (Fig. 1)

Characterstics	Active Group N=30	Sham Group N=30
Female Male	16 (53.3% 14 (46.7%)	17 (56.7%) 13 (43.3%)
Average Age	35.3 (range)	38.4 (range)
Race: Caucasian	30 (100%)	30 (100%)
Pre-fracture Locomotion	30 (100%)	30 (100%)
Diagnosis of Dementia	(0%)	(0%)

All patients received baseline evaluations by the attending physician prior to first treatment session. Outcome measurements included the patients' subjective assessment of their level of pain, range of motion (ROM) in the injured ankle and the extent of oedema. Standard Visual Analogue Scale (VAS) was used to measure pain. Circumferential measurements of oedema were taken around the ankle and ROM was measured using a goneometer. Each of the parameters were measured within 30 minutes of the conclusion of treatment sessions and the assessing physician was blinded. In addition, intake of prescribed NSAID medication was recorded daily throughout the study.

All parameters impact functional status of the lower extremity and impact recovery time to when patient reaches discharge criterion.

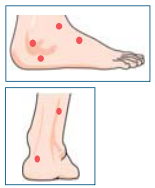
Treatment Procedure:

Patients in both groups initiated treatment twice a day, no more than 24 hours after surgery. Treatment periods took place in the morning and evening over 10 consecutive days for a duration of between 20-30 minutes. Active and Sham devices were set at default pulse parameters, both units were applied around the area of surgical incision and to the exact contralateral area.

The Active device was applied directly to the skin on a minimal intensity and Activity Readings (AR) were taken around the general area to identify optimal treatment points. Optimal treatment points are indicated where sympathetic skin reponse is increased, which causes a lowering of the impedance of the skin[6]. The interactive impedance sensitive waveform and the design of the device allows numerical feedback and identification of optimal treatment points. The highest AR positions (numerically) were then treated on an increased intensity level for a period of 30 seconds - 1 minute each (Fig.2). The high amplitute and high density current stimulates both peripherally and centrally mediated pain relieving mechanisms.

The Sham device was used in exactly the same way with audio and visual signals to imitate treatment with the Active device.

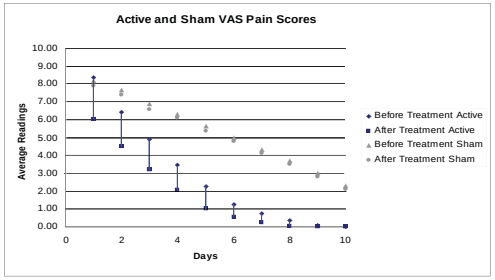
(Fig. 2 Example of treatment points)



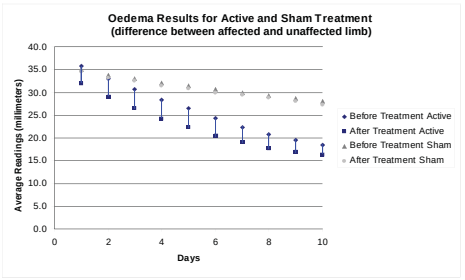
Results:

Post operative VAS pain assessments showed that patients had comparably high mean levels of pain (8/10) immediately after surgery for the Acitve and Sham groups. However, on commencement of daily therapy, the Active group experienced a marked reduction in pain scores compared to the Sham group. The Active group reported a decrease in the mean VAS pain score to 6.01, while the sham group reported a decrease to 7.91 on the first day. This difference persisted throughout the 10 day trial with the VAS declining more rapidly in the Active group. On day 5, pain levels in the Active group were less than those achieved in the Sham group by day 10. (Fig.3).

Evaluation of reduction in oedema is expressed in millimeters and represents the change in oedema that accompanies the surgical wound at the operated ankle site. The difference in circumference between the operated ankle joint and the non-operated ankle joint indicated oedema. Measurements were taken before and after treatment using a metric tape measure. The Active group reported an overall reduction in oedema of 54.6% over the 10 day period from 35.9 immediately post surgical to 16.3 after treatment on day 10, with an average daily reduction of 2.72mm. (Fig.4)The Sham group reported an overall reduction in oedema of 22.2% over a 10 day period from 35.1 post surgical to 27.3 after treatment on day 10, with an average daily reduction of 0.78mm.



(Fig.3)



(Fig.4)

In other parameters measured, an evaluation of the range of dorsiflexion over the 10 day period showed an increase from 14 to 46 degrees (32 degrees in total) in the Active group whereas the Sham group showed an increase from 13.8 to 28, (a total of 14.2 degrees improvement). Medication (Ketorolac) was reported to be reduced to 8mg on day 6 in the Active group compared to 19mg reported in the Sham group. A subjective assessment of the quality of sleep showed that sleep was affected up to 69% post-surgical (100% being complete sleep deprevation) and reduced to 6% by day 10. A comparative report in the Sham group reported an initial 81% reducing to 40.7% on day 10.

Conclusion:

In this randomised controlled study it was hypothesised that non-invasive interactive neurostimulation therapy in addition to standard post operative care would improve outcomes in pain, oedema and ROM and return the patient to full function within an optimal time frame. It was found that Non-invasive Interactive Neurostimulation Therapy as an adjunct to standard care produced a decrease in pain with a mean VAS for pain < 1.0 by the fifth post-operative day. A similar improvement in pain was still not reported at the tenth day in the Sham group. The Active group also reported a 50% greater reduction in oedema than the Sham group at day 10.

The improvement in the rate of recovery after non-invasive interactive neurostimulation therapy suggests that it could play a valuable role in reducing the recovery time in patients following restoration and fixation of unstable bimalleolar ankle fracture. Analysis of the data showed a high level of statistical significance for the reduction of pain (p<.001) and reduction of inflammation (p<.001) between the Active and Sham treatment groups over time.

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