#22 - Clinical Study / Free Papers

A Pilot Clinical Study Comparing The GekoTM Neuromuscular Electrostimulation Device, With Current Standard Of Care To Evaluate Oedema Reduction And Readiness For Theatre In Patients Requiring Open Reduction Internal Fixation Following Ankle Fracture.

Trauma / Foot & Ankle Trauma / Surgical Treatment

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Background
Ankle fractures account for 9% of fractures seen in the UK with 15,000 ankles undergoing surgical fixation each year. Ankle oedema often delays surgery because of the risks associated with operating on swollen tissues. Interventions that expedite swelling reduction have potentially significant clinical and economic benefits. Current pre-operative interventions include the use of backslab plaster cast plus elevation often with the addition of other measures such as Intermittamt Pneumatic Compression (IPC), cryotherapy or temporary external fixation.

Objectives
1) To compare the time from admission to the primary surgical procedure for patients requiring ankle fixation following ankle fracture when treated with geko™, with matched retrospective data
2) To assess oedema reduction in prospective geko™ subjects prior to surgery
3) To assess the health economic beneifts of geko™ use when compared to historical standard of care

Study Design & Methods
Case-control study assessing the effectiveness of the gekoTM neuromuscular electrostimulation [NMES] device for the treatment of pre-operative ankle oedema in patients awaiting surgery for an ankle fracture. The study recruited 20 patients admitted to the trauma ward of a major trauma centre for surgical fixation of an ankle fracture. Patients received the gekoTM device (Intervention arm) which was applied above their plaster backslab. These patients were then matched to a historical cohort of 20 surgically treated ankle fractures (Control arm) for comparison. The time until the oedema had settled to a level permitting surgery ('readiness for surgery') was recorded for each arm of the study. In addition, patient tolerability and any adverse reactions to the geko TMdevice were recorded. Patients in the gekoTM group were recruited between July 2016 and January 2017. Retrospective matches were undertaken based on defined criteria (age (+/- 5 years), gender, ethnicity, fracture type (unimalleolar vs bi/trimalleolar), dislocated at presentation to hospital (Yes vs No)). Matches were achieved by working back from 31st December 2015 through surgically treated ankle fracture cases treated within the trust. The first match was chosen for each case.

Results
Of the 20 participants in each group there were 9 females and 11 males, 6 unimalleolar and 14 bi/trimalleolar fractures, 11 ankles dislocated at presentation and 9 non-dislocated. All patients were white caucasians. Mean age was 45.4 years (Range 19-64) in the gekoTM group and 45.8 years (Range 16-62) in the historical control group. Mean time until the oedema had been reduced facilitating a 'readiness for theatre' was 1.66 days in the gekoTM group versus 3.66 days in the control group ($p=0.001$). Overall 60% of patients were ready for theatre following 2 days of treatment by the gekoTM device compared to just 27% in the control arm ($p<0.01$). In the gekoTM group there was 1 device

deficiency (battery failure) and 1 event related to the device (patient developed a heat rash on the skin around the device). 19 of 20 patients tolerated the device well and wore it 24 hours a day from application until their surgery. Independent Health economic modelling of this scenario suggests a saving per patient compared to current standard of care of £569 base on a 2 day reduction in hospital stay.

Conclusions

The gekoTM is safe and effective at reducing ankle oedema prior to ankle fracture surgery. It is easy to apply, it can be worn continuously and it does not restrict patients to their bed space.