Pulsed Electromagnetic Fields After Rotator Cuff Repair: A Randomized, Controlled Study

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abstract

The current study tested the hypothesis that the use of pulsed electromagnetic fields after rotator cuff repair is effective in the short term as an adjuvant treatment to reduce local inflammation, postoperative joint swelling, and recovery time, as well as to induce pain relief. Sixty-six patients who underwent shoulder arthroscopy for repair of small to medium rotator cuff tears were randomly divided into 2 groups with a block randomization procedure. Thirty-two patients underwent arthroscopic rotator cuff repair and application of pulsed electromagnetic fields postoperatively; 34 patients underwent rotator cuff repair and placebo treatment (placebo group). All patients had the same postoperative rehabilitation protocol. At 3 months from the index procedure, visual analog scale, range of motion, and University of California at Los Angeles and Constant scores were significantly better in the pulsed electromagnetic fields group than in the placebo group ($P<.05$). Three patients in the pulsed electromagnetic fields group and 7 patients in the placebo group had mild to moderate capsulitis ($P=.2$). Severe capsulitis occurred in 1 patient in the pulsed electromagnetic fields group and 2 patients in the placebo group ($P=.6$). At the last follow-up (minimum, 2 years), clinical and functional outcomes were further improved in both groups, with no significant intergroup differences. Application of pulsed electromagnetic fields after rotator cuff repair is safe and reduces postoperative pain, analgesic use, and stiffness in the short term. At 2 years, no difference was seen in outcomes in patients who did or did not undergo treatment with pulsed electromagnetic fields. [Orthopedics. 2015; 38(3):e223-e228.]

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Postoperative pain and inflammation are common after rotator cuff repair.\textsuperscript{1-4} To improve recovery time and reduce postoperative complications,\textsuperscript{5} platelet-rich plasma products have been used, but the effect is controversial.\textsuperscript{2} Microfractures at the footprint may favor healing and integration of the repaired rotator cuff tendon to the bone, with better short-term outcomes compared with arthroscopic repair alone.\textsuperscript{6} The goal of the current study was to assess the effect of pulsed electromagnetic fields after rotator cuff repair. Application of pulsed electromagnetic fields has been successfully used as an adjuvant to standard postoperative protocols after knee,\textsuperscript{7-9} ankle,\textsuperscript{10} and hip\textsuperscript{11} surgery to reduce local inflammation, postoperative joint swelling, and recovery time, as well as to provide pain relief. Pulsed electromagnetic fields are agonists of A2A adenosine receptors on neutrophils, chondrocytes, and synoviocytes.\textsuperscript{12,13} To the best of the authors’ knowledge, there is no clinical evidence of the application of pulsed electromagnetic fields after rotator cuff repair. The rationale for the use of this treatment is that it reduces local inflammation that predisposes patients to joint stiffness and limits the need for analgesic drugs that supposedly interfere with tendon healing. The current trial compared clinical and functional outcomes of 2 groups of patients undergoing arthroscopic rotator cuff repair. One group underwent arthroscopic rotator cuff repair followed by application of pulsed electromagnetic fields postoperatively; the other group underwent rotator cuff repair and placebo treatment.

**Materials and Methods**

The study included 66 patients who underwent arthroscopic repair of full-thickness rotator cuff tears between 2009 and 2010 after approval by the local ethics committee.

The main inclusion criterion for surgery was a diagnosis of rotator cuff tear on clinical examination and magnetic resonance imaging (MRI) scan in patients who did not respond to conservative management. Exclusion criteria were partial-thickness or irreparable full-thickness rotator cuff tears; extension of the tear to the subscapularis tendon; labral pathology amenable to surgical repair; shoulder stiffness; glenohumeral osteoarthritis; rotator cuff tear arthropathy; symptomatic osteoarthritis of the acromioclavicular joint; previous fractures and/or surgery on the same shoulder; congenital, acquired, inflammatory, or neurologic disease (systemic or local) involving the shoulder girdles; and cervical radiculopathy. Patients with cardiovascular pathology, psychiatric illness, or cerebrovascular disease, and those living more than 100 km from the clinic where the investigation was performed (to avoid loss to follow-up) were also excluded.

**Sample Size and Sample Features**

Sample size calculation was based on mean and standard deviation of University of California at Los Angeles (UCLA) scores observed in a pilot study of 18 patients in which the authors found a mean difference of 6 points and standard deviation of 3.3 points. Power analysis showed that a total sample size of 48 patients (24 patients in each group) would have provided a statistical power of 90% with a 2-sided level of .05 to detect significant differences.

The patient selection process is shown in the Figure. Ninety-eight patients underwent arthroscopic repair of full-thickness rotator cuff tears at the authors’ institution during the study period; 32 patients were excluded because they did not meet the inclusion criteria (27 patients) or because they declined to participate (5 patients). Sixty-six patients met the inclusion criteria and were randomly assigned to 1 of 2 groups, depending on whether they received treatment with pulsed electromagnetic fields postoperatively.

**Randomization and Blinding**

An investigator who was not involved in clinical management of the patients used a computer random number genera-
tor to determine group allocation, placing the results in sequentially numbered opaque envelopes. A research assistant who was not involved in clinical management of the patients performed group assignment after opening each envelope intraoperatively at the time of tendon repair. The investigator who assessed treatment outcomes was unaware of each patient’s treatment group. All procedures were designed to protect blinding for all study subjects and study investigators. Patients were shown their group assignment code only at the time of discharge from clinical follow-up.

All patients had small to medium rotator cuff tears. Thirty-two patients underwent arthroscopic rotator cuff repair and application of pulsed electromagnetic fields postoperatively; 34 patients underwent rotator cuff repair and placebo treatment (placebo group). All patients were assessed at the last follow-up. The 32 patients (20 men and 12 women) in the pulsed electromagnetic fields group underwent surgery at an average age of 62.3 years (range, 41-75 years) an average of 15 months from the onset of symptoms (range, 8-23 months). The 34 patients in the control group (21 men and 13 women) underwent surgery at an average age of 61.2 years (range, 39-73 years) after an average duration of symptoms of 14 months (range, 7-21 months).

Preoperative Assessment
The first author (L.O.) examined all patients preoperatively, including history, clinical examination, and MRI findings, and confirmed the diagnosis at arthroscopy in all cases. At the final assessment, at an average follow-up of 26 months for both groups, an orthopedic surgeon (A.D.) who was not involved in the original management and was blinded to the nature of the management, examined all of the patients. For all patients, UCLA, Constant-Murley, and visual analog scale (VAS) scores were obtained before surgery.

Surgical Technique
An interscalene block was performed in all patients. The beach chair position and 10-lb traction were used. Gravity irrigation was provided by 2.5-L water bags suspended at 8 feet. Tear size was measured from medial to lateral and from anterior to posterior, according to the classification by Boileau. Once the footprint was identified, it was prepared with a motorized shaver (Arthrex, Naples, Florida). A single-row repair was performed with 5-mm titanium anchors (Corkscrew; Arthrex). The anchors were inserted through an additional portal and placed at a 45° angle. The anchors contained double-loaded nonabsorbable sutures that were passed through the tendon with a suture passer device (Skorpion; Arthrex). The knots were tied (simple stitches) with a sliding knot. Tenotomy of the long head biceps was undertaken in 24 patients in the pulsed electromagnetic fields group and 25 patients in the control group. Three patients in each group underwent tenodesis of the long head biceps. Patients were instructed to use pulsed electromagnetic fields (I-ONE therapy; I-ONE; IGEA, Carpi, Italy) 6 to 8 hours daily for 6 weeks by an independent, unblinded research assistant who was not involved in patient care or assessment. Physicians and medical assessors were blinded to the allocation of patients in the study groups. All devices were provided by the manufacturer at no cost. Treatment began within 5 days of surgery and was administered at the patient’s home. The battery-operated device (I-ONE; IGEA) generated a peak magnetic field of 1.5 mT at a frequency of 75 Hz. The coil was placed on the treated shoulder and was not in direct contact with the skin. The apparatus had a timer to record the hours of therapy, allowing patient compliance to be monitored. Patients were instructed to interrupt the treatment if they experienced adverse events (eg, burning sensation, skin irritation). In the control group, the power switch of the apparatus was turned off. Both groups underwent the same rehabilitation protocol, starting with pendular exercises, elbow passive flexion-extension, and scapular motion exercises on the day after surgery, and all patients wore a sling for 4 weeks. Passive range of motion exercises were started 2 weeks after surgery and continued for 4 weeks. Active exercises were started at 6 weeks, and strengthening exercises were allowed a minimum of 3 months after surgery.

Follow-up
All patients were assessed 3 months and an average of 26 months after the index procedure (range, 24-55 months; SD, 8.3 months). In all cases, range of motion (ROM) was measured. Passive maximum forward flexion, abduction, external rotation, and internal rotation of the shoulder were recorded. Forward flexion less than 110°, external rotation less than 25°, and internal rotation below S2 were criteria for shoulder stiffness. Constant-Murley and UCLA scores were obtained for all patients. A Constant-Murley final score of 90 to 100 was considered excellent, a score of 89 to 80 was considered good, a score of 79 to 70 was considered fair, and a score of less than 70 was considered poor. A score of less than 80 was considered failure.

Statistical Analysis
After assessment of the distribution with the Kolmogorov-Smirnov test, the Mann-Whitney test was used to compare preoperative vs postoperative UCLA, Constant-Murley, and VAS values, and ROM. Independent sample t tests were used to compare postoperative UCLA, Constant-Murley, and VAS values, and ROM between groups. Mean, SD, and 95% confidence intervals were calculated. The chi-square test was used to analyze dichotomous variables (imaging findings, joint stiffness, use of analgesics, and return to sport activity). P<.05 was considered statistically significant. Data were analyzed with SPSS version 17.0 (SPSS, Inc, Chicago, Illinois).
RESULTS

Forward elevation and external and internal rotation were significantly improved at 3 months ($P<0.001$) compared with baseline in both groups. In addition, VAS, UCLA, and Constant-Murley scores were significantly improved compared with preoperative scores (Table). When the groups were compared, VAS ($P=0.03$), UCLA ($P=0.04$), and Constant-Murley ($P=0.02$) scores were significantly better in the pulsed electromagnetic fields group. In the first 6 weeks after surgery, 15% of patients in the pulsed electromagnetic fields group and 45% of patients in the placebo group used analgesics ($P=0.002$) (Table).

Mild to moderate capsulitis occurred in 3 patients in the pulsed electromagnetic fields group and 7 patients in the placebo group ($P=0.2$); severe capsulitis occurred in 1 patient in the pulsed electromagnetic fields group and 2 patients in the placebo group ($P=0.6$). All of these patients responded to physiotherapy without requiring manipulation under anesthesia or arthroscopic lysis of the adhesions. At the last follow-up, these patients fared well, without any difference compared with the other patients. At the same appointment, the patients were asked about return to activities of daily living. All patients were able to perform routine activities as before the onset of symptoms. In the pulsed electromagnetic fields group, 17 of 26 patients (67%) who performed manual labor returned to the same activities as before the onset of symptoms, without discomfort. In the control group, 16 of 25 (60%) who did manual work could work at the same level as before the onset of symptoms. No statistically significant intergroup difference was found ($P=0.85$). The remaining patients no longer performed manual labor because of residual pain and discomfort; however, they were involved in normal activities of daily living. Patients in the pulsed electromagnetic fields group returned to work and daily activities after an average of 3.4 months after surgery, and patients in the control group returned after an average of 5.3 months ($P<0.0001$).

DISCUSSION

The main finding of the current study was that application of pulsed electromagnetic fields after rotator cuff repair provided significantly better clinical and functional outcomes in the short term (at 5 months) than those in patients undergoing rotator cuff repair only. In addition, the use of pulsed electromagnetic fields reduced postoperative stiffness and the use of analgesics immediately after surgery. Clinical and functional findings were comparable between the 2 groups at a minimum follow-up of 2 years after surgery. The use of pulsed electromagnetic fields allowed patients an earlier return to manual labor, but the percentage of patients who returned to manual labor at 2 years was comparable in the 2 groups. The rationale for using pulsed electromagnetic fields arises from both basic science and clinical evidence. Application of pulsed electromagnetic fields reduces inflammation and improves postoperative recovery. Three randomized, prospective, and double-blind studies have been performed on patients undergoing arthroscopic procedures to the knee. These studies included patients with microfractures for severe cartilage lesions, anterior cruciate ligament reconstruction, and knee replacement. The evidence supported the finding that application of pulsed electromagnetic fields reduces inflammation, joint swelling, and use of nonsteroidal anti-inflammatory drugs; improves pain control; and accelerates recovery. In vitro, this treatment stimulates chondrocytes, osteoblasts, and tenocytes by reducing the pattern of inflammatory cytokines. The mechanism of action of pulsed electromagnetic fields is the agonist effect on A2A adenosine receptors, which are anti-inflammatory modulators that reduce the concentration of interleukin-1ß, tumor necrosis factor-alpha, tumor necrosis factor-beta, and proinflammatory cytokines (interleukin-6 and interleukin-8) within the synovial fluid.
Although nonsteroidal anti-inflammatory drugs are widely used for pain control and to reduce postoperative inflammation, they may be detrimental to tendon repair and healing. Therefore, treatment with pulsed electromagnetic fields can be used to control and manage inflammation and related pain. However, the authors now prescribe analgesic drugs, such as paracetamol and codeine derivatives, immediately after surgery. Improved pain control and lower levels of inflammatory cytokines may account for the better short-term outcomes 3 months after the application of pulsed electromagnetic fields. Improved range of motion and reduced inflammation would explain the lower occurrence of postoperative stiffness. Pain and inflammation may predispose patients to postoperative joint stiffness, the incidence of which is unclear. Shoulder stiffness is common after rotator cuff repair, probably because of postoperative inflammation that may induce capsulitis. Increased levels of inflammatory cytokines have been found in stiff shoulders after rotator cuff repair. There is evidence that treatment with pulsed electromagnetic fields consistently reduces these levels. Increased osteoblastic activity after the application of pulsed electromagnetic fields would decrease bone resorption at the footprint, which theoretically could occur after postoperative immobilization.

This study showed that application of pulsed electromagnetic fields after rotator cuff repair significantly improves short-term UCLA, Constant-Murley, and VAS scores compared with arthroscopic repair only. However, outcomes in the 2 groups were comparable at 2 years. Specifically, 17 of 26 patients (65.4%) in the pulsed electromagnetic fields group and 16 of 25 patients (64%) in the placebo group returned to manual labor as they did before the onset of symptoms, without discomfort. The difference was not statistically significant (P=.85).

Limitations
The main limitation of the current study is that clinical outcomes were not assessed immediately after surgery. In addition, patients did not undergo MRI assessment. Also, the authors did not conduct an economic analysis of the use of this treatment. In the long term, there was no difference between the 2 groups of patients. However, some patients may need or prefer faster postoperative rehabilitation. In clinical practice, when obtaining informed consent and explaining the postoperative process to patients, the authors point out that the use of pulsed electromagnetic fields is beneficial only in the short term, and patients are free to choose whether to use this treatment.

This study had several strengths. It was a randomized, controlled study, and no patients were lost to follow-up. One experienced fellowship-trained shoulder surgeon performed all of the surgical procedures, and an independent investigator who was not involved in the index surgery examined the patients at follow-up. The study included only patients with small to medium rotator cuff tears so that the cuff could be repaired without excessive tension. In addition, in all cases, the authors verified that the tendon could be pulled over the footprint to provide adequate coverage.

CONCLUSION
Application of pulsed electromagnetic fields after rotator cuff repair is safe and reduces postoperative pain, use of analgesics, and stiffness in the short term. At 2 years, there was no difference in outcome in patients who did or did not undergo treatment with pulsed electromagnetic fields.

REFERENCES


