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The use of an alternating magnetic field in the resorption of postoperative joint effusion following anterior cruciate ligament reconstruction

A randomized double-blind controlled trial

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Abstract

Context There are no scientific reports unambiguously describing the efficacy of alternating magnetic field therapy in patients after anterior cruciate ligament (ACL) reconstruction in the early postoperative period.

Objective This study aims to evaluate the efficacy of using an alternating magnetic field in the resorption of postoperative joint effusion in patients after ACL reconstruction.

Study design A randomized, double-blind placebo-controlled study.

Setting Inpatients.

Participants Forty patients were enrolled in the trial. However, the final study group consisted of 38 patients (28 men and 10 women) after ACL reconstruction who were randomly divided into an experimental group (19 patients) and a control group (19 patients).

Intervention Each group received magnetic field therapy in the postoperative period, but only 1 apparatus emitted a magnetic field (the experimental group). Patients used the apparatus every day for 30 minutes for the next 11 days. The parameters in both devices were the same—3 mT and 10 Hz.

Main outcome measures The measurement of the knee circumference and range of motion were made. The knee circumference measurement was performed before magnetic field therapy began and for 11 days after magnetic field treatment. The active knee range of motion was evaluated before and after magnetic field therapy was completed.

Results There were no statistically significant differences between the groups in the reduction of post-operative joint effusion or knee joint function.

Conclusion In patients after ACL reconstruction, in whom an alternating magnetic field was used to treat postoperative joint effusion, there were no beneficial effects on the analyzed variables compared to the control group.

Abbreviations: ACL = anterior cruciate ligament, ACLr = ACL reconstruction, AROM = active range of motion.

Keywords: ACL, joint effusion, physical therapy, physical therapy modalities, rehabilitation

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1. Introduction

One of the main components in the management of patients after anterior cruciate ligament (ACL) reconstruction (ACLr) is postoperative rehabilitation. In recent literature, there are gold standards of physiotherapy on which rehabilitation protocols are based. The literature states that it is not recommended to accelerate the rehabilitation process after ACLr or use continuous passive motion. Early knee mobilization and full weight-bearing exercises are recommended. The authors of numerous publications also advise against using a postoperative knee brace. Early open and closed kinetic chain exercises, cryotherapy, and neuromuscular electrostimulation may be used according to the individual circumstances, whereas strength/neuromuscular training should be used in the early postoperative period.[1–6] Postoperative activities are aimed at providing the patient with appropriate conditions for the regenerative process. An important aspect is to include phases of treatment in the rehabilitation, which play a role in the process of systemic adaptation of tissues to the new ligament system. The first stage of the postoperative rehabilitation includes the reduction of joint effusion and pain because they regularly occur after ACLr.[7,8]

Joint effusion, commonly referred to as water on the knee or fluid on the knee, is the abnormal accumulation of fluid in or around a joint. It is most commonly caused by infection, injury, arthritis or surgery. Knee homeostasis after injury and surgery is crucial for rehabilitation and knee well-being.[9] One of the possibilities in the treatment of postoperative joint effusion is joint cooling.[10,11] It is also possible to use magnetic field therapy to minimize postoperative inflammation.[12] Proposed physiological benefits of an alternating magnetic field include stimulation of blood microcirculation in the skin, faster decrease in lactic acid in the peripheral blood plasma, increase in the absorption of oxygen by tissues, reduction of oxygen debt, acceleration of connective tissue development, and support of the scarring process. A magnetic field also affects the cell membrane structures, and thus it transforms their properties and stimulates enzymatic reactions. A magnetic field may change the pH of the water in the body, the rate of crystallization and the concentration of dissolved gases in it, for example, oxygen, which changes its chemical properties to microbicidal ones. Increased oxygen absorption at the subcellular level stimulates adenosine triphosphate synthesis and activates the mechanisms responsible for secondary regeneration. Dynamic diffusion and increased oxygen absorption by hemoglobin and cytochromes reduce the time needed to regenerate tissues and metabolic processes several times. The therapeutic effects include reducing postoperative joint effusion, faster postoperative wound healing, immunostimulatory action, and microcirculation improvement.[13] According to the research presented in the literature, the magnetic field does not cause a heating effect in the tissues and thus is not directly felt by patients. Increased field intensity, however, may cause vibration and tingling sensation. However, no significant side effects of the therapeutic use of magnetic field were noted.[14–16]

Most studies do not include the treatment of joint effusion and swelling in the joints after ACLr. These 2 symptoms cause pain, limit the range of motion, and play a significant role in rehabilitation after ACLr. Treatment of joint effusion and edema should be included in all types of rehabilitation plans.[17]

Therefore, given the therapeutic and biological effects of magnetic field on reducing postoperative joint effusion, a significant improvement in knee joint function after ACLr in the early postoperative period should be expected. However, is this really so?

To date, to the best of our knowledge, there are no scientific reports unambiguously describing the efficacy of alternating magnetic field therapy in patients after ACLr in the early postoperative period. This study aims to evaluate the efficiency of using the alternating magnetic field in the resorption of postoperative joint effusion in patients after ACLr.

2. Methods

2.1. Design

It was a randomized double-blind and placebo-controlled study. The study was conducted following the Consolidated Standards of Reporting Trials (CONSORT).[18]

The first stage of the clinical trial concerned qualifying patients for ACLr, which was done by an attending physician (all patients were operated on by one orthopedic surgeon).

Forty patients from the Trauma and Orthopedics Clinical Department of the University Hospital participated in the study and underwent ACLr. The patients were qualified for the study by an independent researcher using the sealed envelopes method. The study was conducted at the turn of 2019 at the Faculty of Motor Rehabilitation of the University of Physical Education in Kraków with the collaboration of the Trauma and Orthopedics Clinical Department of the University Hospital.

The results presented in this article are part of a larger research project conducted by the authors.

Eligibility criteria:

- complete isolated ACL tear confirmed by imaging examination (CT);
- reconstruction technique specified by an attending physician – ACLr using the autogenous method—semitendinosus tendon graft;
- no injury to the posterior cruciate ligament confirmed by imaging and clinical research performed by an orthopedist: CT;
- the ability to walk independently without crutches;
- no other injuries and medical conditions that may affect the trial results (eg, meniscus injuries, cartilage injury, degenerative changes in the lower extremity joints);
- voluntary written consent of the patient to participate in the trial.

Exclusion criteria:

- absences from procedures to be performed;
- interruption of the graft continuum;
- lower-extremity venous thrombosis;
- infections—skin injuries, including injuries to tissues located more deeply;
- other situations and medical conditions that exclude the patient from continuing therapy.

The average time between the injury and the surgery was 4 months, standard deviation = 2.4 (the patients were not operated directly after the injury due to posttraumatic inflammation and sustained increased muscle tone).

2.2. Randomization and masking

In terms of postoperative therapy, the second stage of the clinical trials involved dividing the patients into 2 groups and assigning

an apparatus emitting a magnetic field to each of them randomly (the apparatus assignment was based on simple randomization using a coin toss: obverse—apparatus A, reverse—apparatus B). Neither the patient nor the persons performing the clinical trials knew which apparatus emitted a magnetic field. The placebo apparatus was modified by the manufacturer so that it was impossible to deduce whether the apparatus emits a magnetic field or not.

The apparatus (Magneris, Astar, Poland) emitting an alternating magnetic field was apparatus A (experimental group); apparatus B was a placebo (control group). Information about which apparatus emitted the magnetic field was not obtained from the manufacturer until after completing the trials. Before the study started, the placebo device was set by the manufacturer so that both researchers and patients would not know which device emitted the magnetic field (there was no difference in the sound of the device running). Therefore, each time the magnetic field parameters were set on each of the devices. After completing the research, the manufacturer revealed which apparatus was a placebo.

2.3. Intervention

From the first to the eleventh day after ACLr (early postoperative period),[19] each patient was given magnetic field treatment by a therapist. In accordance with physiological healing factors, joint effusion is expected to peak on day three.[20] The magnetic field was used during the hospital stay. The magnet therapy was performed on a daily basis at regular hours (around noon) by the same therapist. The patients used the apparatus for 30 minutes, and the magnetic field parameters in both apparatuses were the same—3 mT and 10 Hz. The parameters were selected following the methodology of the procedure provided by Straburzyński and Straburzyńska-Lupa, which assumes that acute and subacute doses range from 1 to 20 Hz and 1 to 5 mT depending on the patient's ailments.[21] None of the patients reported side effects after using the magnetic field.

During the use of the magnetic field, patients from both groups were given physician's instructions which they followed for 10 days: the knee blocked in the orthosis in full extension, the joint cooled with ice cubes (twice a day for 15 minutes), weight-bearing as tolerated and quadriceps contraction. Postoperative restrictions were put in place to protect the repaired ligament.

2.4. Ethical approval

The research project was approved by the Bioethics Committee at the Regional Medical Chamber, approval No. 19/KBL/OIL/2014.

This study was registered in the Australian New Zealand Clinical Trials Registry. Trial registration number: ACTRN12619001025123.

2.5. Outcome measures

The evaluation of magnetic field efficiency in the treatment of patients after ACLr included a function test: knee circumference measurement and measurement of the knee ROM (*primary outcome)*.

The third stage of clinical trials involved function tests that included measuring the knee circumference and the active range of motion (AROM).

The first knee circumference measurement was performed before magnetic field therapy began and then for 11 days, each time after magnetic field treatment. The knee AROM was evaluated twice—before and after magnetic field therapy was completed.

Various techniques may be used to assess leg edema. The value of these investigations was discussed in the consensus statement made in Vaux de Cernay in 1997 and supported by the Servier Research Group. The most simple technique is leg circumference measurement, which can be made with a tape measure. This device is a cheap and reproducible validated method; it considers the height at which the circumference is measured. Measurements established sufficiently high reliability to justify their use in assessing joint effusion.[22,23]

The knee circumference measurement was done at the kneecap level.[24]

Initially, the project also assumed the femoral circumference measurement, but due to a misinterpretation of the joint effusion and atrophy of the quadriceps, this measurement was abandoned.

The knee AROM was measured with a goniometer in the sagittal plane (flexion and extension) in a supine position by the physiotherapist (first author).[25]

The intervention was supervised by a physiotherapist (first author) who assessed whether the research was consistent with the methodology.

2.6. Statistical analysis

The statistical analysis was performed using Statistica 10 software (StatSoft). Descriptive statistics methods were used to show results in tables containing arithmetic means, standard deviations, minimum and maximum. The total sample size was estimated through a priori power analysis. The analysis was carried out using G*Power V 3.1.3 (Franz Faul, Universität Kiel, Germany) with power = 0.8, effect size f = 0.25, and $\alpha = 0.05$. The second stage of the analysis concerned evaluating the distribution of observed values of knee circumferences using the Shapiro-Wilk test. Subsequently, the observed values were checked for equality of variance. For this purpose, the Fisher-Snedecor F-test was used. The tests performed did not give rise to the conclusion that the distribution of parameters is different from normal and that the variances in both groups are not equal ($P > .05$). To compare the distribution of variables between individual groups of the lower limb circumference measurements in subsequent days, the *t* Student test for independent samples was used. In order to determine the changes in the size of joint effusion within a given group over time, an analysis of the variances for dependent groups (repeated measurements) was also conducted using post-hoc tests (Tukey test). The statistical significance of $P < .05$ was set.

3. Results

In total, 40 patients with a complete isolated ACL tear and after ACLr were enrolled in the trial, of whom 38 met the inclusion criteria and underwent the first trial (**28 men and 10 women**). After the procedure, a random allocation to group A (experimental group) or B (control group) was made. Finally, the research material consisted of two groups, each with 19 patients aged 18 to 40. The characteristics of the groups are presented in Table 1. Figure 1 shows the qualification process for clinical trials.

The knee circumference measurement analysis showed no statistically significant differences between group A and B on none of the 11 research days (Table 2).

Table 1

Anthropometric data of the studied group of patients.

	A		B		
Variable	**x ± SD, y**	**Min–Max**	**x ± SD, y**	**Min–Max**	***P***
Age	28.2 ± 8.1	18–40	27.4 ± 7.8	19-39	0.369
Height, cm	174.6 ± 8.4	165.5-193	172.8 ± 7.6	161.5-191	0.234
BMI	24.7 ± 3.4	16.2-31.5	25.3 ± 3.4	15.1-32.1	0.252
Male/female	15:4	13:6			

A = experimental group, **B** = control group, BMI = body mass index, SD = standard deviation; ***P*** < .05.

Table 3 shows the mean values of the knee circumference observed on the baseline and 11th day in group A and B. The obtained results indicate that the size of joint effusion in patients in both groups significantly decreased; yet, the differences between days in both group A and group B are the same and amount to 1.7 cm (Table 3).

In Table 4, the mean values of knee AROM observed on the baseline and 11th day of the therapy in a given group and between the groups are presented.

The analysis of mean values of the AROM ratio on the baseline day proved to be significantly lower than that observed on the 11th day in both group A and group B.

However, no statistically significant differences regarding the AROM ratio between the groups were found (Tables 4 and 5).

4. Discussion

Analysis of the available literature indicated that there is no information regarding the effectiveness of alternating magnetic field in joint effusion following ACLr. So far, no studies have been conducted to assess the effectiveness of applying a magnetic field in the early postoperative period after ACLr. Therefore, this study aimed to evaluate the efficiency of using an alternating magnetic field in the resorption of postoperative joint effusion in patients after ACLr. The presented research focuses on evaluating knee function before and after applying an alternating magnetic field in the early postoperative period after the ACLr. The analysis covered changes in the knee circumference as well as the knee ROM in patients ACLr. The measurement of the lower limb circumference was performed on a daily basis for 11 successive days, while the AROM was measured before and after the

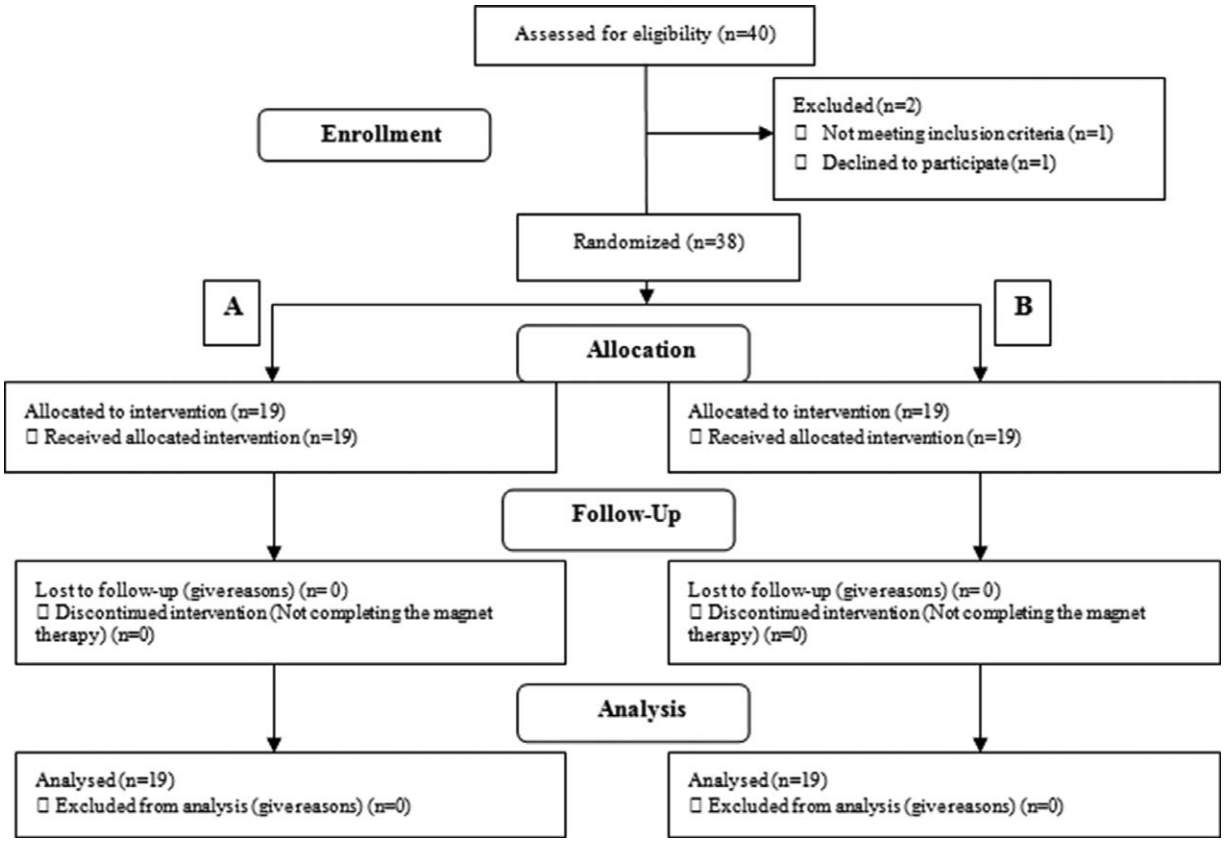

Figure 1. Flow diagram.

Table 2

Comparison of knee circumference measurement results in subsequent days of the therapy between the groups.

Day	A	B	P
	X±SD, cm	X±SD, cm	
Baseline	42.7±3.1	41.5±1.9	.323
2	42.7±3.1	41.3±1.9	.252
3	42.5±3.0	41.0±1.7	.199
4	42.1±3.0	40.9±1.7	.281
5	41.8±3.1	40.6±1.9	.347
6	41.8±2.9	40.6±1.7	.269
7	41.7±3.0	40.5±1.7	.282
8	41.6±2.9	40.3±1.7	.282
9	41.5±2.9	40.0±1.4	.159
10	41.2±2.9	40.1±1.4	.282
11	41.0±2.9	39.8±1.5	.273

A = experimental group, **B** = control group, **Baseline** = the first day after ACLr of magnetic field therapy, SD = standard deviation; ***P*** > .05.

therapy with the magnetic field. The results indicate that alternating magnetic field therapy did not significantly affect the knee circumference and AROM. Postoperative joint effusion decreased significantly in both the experimental and control group. It means that regardless of the magnetic field use, postoperative joint effusion gradually disappears, indirectly translating into an increase in the knee joint's AROM.

Despite its low invasiveness, ACLr is a serious surgical procedure that causes an inflammatory reaction in the joint.[26] Magnetic field therapy is one of the therapies speculated to have a significant impact on anti-inflammatory and anti-joint effusion due to its broad biological effects.

According to Głąb et al,[13] many authors confirm the effectiveness of magnetic field applications in various medical conditions, but there are significant variations in the prescribed dosage. Zorzi et al[27] confirmed the effectiveness of a magnetic field in patients after knee arthroscopy. The study results showed an improvement in the knee function both 90 days and three years after arthroscopy, and the effect was most likely due to better control of inflammation. No differences were found between the research and control groups in patients with osteoarthritis of the knee joints during physiotherapy using a magnetic field.[28–30] Although Ganesan et al[31] stated that a magnetic field has not only analgesic but also anti-inflammatory properties. A meta-analysis conducted by Ganesan et al[31] suggests using a magnetic field as a complementary treatment in comprehensive therapy of knee osteoarthritis, mainly in improving joint function; however, they indicate a weak analgesic effect. The above results were also confirmed by McCarthy et al.[32]

In our study, an improvement in the knee joint function, assessed by changes in the AROM and knee joint circumference, was noted in both groups, which means that the effectiveness of the magnetic field on joint effusion response was negligible. None of the cited studies evaluates the early postoperative period; they only indicate the long-term results and magnetic field influence on the selected parameters.

An alternating magnetic field is also proven to affect degenerative changes of articular cartilage and regulate the synthesis and release of post-inflammatory cytokines in the synovial fluid. These processes confirm that an alternating magnetic field is effective in controlling inflammation and, consequently, joint effusions.[33] This does not coincide with our research results; however, it should be remembered that the etiology and treatment process of degenerative changes are completely different from the therapy after ACLr. Researchers at the Indian Institute of Technology in Roorkee analyzed the effect of an alternating magnetic field on blood in an isolated system with synthetic cannulas to check the dynamics of biological fluids and their behavior during the emission of a magnetic field. The fluid was tested with different pressure gradients using a homogeneous magnetic field applied perpendicularly to the cylindrical tube. The magnetic field ranged from 100 mT to 600 mT in various tests. The results indicate that the speed of blood molecules decreased significantly due to the magnetic field action.[26] With reference to the study by Pasek et al,[34] the therapeutic effect of a magnetic field depends on, among others: frequency, field shape, duration of the procedure, and treatment, and partially on tissue hydration and the size of magnetic field induction. Therefore, the final result of treatment with a magnetic field depends on various parameters.[35,36]

Previous studies also touch on the effectiveness of a magnetic field in pain reduction or regeneration of soft tissue following injuries to the locomotor system and mainly concern patients with degenerative knee joint changes.[37–40] Conducting their study on the long-term effect of a magnetic field in doses of 35 mT in patients with degenerative knee joints changes, Chen et al[41] revealed pain reduction but did not achieve joint effusion reduction.

One group of patients receiving therapy that commonly involves a magnetic field consists of patients after ACLr. As far as these patients are concerned, however, a magnetic field is most

Table 3

Comparison of the measurement results of the knee circumference on the baseline and 11th day of the therapy in a given group.

Group	Baseline	11	X difference (95% CI)	P
	X±SD, cm	X±SD, cm		
A	42.7±3.1	41.0±2.9	−1.7 (1.01 to 3.01)	.008
B	41.5±1.9	39.8±1.5	−1.7 (1.15 to 2.35)	.008

A = experimental group; **B** = control group, **Baseline** = the first day after ACLr of magnetic field therapy, **11**– the last day of magnetic field therapy, CI = confidence interval, SD = standard deviation.

Table 4

Comparison of the measurement results of the range of motion flexion on the baseline and 11th day of the therapy in a given group.

Group	X±SD, degree	X±SD, degree	P
	Baseline	11	
A	70.4±40.1	130.0±10.9	.001
B	77.4±32.9	132.0±3.8	.002

A = experimental group, **B** = control group, SD = standard deviation.

Table 5

Comparison of the measurement results of the range of motion flexion on the baseline and 11th day of the therapy in between the groups.

Group	X±SD, degree	X±SD, degree	P
	A	B	
Baseline	70.4	77.4	.666
11	130.0	132.0	.858

A = experimental group, **B** = control group, SD = standard deviation.

often used during rehabilitation spanning several months in addition to exercises. Nevertheless, there is no research describing the effectiveness of a magnetic field in treating early postoperative joint effusion in patients after ACLr. Therefore, the conducted research is a significant contribution to broadening the knowledge about the effectiveness and usefulness of an alternating magnetic field in the early postoperative period. It allows us to conclude that using a magnetic field for the resorption of joint effusion after ACLr does not bring the desired results.

This study is not without limitations. An important aspect that could affect trial results is determining the level of the patients' physical activity. Another limitation of the conducted research was the small number of comparable studies. This is the first study assessing the effectiveness of an alternating magnetic field among patients after ACLr. This fact impeded the discussions on the data but at the same time reflected the unique design of the study.

If we look at the results, there is a tendency toward less joint effusion. Such minor differences between the groups may result from too short therapies or too low doses. Both the dose and duration of the procedure were selected following the recommendations found in the literature regarding the use of the magnetic field in acute and subacute conditions (ie, postoperative conditions). Therefore, it is possible that these values were too low for patients after ACLr. In the future, the effect of the alternating magnetic field should be checked on a similar group of patients but with a stronger dose and longer duration of the magnetic field therapy.

The conducted trial may be the basis for further consideration of the effectiveness of an alternating magnetic field in the treatment of patients with injuries to the locomotor system, especially since there are no reports based on reliable scientific research that would explicitly determine the usefulness of a magnetic field in the treatment of postoperative joint effusion.

5. Conclusions

In patients after ACLr, in whom an alternating magnetic field was used to treat postoperative joint effusion, there were no beneficial effects on the analyzed variables compared to the control group. There were no statistically significant differences between the experimental and control groups in terms of knee joint function.

6. Application form

The application of an alternating magnetic field in the resorption of postoperative joint effusion does not bring improvement in patient outcomes. The use of an alternating magnetic field in the therapy of patients after ACLr does not improve postoperative treatment effectiveness.

Author contributions

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