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. Standardized Visual Analogue Scale (VAS) for pain assessment 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, a subjective assessment of the quality of sleep showed that sleep was affected up to 69% post-surgical (100% being complete sleep deprivation) and reduced to 9% by day 10. A comparative report in the Sham group reported an initial 81% reducing to 40% on day 7.

Hypothesis:

This study hypothesises 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, which 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 open reduction 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 compliancy 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 Inter- device and 30 were assigned to control for treatment with a Sham device that had been modified to be asthetically identical 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.

Results:

Post operative VAS pain assessments showed that patients had comparably high mean levels of pain (810) 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 7.91 on the first day. This difference persisted throughout the 10 day trial with 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 55.9 immediately post surgery to 18.3 after treatment on day 10, with an average daily reduction of 0.72mm. Fig. 3 shows that the Sham group reported an overall reduction in oedema of 22.5% over a 10 day period from 51.9 post surgical to 27.3 after treatment on day 10, with an average daily reduction of 0.587mm.

Conclusions:

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 role 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 fractures. Analysis of the data showed a high level of statistical significance for the reduction of pain (p<0.01) and reduction of inflammation (p<0.01) between the Active and Sham treatment groups over time.

References:

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