

## **Effects of PEMFs on Patients' Recovery after Reconstruction with Use of Double-looped Semitendinosus and Gracilis Tendon Grafts: a Multicenter, Prospective, Randomized and Double-blind Study**

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### **1 Introduction**

*In vitro* and *in vivo* studies have shown that the treatment with Pulsed ElectroMagnetic Fields, PEMFs (I-ONE, Igea, Carpi, Italy), can control inflammatory processes, to protect articular cartilage from the catabolic effects of pro-inflammatory cytokines, to prevent its degeneration, finally resulting in chondroprotection. The purpose of this multicenter, randomised, prospective and double-blind study was to evaluate the effects of PEMFs in patients undergoing anterior cruciate ligament reconstruction of the knee.

### **2 Materials and Methods**

Patients with rupture of anterior cruciate ligament at knee underwent arthroscopically assisted reconstruction with use of double-looped semitendinosus and gracilis tendon grafts using biodegradable interference fit fixation. They were randomised in placebo or active group according to age, sex, smokers and pathology. All patients were instructed to use PEMFs for 60 days, 5 hours per day. The assessment was performed using the International Knee Documentation Committee form

before, 30, 60 and 180 days after arthroscopy. The control of pain was also recorded by VAS (Visual Analog Scale). Patients will be interviewed for long term follow-up at 1 and 2 years after arthroscopy.

### **3 Results**

Fifty-seven patients completed the treatment until 180 days. Fifteen patients lost to follow-up. Both groups were comparable with regard to demographic data, preoperative subjects' evaluation score, health condition and pre-operative pain value. At the 30, 60 and 180 day subjects' evaluation follow-up, no significant differences were found between the two groups, while we found higher values in the active group than in the control group in the health evaluation form ( $p < 0.05$  at 180 days respect baseline). About the objective score, at 60 days from surgery the percentage of joint swelling was significantly lower in the active group, disappearing at 6 months, versus 12% in the placebo group ( $p < 0.05$ ). We also evaluated the percentage of patients with abnormal range of motion; at day 60 the two groups showed extremely significant differences in the percentage of abnormal passive range of motion (5% active group vs 24% placebo group,  $p < 0.005$ ).

In the active group a clear trend toward decrease in pain intensity could be observed since 30 days follow-up visit. The decrease from baseline is significant at day 60 and month 6 ( $p < 0.05$ ). In the placebo group an increase in pain intensity is observed at day 30, even not significant, then a decrease with respect to baseline is observed at day 60 (ns). At month 6 the decrease in mean VAS is significant ( $p < 0.05$ ).

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#### **4 Conclusion**

Biophysical stimulation with PEMFs after ACL reconstruction significantly reduces the patients' recovery time. PEMFs allow an easier control of pain, of joint swelling and finally it has a chondroprotective effect over the articular cartilage of the knee. We did not observe any side effect that would lead to treatment interruption. Overall, the patient's compliance was good, suggesting that the treatment was well accepted.