Application of the Low Frequency and Low-Intensity Electrostatic Field in Rehabilitation Programs for Patients with Musculoskeletal Disorders

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Chapter

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Galina Mratskova

Abstract

A low-frequency and low-intensity pulsed electrostatic field is applied as a treatment method in Rehabilitation Medicine. The technique is known as Deep Oscillation® therapy. At present, it has been established that the therapeutic effects of the electrostatic field on the tissues depend on the field frequency (5–250 Hz). The advantage of the method is the operation with a low amperage of 5–7 μA and a bipolar form of the wave. Deep Oscillation® was originally created to improve tissue lymphatic drainage. Subsequently, it was found that it reduces acute and chronic pain, improves blood and lymph circulation in the region of application, and reduces edema and fibrosis. In addition to this, tissue elasticity, joint mobility, and the condition of muscle and nerve tissue are improved. The aim of this research project is to investigate the therapeutic impact of a low-frequency and low-intensity pulsed electrostatic field in patients with symptomatic knee osteoarthritis.

Keywords: low-frequency and low-intensity pulsed electrostatic field, Deep Oscillation® therapy, symptomatic knee osteoarthritis, rehabilitation, pain, edema, range of motion, functional activity

1. Introduction

The therapeutic impact of the Deep Oscillation® modality has been applied in Physical and Rehabilitation Medicine recently. This method uses Low-frequency and Low-intensity electrostatic field, which causes a gently acting vibration (oscillation) deep in the tissues. This electrostatic phenomenon is explained through the Johnson-Rahbeck effect. In this phenomenon, there is a dependence between the applied voltage and the force of attraction and relaxation between the contact materials (metal surface and semiconductor material) when an electric potential is applied

at the boundary between them [1]. For the needs of physical therapy, an electrostatic field is created that impacts the tissues (skin, muscles, blood and lymphatic vessels, nervous structures, and connective tissue) that are located below the source creating oscillation [2–4].

The first medical device using a Low-frequency and Low-intensity electrostatic field was developed by H. Seidel и W. Waldner at the end of the twentieth century [4]. Deep Oscillation® therapy is a patent-enhanced practical therapy method that works on the basis of the pulsed electrostatic field of low intensity (U = 100–400 V; I = 150 μA) [2] and low frequency (5–250 Hz). As a result of its application on the surface of the skin in the depth of the application area, a vibration (oscillation) is formed in the underlying biological tissues [2, 3, 5–7].

1.1 Deep Oscillation® therapy - Characteristic of low frequency and low intensity electrostatic field treatment

The following therapeutic effects have been reported from clinical studies conducted up to date:

- Reduction of pain (acute or chronic) in various clinically manifested diseases [2, 5, 6, 8–17];
- Anti-inflammatory effect [18, 19];
- Affects lymphedema with primary or secondary genesis [2, 5, 20–23];
- Reduces and modulates the process of tissue fibrosis [24, 25];
- Leads to reduction of increased muscle tone and relaxation, mobilizes fascial tissue, and increases reduced range of motion in joints [2, 8, 9, 26–28];
- Improves and accelerates the tissue recovery process in wound defects [12, 29];
- It improves the process of recovery after a training cycle, decongestion, and leads to improvement of the function of the respiratory system in obstructive lung diseases [12, 30–32].

The therapeutic effect of Deep Oscillation® is based on the pulsating electrostatic field of very low frequency and low intensity, an electromagnetic field in which no thermal effect is observed [7, 10, 33]. The mechanism of physiological action is carried out in the formation of tissue vibration to a depth of 8 cm (skin, subcutaneous tissue, connective tissue, neuromuscular apparatus, blood, and lymph vessels), which are located in the area under the applicator during its movement in the sagittal plane [7].

The frequency of the electrostatic field is low and varies from 5 to 250 Hz. The established physiological effects are directly dependent and determined by the applied frequency. At a frequency in the range of 80–250 Hz, an analgesic, spasm-reducing, and anti-edematous effect is observed; the frequency in the range between 25 and 80 Hz leads to the improvement of the metabolism and recovery processes in the tissues, the venous and lymphatic circulation is optimized; frequency in the range of 5–25 Hz can improve local hemodynamics, the functional status of muscle tissue,

and tissue trophicity. For the needs of practice, a small current amperage (5–7 μA) is used. The pulses have a biphasic form, and the usual electrotherapy effects of electrolysis are not observed. The electrostatic field is discharged during each pause, which protects the patient's body from the accumulation of static electricity [7, 10].

There are two main methods of practical application of Deep Oscillation® therapy. One method uses a handheld applicator (oscillating head) with a different size in diameter depending on the area of the field being treated. In the other application method, the therapist's hands are connected to the oscillation device and simultaneously placed in vinyl gloves. The therapist performs the basic massage techniques, which allows to combine the effect of the electrostatic field with massage. In this second method, the electrostatic field affects both the therapist and the patient at the same time, which implies that the rules of contraindications must be strictly observed for both at the same time. The therapeutic course includes between 5 and 15 procedures, which can be carried out every day or every other day. Deep Oscillation® can be conducted in combination with therapeutic exercises, cryo or heat therapy, as well as other physical modalities (electrotherapy). To achieve a better effect, it is recommended to sequentially apply combinations of different modalities with different durations depending on the phase of the disease in one procedure.

Deep Oscillation® therapy can be a suitable therapeutic alternative for various diseases including:

- Traumatic, degenerative, and inflammatory diseases of the musculoskeletal system [10, 34–39];
- In the recovery period: after bone fracture, after surgical interventions on different occasions, and after osteotomy, metal osteosynthesis, joint replacement, to prevent the appearance of decubitus wounds and the formation of rough cicatricial tissue [15, 19, 40–42];
- In some diseases of the nervous system of peripheral origin (dorsopathies, etc.) [33];
- After pathological damage of central nervous origin (damage to the brain and spinal cord as a result of vascular or post-traumatic damage to the brain and spinal cord, Parkinson's disease, multiple sclerosis, and migraine [7, 43–45];
- In cardiovascular diseases (hypertension, chronic diseases occurring with insufficiency of the venous and lymphatic systems, lymphedema, etc.) [2, 7, 21];
- In pathology of the respiratory system, which includes inflammatory diseases (chronic bronchitis, pneumonia), bronchial asthma, COPD, and cystic fibrosis [32];
- In some diseases of the digestive tract (chronic gastritis or gastro duodenitis), diseases with disturbed motility of the bile ducts; in inflammatory diseases of the upper respiratory tract–chronic sinusitis, laryngitis [7];
- After extracorporeal lithotripsy in renal calculus, chronic nonbacterial prostatitis [7];
- For the treatment of wounds of various origins and burns [7, 29].

Deep Oscillation® therapy provides a number of advantages, which makes it a preferred physiotherapeutic method for acute and chronic diseases, both of the musculoskeletal system that cause pain, and for diseases of the central and peripheral nervous system, after acute, chronic, and sports injuries, for the prevention of thrombotic phenomena. The inclusion of the intervention with Deep Oscillation® shortens the time of hospital treatment, reduces the period required for recovery, improves lymphatic and venous circulation, and has a lymphatic drainage effect, which is a consequence of the gentle impact on the target tissues. The therapy leads to relaxation of the muscles that have increased tone. Treatment with the Deep Oscillation® device is pleasant for the patient and comfortable and easy for therapists to use. Despite the many benefits and few side effects, with Deep Oscillation® therapy, it is necessary to monitor for manifestations of a sense of sharp pain in the area of application, increased sensitivity during urination, symptoms of fatigue and/or exhaustion, increased local temperature, and signs of hypotension [10].

1.2 Characteristics of knee osteoarthritis

Osteoarthritis (OA) is a disease of the musculoskeletal system with a widespread occurrence worldwide. It can affect any of the upper/lower limb and axial skeleton joints, but degenerative changes are most common in the weight-bearing joints of the lower limbs with the knee joint (KJ) being most affected [46]. The disease is linked to a negative impact and increased economic burden, both on the part of patients suffering from OA and on the part of society, due to increased treatment costs and reduced work capacity [47]. Knee OA has the highest proportion (over 80%) in the distribution of disease burden. According to US research data, approximately 19% of the population over 45 years of age exhibit clinical symptoms of OA [48–51].

Osteoarthritis is typically more prevalent after the sixth decade, in individuals 65 years of age and older [50, 52, 53]. The disease impairs the joint structurally, including destruction and reduction of cartilage tissue, which is demonstrated by limitations in functional activity [54]. Routine radiological images show a narrowed interarticular gap and subchondral bone changes, with gradual appearance of osteophytes. In practice, however, joint pain sensations are often poorly correlated with the changes seen in joint structure [55]. Knee pain is not reported by a significant proportion of patients whose imaging studies demonstrate the presence of OA [56, 57].

Symptomatic OA is thought to be preceded by a prolonged preclinical phase characterized by the appearance and development of structural changes in the joint without the presence of clinical symptoms and subjective complaints. Not only changes in the subchondral bone and articular cartilage but also changes in the muscles around the joint are essential. Muscle weakness is one of the earliest and most common symptoms in patients with knee osteoarthritis and is considered a better predictor of joint narrowing and pain [55, 58]. Decreased functional activity and disability have a significant impact on the psychosocial status of both patients and their families [59, 60]. In recent years, the severity of musculoskeletal diseases has increased Wallace et al. [51] believe that the prevalence of knee OA is 2.1 times higher in postindustrial society than in the early industrialization era [51]. There is a global trend of increasing life expectancy, which suggests that the need for health care for these patients will increase. Until recently, population aging and high body mass index were considered to be major factors in the prevalence of OA [51], but the role of other factors is likely to need to be assessed.

According to some investigators, symptomatic osteoarthritis of the knee with clinical symptoms is present in only about 15% of those affected with radiological evidence of OA [53, 61]. This is probably due to the slow evolution of the disease, which is preceded by a prolonged asymptomatic phase during which, in the absence of clinical symptoms and history complaints, degenerative changes slowly progress. The changes affect not only the subchondral part of the bone and the cartilage plate but also the joint motor muscles. One of the first signs commonly seen in knee OA is weakness of the surrounding joint musculature, and it is even considered to be a better prognostic sign than a decrease in joint space dimensions and pain sensation [55, 58]. The pathological changes occurring in the OA joint lead to increased psycho-emotional strain in patients and their families due to decreased functional activity and associated negative effects [59, 60]. In relation to the increase in degenerative musculoskeletal diseases and their burden in modern society, Wallace et al. [51] assumed that the prevalence of knee osteoarthritis is twice as high today compared to the early industrialization period [51]. According to objective data, life expectancy is increasing in countries around the world, which in turn will lead to increased demand for healthcare services. On the other hand, a reassessment of the major risk factors and their role in the prevalence of OA will probably have to be made, although today, the increase in the elderly population and the high body mass index are considered to be the main ones [51].

Recurrent inflammatory responses derived from excessive mechanical loading of the joints [62, 63], abnormal weight gain, gender, hormone levels, age, and possible past trauma have a direct impact on the onset and development of OA and are considered to be factors of high significance. Concurrent with these, gradual changes in the surrounding musculature, including that of the knee, are also likely to be important in the onset and progression of the disease. Decreases in muscle strength is likely to be a uniting factor in the interaction between significant risk factors [55, 64, 65]. Gradually, chronicifying pain and progressive functional impairment lead to an increased need for medical care and rehabilitation, which in turn increases healthcare costs. Therefore, it is important that the patients form an active and responsible attitude regarding their own health in accordance with the current recommendations for the treatment of musculoskeletal degenerative diseases. Self-monitoring, personal healthcare, and active collaboration with health professionals are important elements of the OA self-management process. Good awareness of the positive effects of lifestyle changes, physical activity, and possible therapeutic approaches in the treatment of OA are also likely to improve health outcomes [66]. Despite the availability of various treatment programs for OA, there is an ongoing search for resources to develop long-term programs that will be effective in the treatment and rehabilitation of musculoskeletal disorders directly related to the joint degeneration process [67, 68].

2. Therapeutic use of Deep Oscillation® therapy in the rehabilitation program of patients with knee osteoarthritis

The aim of the research project is to investigate the therapeutic effects of the low-frequency and low-intensity pulsed electrostatic field application, using the Deep Oscillation®-therapy in patients with knee osteoarthritis and to compare the therapeutic effects of the application of Deep Oscillation® and placebo-Deep Oscillation® and kinesitherapy.

2.1 Materials and methods

The study included 90 patients with knee OA, with symptomatic osteoarthritis of the knee joint in a subacute and chronic phase without clinical evidence stage of active inflammation, randomized into two groups: Therapeutic (n = 57) and Control group (n = 33).

Treatment is carried out in accordance with the Helsinki Declaration (1964), after informed consent. The rehabilitation program included a ten-day therapeutic course: Deep Oscillation® and placebo-DO and Kinesitherapy (KT) complex.

Patients were assessed at four time points before, after treatment, after 1 month, and 3 months after therapy, using a visual analog scale (VAS) to measure pain at rest, at move, climbing and descending stairs, Manual Muscle Test, Measurement of the knee joint circumference, Test Range of Motion and WOMAC Osteoarthritis Index (Western Ontario and McMaster University Osteoarthritis Index).

2.2 Criteria for inclusion and exclusion

2.2.1 Criteria for inclusion

The research included eligible patients who satisfied the following criteria: age more than 38 years; X-ray data for knee OA of Kellgren—Laurence grades II and III; pain in knee joint in most days of recent months; crepitations during active movement of the knee joint; morning stiffness lasting 30 minutes or less.

2.2.2 Criteria for exclusion

Age less than 38 years; X-ray data for knee OA of Kellgren—Laurence grade I and IV; data on OA accompanied by a history of acute knee injury, reflected pain from the lumbar spine or hip joint; active synovitis; treatment with nonsteroidal anti-inflammatory drugs NSAIDs and / or analgesics, intraarticular manipulations with hyaluronic acid, or corticosteroids up to 6 months after application; contraindications to electrotherapy, including pacemaker.

2.3 Characteristics of the therapeutic course by groups

The therapy is administered in 10 sessions. All Therapeutic group patients underwent a therapeutic course with low-frequency and low-intensity electrostatic field and complex of therapeutic exercises and Placebo-Deep Oscillation and complex of therapeutic exercises for Control group. All patients included in the study gave informed consent to participate in the treatment course and could give up at any time from the treatment course.

2.3.1 Therapeutic group (TG)

In the Therapeutic group (TG), the low frequency, and low-intensity electrostatic field was applied by the Deep Oscillation® method using a 9.5 cm hand applicator (Deep Oscillation Evident® CLINICS, Physiomed Elektromedizin AG). The procedure involves treatment of KJ, surrounding tissues, and the m. Quadriceps femoris area. Therapeutic Modality: Variable Frequency 100–144 Hz 5 min. Permanent frequency 85 Hz 5 min.

Variable frequency 14–20 Hz 4 min. Modulation mode 1:1 (light vibrations). The complex of therapeutic exercises was carried out immediately after the electrical procedure.

2.3.2 Control group (CG)

Control group (CG) Patients underwent a ten-day placebo course using the Deep Oscillation® method. The application methodology was similar to the Therapeutic group, with minimal intensity (device turned on, contact indicator activated) but no deep tissue vibration in the treated area. The placebo procedure is followed by the therapeutic exercise complex.

The therapeutic exercise program included aerobic exercise, analytical exercise for femur muscles, focusing on Vastus medialis et lateralis m Quadriceps femoris, relaxation techniques for shortened muscles, resistance exercises, and exercises to increase the range of motion in the knee joint.

The possible therapeutic goals of the rehabilitation of patients with symptomatic gonarthritis with low-frequency and low-intensity electrostatic field and complex therapeutic exercises were reduction of pain and stiffness, reduction of edema of the around joint tissues and muscular weakness, increasing range of motion in affected joint and locomotive function, and increase of the daily functional activity.

2.4 Tools for evaluating the studied indicators

2.4.1 Functional methods for kinesiological assessment of the knee joint

2.4.1.1 Manual muscle testing (MMT)

Manual Muscle Testing (MMT) is a method used to determine the degree of muscle weakness. Skeletal muscles can have weakness as a result of disease, trauma, or reduced or lack of movement. Testing on the MMT scale provides information that allows the creation of an exact program of therapeutic exercises or other physical methods for disorders in the musculoskeletal system. The scale enables muscle weakness to be assessed in six grades (0–5 grade). 5, 4, and 3 according to MMT are accepted as functional grades. There are cases where these grades do not accurately reflect muscle weakness. In these circumstances, a„ + "or„ – "sign is added to the corresponding test item, corresponding to 5 to 10% strength. 3 (+) corresponds to a movement that can be performed and repeated several times against gravity or once against light resistance; 3 (–) corresponds to movement that can overcome gravity but has an incomplete range of 50–90% of the range of normal movement; score 2 (+) – corresponds to initiated antigravity movement (50% or less of normal range of motion); A score of 2 (–) receives movement performed with gravity eliminated and at incomplete range [11].

In order to objectively present the results of the performed MMT testing, when the signs "+" or "-" are used to the corresponding degree, numerical equivalents for determining muscle weakness are used, which are presented in **Table 1**.

MMT	**2**	**2+**	**3-**	**3**	**3+**	**4-**	**4**	**4+**	**5-**	**5**
	2	2.25	2.75	3	3.25	3.75	4	4.25	4.75	5

Table 1.
Degrees of muscle weakness according to the Manual muscle test (MMT).

2.4.1.2 Range of motion

In this kinesiological measurement, joint plane range of motion (SFTR) is determined using a goniometer. It is one of the main parameters characterizing motor function. For functional assessment of the knee joint, the measurement is in the sagittal plane, in which the range of extension and flexion in the tested joint is considered: S – 0°-0°-130°.

2.4.1.3 Measurement of circumferences

Centimetry is a kinesiological method for measuring anthropometric indicators. With a plastic centimeter, the condition of the musculature is determined and the presence of pathological conditions, such as muscle hypotrophy or atrophy, joint circumference—in different conditions, norm or pathology (edema) [11].

2.4.2 Pain and functional activity self-report questionnaires for knee joint assessment

2.4.2.1 Visual analogue scale (VAS)

In practice, this scale is routinely used to assess the degree of pain in different age groups and in patients with different diseases. VAS is a one-dimensional scale, representing a straight line from 0 to 10 cm (0 mm to 100 mm). At the beginning, a baseline value of 0, which corresponds to a no-pain condition, is noted. At the end, the maximum value corresponding to the worst possible pain is noted. Between these two values, there are intermediate values that can describe the nuances in subjective pain (2—corresponds to mild pain, 4- indicates moderate pain, 6- corresponds to severe pain, 8- is indicative of very severe pain). It is necessary for patients to independently determine the level of their pain by marking on the line how strong a feeling of pain they have.

Knee joint pain was assessed using a Visual Analogue Scale (VAS), assessing pain at rest, walking, descending, and climbing stairs.

2.4.2.2 Western Ontario and McMaster universities osteoarthritis index (WOMAC index)

A self-administered WOMAC Osteoarthritis questionnaire was used to assess subjective complaints and degree of functional impairment. It was developed for adult patients with damage to the knee and hip joints. Osteoarthritis Index LK 3.1 modification was used in the study.

The WOMAC Index is a disease-specific for knee and hip OA, a self-administered questionnaire used for subjective self-assessment of health and physical function.

It consists of 24 elements, divided into three subscales: Pain (5 questions), Stiffness (2 questions), and Physical function (17 questions).

The severity of symptoms is assessed on the verbal Likert scale in 5 points: 0—None, 1—Mild, 2—Moderate, 3—Severe, 4—Extreme.

Higher scores on the WOMAC Index indicate worse pain, stiffness, and functional limitations. The results are generated by summing the coded responses. Psychometric studies show high validity and reliability of the WOMAC questionnaire.

2.5 Evaluation of the obtained results

Results were tracked at the beginning, immediately after therapy, on the 1st month after rehabilitation and after the 3rd month of the end of the treatment course by: Visual Analogue Scale (VAS) pain test at rest, at move, climbing and descending stairs, Manual Muscle Test, Measurement of the knee joint circumference, Test Range of Motion, and WOMAC Osteoarthritis Index (Western Ontario and McMaster University Osteoarthritis Index), developed for adult patients with osteoarthritis. Modification Osteoarthritis Index LK 3.1 has been used. Statistical analysis: Quantitative data is represented as Mean and Standard Deviation (SD) if the distribution is either normal or Median (Me) and Range if different than normal. The normality was tested by the Shapiro-Wilk test. Comparisons of quantitative data before and after therapy were performed by the One sample Student t-test or the Wilcoxon Signed Ranks test. The category data was presented in percentages and analyzed by Fisher's Exact Test. The measured WOMAC Index in patients is presented as Mean ± SD (Range) standard deviation (range). The difference between a pair of groups was assessed using the nonparametric Mann-Whitney U test. Changes in the various WOMAC scales over the four time periods

Indicators	**Therapeutic group (n = 57)**	**Control group (n = 33)**
Age (Mean ± (SD)Range)	65.6 ± 11.3 (42–85)	67.6 ± 9.5 (44–87)
Gender identity (Mean ± (SD)Range)	42 women 65.9 ± 11.7(42–85)	22 women 65.9 ± 11.7(42–85)
	15 men 64.9 ± 10.4(45–81)	15 men 65.9 ± 8.4(48–76)
Duration of the disease (Me(Range)) years	10(1–15) years	7(2–15)
Duration of the current exacerbation period (Me(Range)) weeks	6.37 ± 1.74 (4–12)	6.27 ± 1.88 (3–10)
X-ray degree of Kellgren-Lawrence scale:		
II degree n (%)	30 (52.6)	20 (60.6%)
III degree n (%)	27 (47.4)	13 (39.4)
Body weight in kg.	78.0 (50–155)	82.0 (60.0–91.0)
BMI kg/cm^2	29.1 ± 5.4 (20.0–58.3)	28.6 ± 2.9 (23.3–35.1)
Reason for visiting a doctor (the number (%) is greater than the total (100%) for the group because some patients donated more than one answer)		
Pain	57 (100.0)	33 (100.0)
Difficulties while walking	47 (82.5)	28 (84.8)
Stiffness	22 (38.6)	11 (33.3)
Limited daily activity	16 (28.1)	10 (30.3)

Table 2.
Characteristics of the patients in therapeutic and control group.

were analyzed using the Friedman test. The doubles comparison in the presence of interdependence across the periods was made with a Dunn *post hoc* test. Data were analyzed with SPSS for Windows v.24. Significance level $p < 0.05$ was used to determine the statistical differences.

2.6 Characteristics of the patients in therapeutic and control group

90 patients with clinical symptoms, diagnosed with II and III stage of gonarthritis according to Kellgren-Lawrence, aged between 42 and 85 years, were included in the study. Patients were randomized into two groups: Therapeutic group (n = 57) and Control group (n = 33). Characteristics of the patients in Therapeutic and Control groups are shown in **Table 2**.

3. Therapeutic results of Deep Oscillation therapy in the rehabilitation program of patients with knee osteoarthritis

3.1 Comparative analysis of data in MMT m. Quadriceps femoris by groups

After the therapeutic course in the Therapeutic group, there was a statistical difference in MMT values between the four follow-up periods ($p < 0.001$). Muscle weakness decreased significantly immediately after completion of Rehabilitation, 1st month ($p < 0.001$), and 3rd month ($p < 0.001$) compared to the beginning of therapy. The treatment effect was maintained between months 1 and 3 ($p = 0.822$) (**Table 3**).

In the Control group, there was a decrease in muscle weakness compared to baseline at two time points (after completion of the treatment course ($p < 0.001$) and 1 month of therapy ($p < 0.001$). At month 3 of treatment, no statistical difference was found ($p = 0.192$) and MMT values returned to pre-therapy values. The effect of therapy persisted up to 1 month, compared to after treatment ($p = 1.000$). At month 3, there was an increase in muscle weakness compared to posttreatment as well as compared to month 1 ($p < 0.001$) (**Table 3**).

3.2 Comparative analysis for measured knee joint flexion range by group

The mean value of flexion range (Mean ± SD (Me (range)) before the start of the rehabilitation course in the Therapeutic group was 106.4 ± 8.3(110° (90.0–120.0)° and for the control group was 108.6 ± 8.4 (110°(90.0–125.0)°. For Therapeutic group, there was statistically significant difference in flexion range before therapy versus after therapy ($p < 0.001$), at 1st month ($p < 0.001$), and at 3rd month ($p < 0.001$). There was no statistical difference between flexion measured after the 1st and 3rd

Periods	Therapeutic group	Control group
Before therapy	3.00 (2.25–4.0)	3.00 (2.72–4.0)
After therapy	3.75 (3.00–4.75)	3.75 (3.00–4.75)
After 1st month	4.00 (3.25–5.00)	4.00 (2.75–5.00)
After 3rd month	4.00 (3.25–5.00)	3.25 (3.00–4.25)

Table 3.
Dynamics in MMT testing—m. Quadriceps femoris (Me (range)) for the four time points by group.

months (p = 1.000). A prolonged therapeutic effect was achieved up to 3 months after rehabilitation (**Table 4**).

3.3 Comparative analysis of knee joint measurement of circumferences by groups

The measured knee joint circumferences in the groups were followed at the beginning of the therapeutic course, immediately after therapy at 1 and 3 months. Mean ± SD (Me (range)) Knee joint centimetry before the start of the rehabilitation course in the Therapeutic group was 40.9 ± 4.0 (40.0(32.0–52.0) cm, control group was 41.3 ± 2.3(42.0(36.0–44.5))cm (**Table 5**).

For the Therapeutic group (n = 57), there was a statistically significant difference in the measurement of circumferences values before therapy compared to after therapy (p < 0.001), at 1st (p < 0.001), and at 3rd months (p < 0.001). There was no statistical difference in measurement of circumferences values after therapy and at 1st month (p = 1.000), and after therapy and at 3rd month (p = 1.000) and between 1st month and 3rd month (p = 0.162). A sustained therapeutic effect was achieved up to 12 weeks after rehabilitation (**Table 5**).

For the Control group (n = 33), there was a statistical difference in measurement of circumferences at month 3 compared to baseline (p = 0.022), after therapy and at month 3 (p = 0.003), and between month 1 and month 3 (p = 0.034). There was no difference in measurement of circumferences before and after therapy (p = 1.000) and at 1st month (p = 1.000), and after therapy and month 1 (p = 1.000).

3.4 Comparative analysis of knee joint pain (VAS) by groups

Pain in the affected knee joint was assessed by VAS before therapy, after therapy at months 1 and 3 for each treatment group in terms of pain at rest, while walking on flat surfaces, descending, and ascending stairs for the four time points. No statistically significant differences regarding gender and age distribution between groups were found in the statistical analyses performed.

Periods	Therapeutic group	Control group
Before therapy	106.4 ± 8.3(90.0–120.0)	108.6 ± 8.4(90.0–125.0)
After therapy	116.8 ± 6.3(100.0–125.0)	117.4 ± 7.3(100.0–130.0)
After 1st month	119.7 ± 4.7(110.0–125.0)	117.4 ± 6.3(105.0–125.0)
After 3rd month	120.3 ± 3.9(110.0–125.0)	113.3 ± 5.6(100.0–120.0)

Table 4.
Dynamics in knee joint flexion range KJ by group at the four time points (Mean ± SD (Me (range)).

Periods	Therapeutic group	Control group
Before therapy	40.9 ± 4.0 (32.0–52.0)	41.3 ± 2.3 (36.0–44.5)
After therapy	39.3 ± 3.7 (30.5–50.0)	41.2 ± 2.2 (36.0–44.0)
After 1st month	39.1 ± 3.7 (30.0–49.0)	41.4 ± 2.2 (36.0–44.0)
After 3rd month	39.4 ± 3.7 (30.0–49.0)	41.7 ± 2.2 (36.0–45.0)

Table 5.
Knee joint measurement of circumferences (Mean ± SD (Me (range)) for the four time points by group.

3.4.1 Pain at rest

Prior to therapy, there was no statistically significant difference in baseline VAS (Mean ± SD) rest pain scores between the Therapeutic group 2.72 ± 0.90 and the Control group 2.52 ± 0.71.

For the Therapeutic group, there was a statistically significant reduction in pain at rest according to VAS at the end of therapy ($p < 0.001$), 1st month ($p < 0.001$) and 3rd month ($p < 0.001$) compared to baseline values. It was also observed retention of pain level at rest at 1st month ($p = 0.082$) and 3rd month ($p = 0.490$) compared to post-therapy was observed (**Table 6**).

In the Control group, after completing the course of treatment, VAS pain decreased at 1st and 3rd months compared to baseline. Pain at rest increased after the 1st month, with the effect persisting until the end of the 1st month ($p = 0.002$) and such increasing at 3rd month compared to the 1st month post treatment ($p < 0.001$). With a more long-lasting effect in terms of pain at rest, treatment in TG showed no significant difference in pain level after treatment at 1st and 3rd months, and between 1st and 3rd months; that is, the effect of treatment persisted even 12 weeks after therapy. In CG, a significant reduction in pain was achieved by the end of the first month with a subsequent increase in pain at month 3rd compared to month 1st, but the pain level was lower compared to baseline values.

3.4.2 Pain while walking (Mean ± SD)

Pain while walking (Mean ± SD) before therapy for the Therapeutic group was 4.19 ± 1.01 and for the Control group - 3.85 ± 0.76. There was no statistically significant difference in baseline values between the groups.

The results of the Deep Oscillation therapy conducted in TG showed sustained reduction in pain while walking by the end of month 3rd compared to baseline values ($p < 0.001$) and retention of therapeutic effect and pain level to values achieved post therapy. No statistical difference was observed between months 1st and 3rd ($p = 0.386$).

In CG, pain while walking decreased after the end of therapy. The effect persisted until the end of the first month; then, there was a statistical difference between the end of therapy and month 3rd, and between month 1st and 3rd and an increase in pain while walking after month 1st ($p < 0.001$) (**Table 7**).

Longer-lasting effect in terms of pain while walking was the therapy carried out in TG, in which no statistical difference was observed after the end of the treatment compared to months 1st and 3rd; a significant reduction in pain syndrome was observed at months 1 as well as 3. In CG, the effect persisted up to 1st month, after which there was a statistical difference between posttreatment pain and 3rd month, as

Periods	Therapeutic group	Control group
Before therapy	2.72 ± 0.90	2.52 ± 0.71
After therapy	0.67 ± 0.83	0.82 ± 0.81
After 1st month	0.12 ± 0.33	0.45 ± 0.62
After 3rd month	0.23 ± 0.50	1.76 ± 0.75

Table 6.
Pain dynamics at rest (Mean ± SD (Me(range))).

Periods	Therapeutic group	Control group
Before therapy	4.19 ± 1.01	3.85 ± 0.76
After therapy	2.09 ± 0.74	2.15 ± 0.57
After 1st month	1.21 ± 0.62	1.73 ± 0.72
After 3rd month	1.51 ± 0.69	3.06 ± 0.66

Table 7.
Pain at walking dynamics (Mean ± SD (Me (range))).

well as between 1st and 3rd months, and an increase in the degree of pain on walking at 3rd versus 1st month (**Table 7**).

3.4.3 Pain when descending stairs (Mean ± SD)

There was no statistically significant difference between Therapeutic group and Control group with respect to baseline values. For Therapeutic group, there was a statistically significant improvement in pain when descending stairs at all four time points ($p < 0.001$), at the end of therapy, at 1st and 3rd months, compared to baseline values ($p < 0.001$), at 1st month ($p < 0.001$) and 3rd months ($p < 0.001$). Retention of pain level when descending stairs at month 3rd ($p = 1.000$), versus after the end of therapy (**Table 8**).

For Control group, there was a reduction in pain when descending stairs over the posttreatment period, at 1st and 3rd months ($p < 0.001$); an increase in the degree of pain when descending stairs after 1st month, with the effect persisting until the end of 1st month; and an increase in pain at month 3 ($p = 0.016$), compared to post therapy, and at month 3 compared to month 1 ($p < 0.001$) (**Table 8**).

After analyzing the results for pain when descending stairs, it was found that the treatment conducted in the Therapeutic group had a more long-lasting effect, with no statistical difference observed after therapy compared to months 1 and 3, and between months 1 and 3; that is, the effect of the treatment persisted at month 3 after therapy.

3.4.4 Pain when ascending stairs

The pain score (Mean ± SD) on VAS before therapy for TG was 5.68 ± 1.07 and CG 5.36 ± 1.06. There was no statistically significant difference in baseline values of this parameter between groups. The treatment performed in TG was effective in terms of pain reduction ($p < 0.001$). No statistical difference was observed for the posttreatment period and month 3 ($p = 0.001$); the posttreatment effect was maintained at month 3, but an increase in pain was found between the end of months 1 and 3 ($p = 0.031$).

Periods	Therapeutic group	Control group
Before therapy	7.05 ± 1.04	6.76 ± 0.90
After therapy	3.89 ± 0.94	4.27 ± 0.84
After 1st month	3.26 ± 0.64	3.94 ± 0.83
After 3rd month	3.61 ± 0.62	5.24 ± 0.97

Table 8.
Dynamics of pain when descending stairs (Mean ± SD).

Periods	Therapeutic group	Control group
Before therapy	5.68 ± 1.07	5.36 ± 1.06
After therapy	2.96 ± 0.82	3.09 ± 0.88
After 1st month	2.40 ± 0.70	2.73 ± 0.91
After 3rd month	2.88 ± 0.63	4.15 ± 0.97

Table 9.
Dynamics of pain during stair climbing (Mean ± SD).

In the CG after completion of the treatment course, pain during ascending stairs decreased ($p < 0.001$). The therapeutic effect persisted until the end of the first month, after which there was an increase in pain and a statistical difference between completion of therapy and month 3, and between months 1 and 3 ($p < 0.001$).

After analyzing the results obtained, it was found that the complex rehabilitation carried out in the Therapeutic group had a longer lasting effect, with retention of the pain level at month 3 at the level immediately after therapy (**Table 9**).

3.5 Comparative analysis Western Ontario and McMaster universities osteoarthritis index (WOMAC index)

The total WOMAC Index (Mean ± SD (range)) at baseline for Therapeutic Group are (61.5 ± 8.2 (40–78)), for Control Group (59.0 ± 7.2(46–77)). No statistical difference was observed before therapy for the total WOMAC Index between groups ($p = 0.125$) (**Table 10**).

In the 3rd month after therapy, there was a statistically significant improvement in total WOMAC Index for TG patients (46 ± 4.5(36.0–54.0)) compared to CG

WOMAC index (Me(Range))	Therapeutic group	Control group	Statistical difference
WOMAC Index	62(40–78)	59(46–77)	$p = 0.125$
WOMAC Pain	13(7.0–16)	13(7.0–15.0)	$p = 0.684$
WOMAC Stiffness	5(2.0–7.0)	5(3.0–7.0)	$p = 0.098$
WOMAC Function	45(36.0–56.0)	43(34.0–56.0)	$p = 0.015$

Table 10.
Total WOMAC index and subscales pain, stiffness, and function (Me(Range)) before the therapy, divided into groups, at baseline.

WOMAC index (Me(Range))	Therapeutic group	Control group	Statistical difference
WOMAC Index	47(36–54)	56(46–73)	$p < 0.001$
WOMAC Pain	8(5–10)	11(8–14)	$p < 0.001$
WOMAC Stiffness	3(1–4)	4(3–6)	$p < 0.001$
WOMAC Function	35(28–42)	42(34–56)	$p < 0.001$

Table 11.
Total WOMAC index and subscales pain, stiffness, and function (Me (range)) 3 months after therapy, and dynamics compared to the beginning of therapy, divided into groups.

patients (56.2 ± 7.0(46.0–73.0)) and a statistically significant difference between the groups ($p < 0.001$) in favor of the group with complex rehabilitation with DO and KT (**Table 11**).

4. Discussion and findings

The conducted research project aimed to investigate the therapeutic effects of the low-frequency and low intensity pulsed electrostatic field application using the DO-therapy in patients with knee osteoarthritis and to compare the therapeutic effects of the application of Deep Oscillation® and placebo-DO and kinesitherapy (KT). The relevant value of the reformed physical factor on the basis of the KT was evaluated.

A statistically significant decrease in edema, increased range of motion (flexion) in knee joint, and m. Quadriceps femoris muscle weakness for three-time periods (TTP) versus baseline was observed in the Therapeutic Group, as well as a tendency to a better influence of the levels of muscle weakness and range of motion in the KJ for the Therapeutic group in which patients received complex physiotherapeutic treatment: electro-procedure and KT.

A statistically significant reduction in pain after treatment in Therapeutic Group and 1st and 3rd months at rest, motion, descent, and ascending were reported compared to baseline values and retention of posttreatment outcomes and at the 3rd month.

The Control Group showed a reduction in pain at rest for the three time periods (TTP), compared to baseline values, increase in the 3rd month compared to post-treatment, pain-motion reduction after treatment, and increase in the 3rd month compared to post-treatment, pain when descending stairs reduction for TTP, compared to baseline, increase in 3rd month versus post-therapy, pain-upstairs decrease in TTP, and retention of the effect achieved up to the 1st month after treatment.

The total WOMAC Index for Therapeutic Group shows a statistically significant reduction in the TTP score as well as retention of the effect on the 3rd month post-therapy versus post treatment was observed. In Control Group, a significant reduction after treatment on 1st month was observed and no statistically significant difference on 3rd month compared to baseline was found.

The frequency used in Deep Oscillation® determines the therapeutic effects achieved by the application of a low-frequency and low-intensity electrostatic field. The reduction of pain is an effect that appears relatively quickly and has a long-lasting effect [5, 6], which is probably due to the inclusion of the mechanism for Gate control of pain nociception [29], and a psychological effect of the conducted therapeutic intervention [69]. Oxidation processes in lipid substances are suppressed and also probably the formation of oxygen-containing reactive species, which is probably the basis for the manifestation of the anti-inflammatory effect [70, 71].

Microcirculation in the affected region was improved by reducing inefficient shunt blood flow and dilating capillary blood vessels [72, 73]. The observed long-term vasodilatation is a consequence of the biologically active substances (histamine, protease, serotonin, and heparin) released by the mast cells [73]. A reduction in the swelling of the tissues is found as a result of improved lymphatic drainage [2, 70]. The tissues increase their elasticity and the possibility of developing fibrosis is reduced, and the range of motion in the joints is also improved. In the area of application of low-frequency and low-intensity electrostatic field, muscle spasm is reduced,

probably through a mechanism of impact on the nerve endings and the nerve conductors. The application of Deep Oscillation® leads to improvement of trophic and restorative processes in the tissues, by activating local blood flow, improving local microhemodynamics, optimizing blood transport functions, and improving the exchange that takes place through the capillaries [4, 7].

The therapeutic results achieved in placebo treatment have been associated by a number of authors with various etiological factors, such as gender, age, diagnosis, study design, trust in the therapist, and sociocultural characteristics of the ethnicity [74, 75]. One mechanism of the placebo effect has been associated with an expectancy of an outcome from the therapy conducted [76]. Expectancy associated with the treatment effect represents the likelihood that the procedure or drug substance will have an effect in relieving pain [77]. If the patient has an expectation of pain reduction after administration of a placebo treatment, this fact alone may lead to pain relief [78, 79]. Scientific evidence suggests an association with the endogenous opioid system for the expression of the placebo effect in the setting of an expectation of pain reduction [80, 81]. For this reason, an effective treatment should be considered to be one in which the analgesic effect is greater than that of placebo therapy [82].

A number of authors have reported that patients with KJ osteoarthritis suffer from Quadriceps muscle weakness, proprioception deficits, loss of balance, and consequently are at risk of frequent falls. Muscle weakness is often associated with the level of pain and functional limitations. It is assumed that these disorders are caused by a decrease in voluntary contractions with arthrogenic genesis and reflex inhibition as a result of pain and edema [83, 84]. These symptoms of osteoarthritis, especially of the knee, can be reduced or prevented by therapeutic exercises, for which there is significant evidence. Age-related changes in the neuromuscular system affect motor function in adults over 60 and especially over 80 years. Reduced muscle strength, slower contractile speed, increased fatigue, and reduced joint stability, which can vary in different individuals, are observed [85]. The extent to which muscle weakness and atrophy are caused by KJ degeneration or muscle weakness precedes it is discussed [55]. Quadriceps femoris muscle weakness is currently thought to be a predictor of OA more often in women [86], and the role of afferent sensory dysfunction is important for the progression of KOA. Muscle function is more related to joint pain than narrowing of the joint space and is easier to change, making it a realistic therapeutic goal [55, 87, 88]. Physical activity can change the properties and function of the motor unit in adults, although the effects on the variability of motor characteristics are largely unknown [85].

There is considerable evidence for the effectiveness of therapeutic exercises in knee joint osteoarthritis. A summary of a large number of systematic studies evaluates the effect of exercise and identifies improvements in pain, function, and overall assessment [89]. Therapeutic exercises are likely to prevent degenerative changes in cartilage, to reduce inflammatory activity and changes in the subchondral and metaphyseal areas of bone. There is growing evidence that therapeutic exercises can affect pain, stiffness, muscle weakness, and joint dysfunction in KOA. Therapeutic options include exercises to increase muscle strength, aerobic exercises, neuromuscular exercises, balance exercises, proprioception, water exercises, and some traditional exercises [90].

Induced endogenous analgesia as a result of therapeutic exercise is thought to be due to the release of endogenous opioids and growth factors [91], as well as the activation of cerebrospinal nociceptive inhibitory mechanisms controlled by the brain [92]. The improvement can also be explained with the biomechanical changes

in the joint and increased stability [93]. The application of exercises to increase muscle strength (with/without other types of therapeutic exercises), depending on their characteristics (type of resistance, type of muscle contraction, intensity, and duration) can significantly reduce pain and improve physical function and quality of life in knee osteoarthritis. Combining them with other therapeutic agents, such as patellar taping or manual therapy, is subject to further study. It is necessary to develop a combination therapy including behavioral strategy and exercises to increase muscle strength, which has a longer-lasting effect [94]. Positive results from the combined application of Deep Oscillation and therapeutic exercises have also been reported by other research groups in recent years [95–98].

The conducted study confirms the results obtained in the complex rehabilitation of patients with knee arthritis involving the application of Deep Oscillation® therapy. Some authors report reported reduction in pain and improved movement in patients with osteoarthritis in a complex with targeted kinesitherapy [35, 38, 95]. Pain-related decline in physical function further exacerbates permanent disability in patients with knee osteoarthritis. Most patients require oral NSAIDs for pain relief, which increases the risk of adverse effects: gastrointestinal, cardiovascular, or renal. Non-pharmacological treatment modalities are recommended: topical NSAIDs, physiotherapy, therapeutic exercise, weight reduction, orthoses, intraarticular administration of corticosteroids, hyaluronic acid, and platelet-rich plasma PRP therapy [54].

The long-lasting effect we found in reducing pain at rest and during physical activity, improving range of motion and reducing knee joint swelling for the Therapeutic Group, is probably due to the complex use of low-frequency and low-intensity pulsed electrostatic field (Deep Oscillation®) and the applied therapeutic exercise program. The effect achieved in the Control group is less pronounced and is probably based on the effect of the applied kinesitherapy and the psychological effect shown by the application of the placebo-Deep Oscillation®.

5. Conclusion

Deep Oscillation® effectively reduces edema, stiffness, pain in rest position, and physical activity in knee osteoarthritis. The complex application of low-frequency and low-intensive electrostatic field with therapeutic exercise permanently affects the muscle imbalance and the range of motion in the affected joint. The established therapeutic effects of Deep Oscillation® have a long-term effect (at least 3 months) versus placebo-DO. The use of Deep Oscillation® in rehabilitation programs leads to improvement of the psycho-emotional state, functional activity, and quality of life (WOMAC Index).

There was no established discomfort in the patients treated with Deep Oscillation. Compliance with safety rules reduces the risk of side effects. The proven methodology for therapy has an easy practical application. For better objectifying of the effects of the low-frequency and low-intensity electrostatic field, the studies should continue.

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