

물리학

게시일시 및 장소 : 10 월 19 일(토) 08:30-12:30 Room G(3F)

질의응답 일시 및 장소 : 10 월 19 일(토) 11:00-11:30 Room G(3F)

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Clinical RCT to Evaluate the Efficacy and Safety of High Frequency Flexible Stimulator on OA

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Introduction

In recent years, electrical stimulation through the skin has been widely applied as the easiest and most effective pain treatment with no side effects, and interest is increasing. The medical team needed a clinical basis to accurately perform these effects and performed this clinical trial to evaluate the efficacy and safety of high frequency stimulators widely used for pain relief at home and abroad.

Methods

We selected the test subjects with a total score of 30 points or more through the K-WOMAC evaluation. The clinical trial enrolled volunteers who signed the clinical trial agreement and met the selection and exclusion criteria through screening (visit 1). We then investigated the osteoarthritis-related medicines that are currently being taken through questionnaires from previous drug dosing questionnaires. We set up the drug wash-out period of 3 to 10 days for those who need drug wash-out. Then, we trained about the use of antibiotics during the trial, how to use old drugs, how to apply the devices for the test, and overall clinical trials at baseline (visit 2). We conducted radiofrequency stimulation twice per week (every 3 days) for 3 weeks at daytime (30 minutes once) after the baseline (visit 2) of the subject, total of 6 stimulation were conducted until the last visit (visit 3). The followings are conducted to evaluate the efficacy of high frequency flexible stimulator, which are 100mm-VAS, K-WOMAC, X-ray and serum biomarker test related to osteoarthritis, C-terminal Cross-linking Telopeptide of Type 1 Collagen (CTX) at the visit 2 and visit 3. The safety was evaluated via checking the adverse events to high frequency treatment at each visit.

Results

As a result of comparing the clinical characteristics of the subjects, there were statistically significant differences in baseline CTX and no statistically significant differences in other clinical characteristics.
However, in follow-up results, K-WOMAC, VAS, and CTX showed statistically significant differences in the test group compared to the control group.

Conclusion

Clinical Efficacy : In this clinical trial, 34 subjects with knee osteoarthritis were treated with high frequency intervention twice a week for 3 weeks. In the evaluation results before and after treatment, we could observe a significant decrease in joint pain (VAS) and an improvement in the evaluation of functional and daily life performance (K-WOMAC) in the test group using this clinical test high frequency device compared to the control group.

Clinical Safety: In the high frequency intervention performed in 34 subjects, 4 subjects complained of an abnormal sensation such as pain and tingling immediately after intervention, but this symptom disappeared without any treatment in all subjects. No burns or systemic abnormalities were observed at the intervention site.

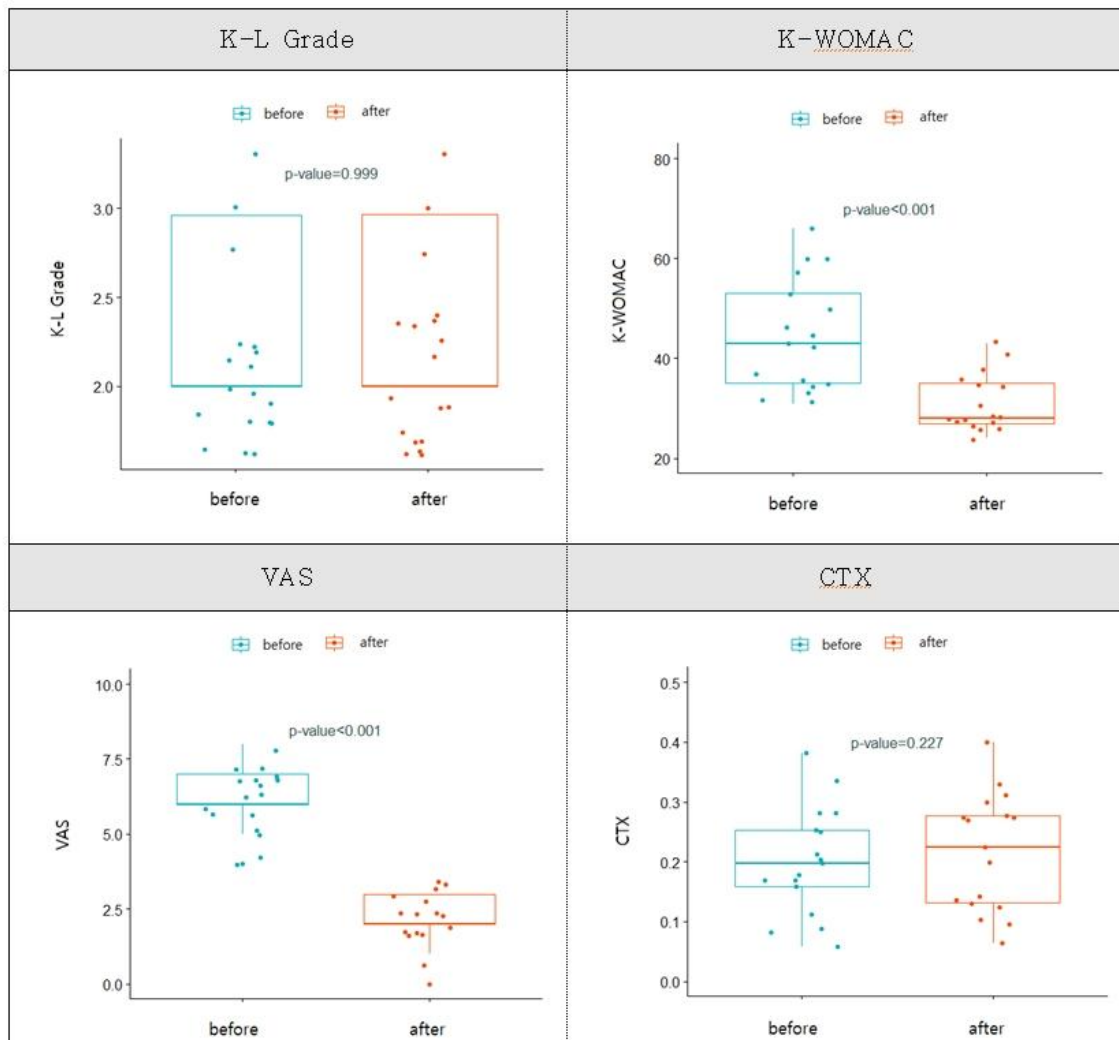


Fig. 1 As a result of verifying the differences before and after the intervention for only the test group among the subjects of this study, K-WOMAC and VAS showed statistically significant differences.