Prospective, Double Blind Randomized Controlled Trial on the Use of Immediate Post-Operative Electrical Muscle Stimulation to Preserve Muscle Function and Volume Following Achilles Tendon Surgery

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Introduction/Purpose: Post-surgical muscle atrophy is common after Achilles tendon repair and immobilization. Muscle atrophy takes significant rehabilitation effort and time to recover, sometimes never returning to pre-operative level. Neuromuscular stimulation has been shown to improve pain and accelerate recovery following orthopedic surgery. The mechanism of this effect has not yet been elucidated. We theorized that muscle atrophy was a critical link to positive patient outcomes and that NMES could be achieving its effect by a muscle volume preserving mechanism. It was theorized that electrical muscle stimulation used immediately after surgery and through the course of immobilization could mitigate calf muscle atrophy, improve post-operative patient reported scores, and perhaps speed functional recovery of Achilles tendon repairs.

Methods: This was an IRB approved prospective, double blind randomized controlled trial with 40 patients. Pre-operative and post-operative measurements of calf circumference, Focus on Therapeutic Outcomes (FOTO) Score, and AOFAS ankle-hindfoot score were measured. All subjects had MRI scans pre-operative and at post-operative weeks 2 and 6 to measure cross sectional muscle volumes. A four lead NMES device was applied in a standardized fashion at time of surgery with both patient and surgeon blinded to activity of the device (20 active, 20 ‘sham’). All patients followed a standardized post-operative protocol. Chi-square test was used for categorical variables and two-sample t-tests for continuous variables. Linear mixed models were used to compare changes in muscle cross sectional area and clinical outcomes of interest over time between the groups. Statistical significance was set at p<0.05 for all tests. The study was powered at 80%.

Results: There were 40 subjects with a mean age and BMI of 48.9 years and 32.2, respectively. There were no differences in demographic characteristics or pre-operative scores between groups. The active treatment group trended toward higher FOTO and AOFAS scores at post-operative weeks 2 and 6, though not statistically significant, and both groups were similar at 12 weeks. Volumetric MRI measurements trended toward less muscle loss in the active treatment group at 6 weeks post-operative, but failed to reach statistical significance. Calf circumference measurements were not different between groups at any post-operative interval. Both groups used the devices similarly, but there was a 6.4% incidence of stimulator use on an incorrect setting (8% in active, 5% in sham), which was statistically significant (p<0.001).

Conclusion: This prospective RCT was undertaken to quantify and validate the effect and ability of NMES to minimize calf atrophy. No statistically significant difference was found between active NMES and sham treated patients. There was a trend showing some maintenance of calf volume per MRI. It is possible the reported beneficial effect of NMES is due to an induced cortical plasticity that would be manifest later in the rehabilitation cycle and is not due to a size preserving effect alone. Neuromuscular stimulation does not improve muscle volume or patient reported functional outcomes when used for 6 weeks following Achilles tendon surgery.

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