Effects of Pulsed Electromagnetic Fields After Debridement and Microfracture of Osteochondral Talar Defects: Letter to the Editor

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Effects of Pulsed Electromagnetic Fields After Debridement and Microfracture of Osteochondral Talar Defects: Letter to the Editor

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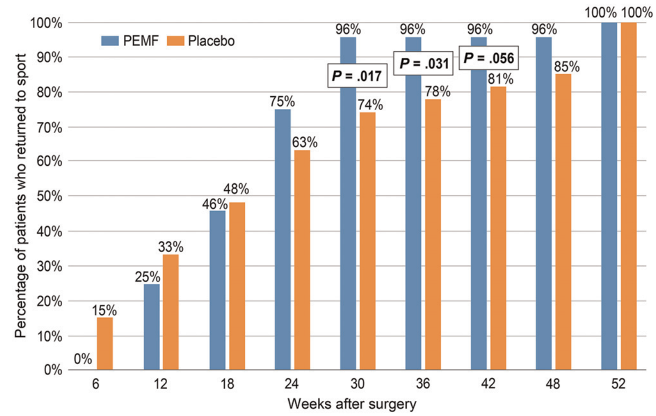

Figure 1. Percentage of patients who resumed to sport after surgery. Statistical analysis by chi-square test.

Dear Editor:

We have carefully read the paper by Reilingh and collaborators entitled "Effects of Pulsed Electromagnetic Fields on Return to Sports After Arthroscopic Debridement and Microfracture of Osteochondral Talar Defects: A Randomized, Double-blind, Placebo-controlled, Multicenter Trial,"[11] and we believe that it deserves a few comments.

In the Outcome Assessment section the authors write, "the primary outcome measures were the number of patients that resumed sports and the time to resumption of sports."[11(p1294)] Although the results showed no difference between the treated and control groups in the number of patients who returned to sport 1 year after surgery, in Figure 3 of the article, the 2 Kaplan-Meier curves are clearly not superimposed after the 20th week after surgery. In the pulsed electromagnetic field [PEMF]–treated group, 96% of patients returned to sport by week 30, while in the control group the same percentage was achieved at week 52. This trend is clearly shown in our Figure 1, elaborated from Figure 3 of the Reilingh et al article. This finding is in agreement with previous experiences reported in literature.[1,2,10,12]

Reilingh et al based the power analysis for their study on their experience that "50% of patients would resume and maintain sports within 1 year after the surgical intervention."[11(p1294)] This contrasts with the study finding that 80% of patients in the control group returned to sport at 1 year. Although the relative prognostic significance of the location of an osteochondral talar defect remains controversial,[3] the high return-to-sport rate observed in the control group might be explained by the unbalanced randomization of patients: The medial location of the lesion was 53% in the control group versus 75% in the treatment group, a difference marginally significant with the chi-square test (P = .059).

In the Methods section, the authors reported that a clock inside the device was used to monitor the hours of stimulation. It is unusual to provide the information on hours of use as median and interquartile range because it leaves out relevant information on the 50% extremes of the entire population. According to the information provided, 25% of patients used the device less than 180 hours (3 hours/day)[11]; average daily stimulation has been shown to have a significant impact on treatment outcome.[4]

In the Discussion section, the authors write that they "consider bone regeneration more important than cartilage regeneration."[11(p1298)] If this is the case, they should have used a specific PEMF generator for bone growth stimulation. Bone growth stimulation requires higher field values and longer daily exposure.[5,8]

Referring to Hanneman et al[6,7] papers, Reilingh et al seem to support the concept that PEMFs do not accelerate bone healing on computed tomography; however, in their Discussion Hanneman et al[7] write, "post hoc log-rank analysis revealed a significantly shorter time to union in the active PEMF group for undisplaced transverse fractures of the scaphoid waist. PEMF bone growth stimulation seems to have an accelerating effect on union in stable scaphoid waist fractures."[(p1075)] Also, Hanneman et al[6] reported that "based on trials with substantial methodological quality, this study suggests that bone growth stimulation with PEMF or LIPUS decreases healing time to radiological union for acute fractures undergoing non-operative treatment and fractures of the upper limb."[(p1105)]

In conclusion, much valuable research has been conducted in the past 30 years on the use of physical stimulation of bone and cartilage, and it should be properly considered.[8]

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Effects of Pulsed Electromagnetic Fields After Debridement and Microfracture of Osteochondral Talar Defects: Response

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Authors' Response:

The hypothesis of our randomized, double-blind, placebo-controlled study was that the use of pulsed electromagnetic fields (PEMFs) after arthroscopic debridement and microfracture of an osteochondral defect (OCD) of the talus leads to earlier resumption of sports and an increased number of patients who resume sports. However, we concluded that PEMF does not lead to a higher percentage of patients who resume sports or to earlier resumption of sports after arthroscopic debridement and microfracture of talar OCDs.

Cadossi et al write in their letter that "although the results showed no difference between the treated and control groups in the number of patients who returned to sport 1 year after surgery, in Figure 3 of [Reilingh et al[5]], the 2 Kaplan-Meier curves are clearly not superimposed after the 20th week after surgery." Figure 3 in our original article displays the time to resumption of sports for the 2 arms of the trial. The curves are clearly superimposed until around 20 weeks and cross again around 52 weeks. This is in line with the P value of .69 presented and the conclusion that there was no difference between the groups. In addition, Cadossi et al appear to have performed Fisher exact tests on the proportion of patients who returned to sport for 9 time points, and in their graph they selectively report P values of $\leq .056$ for 3 time points. Our trial was not powered to examine 9 primary outcomes in this way. If Cadossi et al wish to analyze our data in this way, they should correct for multiple testing and consider using the individual time to sport resumption (eg, a log-rank test). Using Bonferroni correction for multiple testing would mean that only P values $<.0056$ (or .05/9) would be regarded as demonstrating a statistically significant difference between the 2 arms. As such, the P values presented by Cadossi et al do not support rejection of the null hypothesis that the 2 treatment arms are equivalent.

Furthermore, Cadossi et al suggest that the high return-to-sport rate observed in the placebo group might be explained by the unbalanced randomization of the defect location. However, defect location was not included in our stratification factors because defect location is not associated with clinical and radiological outcomes.[3,6]

Cadossi et al write, "In the Methods section, the authors reported that a clock inside the device was used to monitor the hours of stimulation. It is unusual to provide the information on hours of use as median and interquartile range because it leaves out relevant information on the 50% extremes of the entire population." It is common statistical practice to present nonnormally distributed continuous variables in terms of the median and interquartile range. This choice minimizes the influence of outlying points on the summary statistics. Summary statistics are supposed to describe the group of patients as a whole, rather than emphasize individuals.

Furthermore, the authors of the letter state that bone growth stimulation requires higher field values and longer daily exposure, as in our study we considered bone regeneration more important than cartilage regeneration. We therefore agree that the secondary outcome measure in bone repair might be worth further discussion. However, our pulse frequency and duration was based on different in vivo and clinical studies in OCD.[1,2,7]