Prospective, Multi-Center, Randomized Study to Evaluate the OrthoCor Active System for Pain Relief

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OBJECTIVE

The objective of this study was to evaluate the efficacy of the OrthoCor Active System for reducing pain in superficial soft tissue.

METHODS

The OrthoCor Active System is a portable, battery operated, non-invasive device that delivers Pulsed Electromagnetic Field (PEMF) therapy for pain relief. It utilizes wraps to position the therapy over the painful area, such as on the ankle, back, knee, wrist, elbow, shoulder, foot, or neck. It delivers heat and a pulsed RF signal to the tissue target that accelerates the natural anti-inflammatory and healing responses.

120 patients with a history of pain in superficial soft tissue (such as in the ankle, back, knee, wrist, elbow, shoulder, foot, or neck) were enrolled. Analysis was conducted on data from 91 patients, 48 using the OrthoCor Active system and 43 using the SOC, after 2 patients withdrew consent and 27 were withdrawn for noncompliance with the protocol.

Participants in the active group received 2 hours of therapy each day from the OrthoCor Active System while participants in the control group (SOC) received alternative treatments such as NSAIDs, ice therapy, physical therapy, and other standard treatments. For 14 consecutive days the participants received treatment and rated their pain using the Mankoski pain scale.

RESULTS

When analyzing the efficacy of the OrthoCor Active System, a significant analgesic benefit was observed compared to Standard of Care (SOC). The OrthoCor Active System Group exhibited the least squares (LS) mean change in pain score from baseline of -1.8 (36% reduction, SE: 0.171), surpassing the SOC group's reduction of -0.5 (10% reduction, SE: 0.181). The LS mean difference of -1.3 between the two groups (95% CI: -1.8 to -0.9), representing a 26% greater decrease in pain for the OrthoCor Active System Group, was statistically significant with a p-value <0.0001. The incidence of adverse events in this study was notably low, with only 4 out of 120 experiencing minor complications equally across both groups.

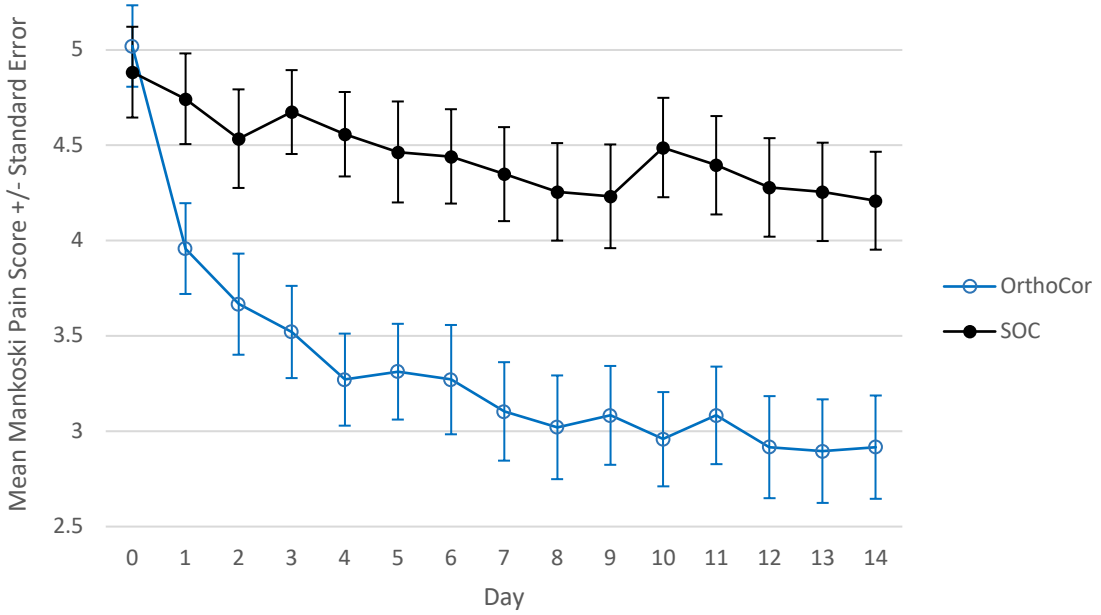

Figure 1: The mean pain score (Mankowski) for the OrthoCor Active System group was significantly lower than the SOC for the 14 days of the trial.

After the 14-day treatment, some patients from the SOC group elected to crossover to using the OrthoCor Active System. The 18 patients from the crossover group who submitted all pain scores experienced a further decrease in pain score, showing that adding the OrthoCor to the SOC treatment provided additional pain relief.

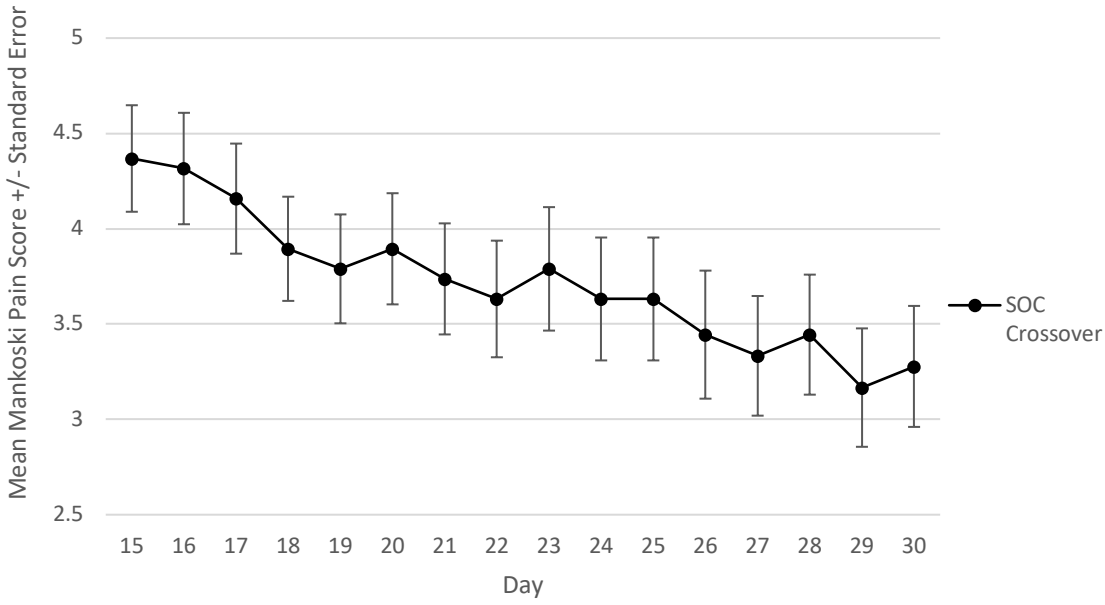

Figure 2: The mean Mankoski pain score for the SOC patients who crossed over decreased further with use of the OrthoCor Active System.

CONCLUSION

The OrthoCor Active System was significantly more effective than the Standard of Care (SOC) in reducing pain for soft tissue, with a 26% greater reduction in pain scores and a p-value of <0.0001. The number of adverse events was equivalent in the two groups and there were no significant complications, proving safety and tolerability. The crossover patients demonstrated that adding the OrthoCor Active System to the SOC treatment provided additional pain improvement. This randomized controlled clinical trial demonstrated that the OrthoCor Active System is an effective non-opioid solution in pain management that should be considered in the conservative treatment of pain and soft tissue injuries.