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 fracture seen by orthopaedic 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 oedema, Standard Ankle Visual Analogue Scale (VAS) with the Sham group, Active group and Physiological monitoring was used to measure pain. Circumferential measurements of oedema were taken around the ankle and ROM was measured using a goniometer. 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.

Results:
Post operative VAS pain assessments showed that patients who had comparably high mean levels of pain (8.0) immediately after surgery for the Active 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 7.59 on the first day. This difference persisted throughout the 10 day trial that 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 56.4% 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 0.727mm. (Fig.4) the Sham group reported an overall reduction in oedema of 22.5% over a 10 day period from 35.1 post surgical to 27.3 after treatment on day 10, with an average daily reduction of 0.578mm.

Hypothesis:
This study hypothesised that Non-invasive, Interactive Neurostimulation Therapy will provide enhanced benefit 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 optimal time frame.

Materials and Methods:
Eligible patients were selected between the ages of 20 and 60 years old following operative restoration 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 acute malignancies. The protocol included 60 patients; 30 patients were assigned to receive treatment with an InterX device and 30 were assigned to control for treatment with a Sham device that had been modified to be aesthetically similar 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)

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 contoured area.

The Active device was applied directly to the skin on a minimal intimacy and Activity Readings (AR) were taken around the general area to identify optimal treatment points. Optimal treatment points are included where sympathetic skin responses is increased, which causes a lowering of the impedance of the skin. 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 amplitude 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.

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