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RANDOMIZED COHORT CONTROL STUDY COMPARING THE USE OF STANDARD THERAPY VERSUS STANDARD THERAPY PLUS "SUPER INDUCTIVE MAGNETIC SYSTEM" IN THE TREATMENT OF MUSCULOSKELETAL INJURIES

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Annotation. The pulsed electromagnetic field (PEMF) is considered a promising innovative means in physiotherapy and medicine. The method has wide range of therapeutic effects that address mainly musculoskeletal and neurological disorders. The application of electromagnetic fields (EMF) in medicine has a long history. Magnetic fields (MF) were created by passing electric currents through a wire coil placed above the fracture. Through Faraday induction, periodic variations in the MF created the appropriate electrical field in bone [1]. The biological effects of pulsed MF on nerve tissue have received significant study in recent decades [2]. The aim of this study was to evaluate the efficacy of Super Inductive Magnetic system in people with musculoskeletal pain. SIS therapy was compared with standard therapy. Statistical analysis showed that the difference between groups was significant ($p < 0.001$), which proves that SIS therapy is more effective compared to standard therapy. SIS is safe and effective method for treatment of musculoskeletal pain. Further investigations need to be done to provide more accurate data and to evaluate the effectiveness of this method compared to other treatment methods.

Keywords: *Super Inductive System, pulsed electromagnetic field, musculoskeletal pain, VAS scale, standard therapy.*

Introduction. Magnetic field therapy was applied to promote bone healing, treat osteoarthritis and inflammatory diseases of the musculoskeletal system, alleviate pain, enhance healing of ulcers and reduce spasticity and also extremely low frequency (ELF) magnetic fields in the pico tesla and milli tesla ranges are aimed at improving neurotransmission and correcting local immune pathology, respectively [3]. Scientists have documented analgesic and anti-nociceptive efficacy of pulsed electromagnetic field (PEMF), similar to the opioid analgesic effect, but the clear molecular and biochemical mechanism of magnetic therapy's effect on pain remains unclear [4].

Furthermore, the usefulness of magnetotherapy in treating chronic pain, such as fibromyalgia (FM), is currently being challenged [5].

Furthermore, in neurological disease, an ELF magnetic field was shown to enhance functional and mental state in brain stroke patients, and clinical parameters correlated positively with the amount of enzymatic antioxidant protection [6].

Literature review. Indications for use of pulsed magnetic field were discussed in several review and meta-analysis.

In the review article of pulsed magnetic-Field Exposure for Therapeutic Purposes [7] Bassett, Pilla, and Pawluk [8] provided the first description of PEMFs' therapeutic efficacy in people. These researchers claimed that PEMF stimulation (300 pulse width; 75 Hz) on delayed non-unions resulted in osteogenesis. After one month of stimulation, 25 of the 29 individuals in the research showed radiographic indications of bone growth. Additionally, these researchers were able to keep numerous people who had been recommended for ampu-

tations from undergoing these painful and debilitating treatments.

In other research from this article Heckman et al. [9] found a 64.4% success rate in 149 patients treated with PEMF stimulation for nonunion fractures. Patients who used the stimulation intensively for three months saw an increase in efficacy in 85% of cases.

Konrad et al. investigated [10] the usage of PEMF in a non-blinded, uncontrolled trial of twenty-four patients suffering from aseptic loosening of hip prosthesis. Prior to and after magnetic field exposure, patient's pain levels and hip motions were evaluated. (50 Hz, 5 mT). No patients were chosen to the sham condition. Following sessions, patients suffering from loose hip replacement had significant improvements in pain and all hip motions (except flexion and extension), but not those suffering from acute discomfort due to substantial loosening of the hip prosthesis. This shows that PEMF treatment may only be helpful in relieving mild-to-moderate hip pain, while it is not effective in severe pain.

The aim of other systematic review was to look at the scientific evidence from the past ten years about the use of EMF in rehabilitation for acute and chronic pain in musculoskeletal conditions [11]. According to the PRISMA declaration, a systematic review of the literature was conducted using the following search platforms: (PubMed, Cochrane, PEDro, SCOPUS, and Web of Science (WoS) [12]

According to this study, PEMF are the most often employed magnetic fields, notably in knee OA [13]. Nelson et al [14] proposed a 2-week protocol (15 minutes per session, twice daily) with 6.8 MHz and 30 Gauss intensity in OA: patients in the PEMF group had a mean VAS pain score 6.850 at baseline and 4.190 at the end of treatment, compared to 7.180 and 6.110 in the placebo group. It means, PEMF causes wide and quick pain reductions in early knee OA (p=0.036). Likewise in other study, [15] forty patients with OA were randomly assigned to one of two groups: both groups got a 20-minute hot pack and a 5-minute therapeutic ultrasound, but the treatment group additionally received 30 minutes of PEMF therapy. One advantage was that patients may take acetaminophen as required. Their findings indicate that PEMF had no further benefit in reducing knee discomfort. After therapy, there were no statistically significant difference in pain, stiffness, or physical function ratings across groups ($p = 0.906$, $p = 0.855$, and $p = 0.809$, respectively).

As a conclusion, mentioned systematic review from twenty-one articles (N=21): 8 articles treated pain of the knee for osteoarthritis (OA), 2 articles treated Shoulder Impingement Syndrome [16], 5 articles treated spine pain [17], of which 1 study about chronic mechanical neck pain (CNP), and 4 studies were about low back pain (LBP) [18], 3 articles treated Fibromyalgia Syndrome (FM) [19], 1 article showed the effect of EMF respect of patellofemoral pain (PFP) [20], 1 article treated Plantar fasciitis (PF) [21] and 1 article treated Hand osteoarthritis (HO) [22] reveals that using an electromagnetic field to treat musculoskeletal injuries decreases pain and increases function. After summarizing all articles, it is concluded that additional research is needed to investigate the use of more standardized protocols in terms of the duration, exposition time, and frequency characteristics of the magnetic field, applied to certain diseases to alleviate musculoskeletal pain with appropriately safe and conservative treatment.

Other review analysis was studied the main clinical applications of PEMF [23]

One of the conditions in which PEMF applied is tendon disorders such as tendon injuries and chronic tendinopathies. Rehabilitation timeframes for tendon diseases can be lengthy, and the outcomes are frequently disappointing [24]. This is owing in part to the ECM's complicated architectural structure, the scarcity of low activity tendon-resident cells, and the avascular character of tendons [25]. There are still many disagreements concerning the involvement of inflammation in tendinopathy etiology [26]. Recent data, however, shows that a cascade of inflammatory processes, including as inflammatory mediator production, lymphocyte and macrophage infiltration, and matrix metalloproteinase (MMP) ac-

tivation, play a critical role in the pathophysiology of tendinopathies [27]. Many studies have lately been conducted to assess the feasibility of using PEMFs to treat tendon problems [28]. Gehwolf et al. [29] demonstrated that in vitro treatment of tendon-derived cells with PEMFs might minimize the catabolic effects of an Il-1 pro-inflammatory stimulation, resulting in a more tissue reparative state. Girolamo et al. [30] investigated the biological effects of different treatment intensities, durations pf PEMF and determined the best effect might be achieved at repeated 1.5 mT-PEMF therapy. Even though that the studies evaluated the effect of PEMF on cell level are not completed they might open new perspectives for use of PEMF for tendon regeneration. Also, there are several limitations in conducted studies. Most studies frequently assessed the underlying mechanism of action, meanwhile the deeper mechanism remain unknown [31]. Another limitation is that no defined clinical methods or rationales for parameter selection exist. In many clinical and experimental trials, different PEMF parameters like as frequency, intensity, and exposure time were varied [32]. Furthermore, the small sample sizes utilized in many research continue to be a constraint [33]. To validate the benefits of PEMFs on patients with musculoskeletal problems, properly planned high-quality, large-scale randomized controlled studies with long-term follow-up are required. Finally, it has to be determined if PEMFs offer any health concerns to operators and patients in normal clinical use. Several safety recommendations and expert opinions from licensed officials and expert groups have suggested that contact with electromagnetic fields may have negative effects on the brain and peripheral nervous system, cardiovascular system, cognitive and vestibular function [34]. For the interest of safety, more research must focus on the possible negative consequences of long-term PEMFs.

Results. 60 patients (n = 60) with different kind of musculoskeletal pain (35 men and 25 women) were randomized in two groups with equal number of patients in each group. All the participants received the 10 sessions treatment and completed the study. No abnormal finding or adverse events were observed. The mean age of patients was 28,70±9,26 in control group and 38,70±9,33 in target group. There was no statistically significant difference among the groups for age, gender ($p > 0,001$). Pain intensity decreased significantly in control groups, mean VAS scale scores at baseline 5,87±1,14 declined to 1,67±0,71 ($p < 0,001$). Table 3 represents the VAS scale scores in control group:

Table 3. Mean scores of VAS scale in Control group

Parameter	Pretreatment	Posttreatment
VAS scale	5,87±1,14	1,67±0,71

Outcome measures in target group also showed significant difference in target group, mean scores of VAS scale 6,07±1,05 at baseline decreased to 6,07±1,05 ($p< 0.001$). The results from target group represented in Table 4 below:

Table 4. Mean scores of VAS scale in Target group

Parameter	Pre-treatment	Post-treatment
VAS scale	6,07±1,05	0,93±0,74

According to these results there were statistically significant difference after treatment in both groups ($p < 0.001$).

Comparison between groups, showed that the decreasing of pain intensity in group treated with SIS was significantly higher than in the group treated with standard therapy methods ($p < 0.001$). The comparison of VAS scale score in each group is demonstrated Figure 2. below:

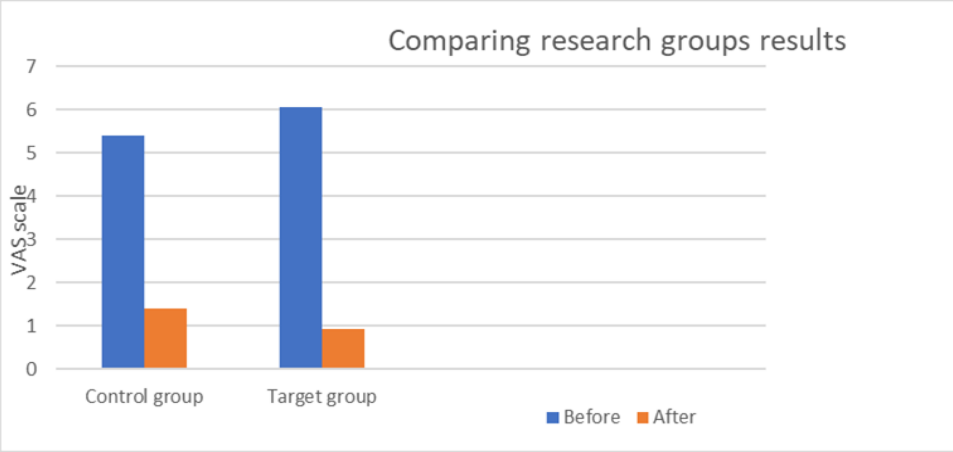
Discussion. Statistical assessment of the data from the current study showed that both treatment methods are effective in treatment of musculoskeletal pain ($p<0,001$). The mean

scores of VAS scale decreased from 5,87±1,14 to 1,67±0,71 in control group (p<0,001) and from 6,07±1,05 to 0,93±0,74 in target group (p<0,001).

Statistical results compared two groups show significant difference between the intervention group and the control group (p<0,001).

An apparent limitation of this study is the number of patients, small number of sample size makes generalizing the trial's findings challenging. Another limitation of this study is that the follow up period after treatment is short and we don't have data for a long-term period after treatment. We could not make a conclusion regarding long term effects of SIS therapy. Also, pain measurement tool that we used is a subjective tool which do not express the real level of pain decreasing.

Fig.2. VAS scale scores comparing in each group.



Conclusion. In conclusion, even though the obtained study results showed the effectiveness of SIS method in treatment of different kind of musculoskeletal pain, limitations of the study indicate that future research should consider to evaluate the potential effects of this method. Future studies should aim to replicate results in a larger population group and for a longer follow up periods. It would also be of interest to investigate the effectiveness of SIS depending on various intensity and duration of session. Further investigations need to be done to provide more accurate data and to evaluate the effectiveness of this method compared to other treatment methods.

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РАНДОМИЗИРОВАННОЕ КОГОРТНОЕ КОНТРОЛЬНОЕ ИССЛЕДОВАНИЕ, СРАВНИВАЮЩЕЕ ИСПОЛЬЗОВАНИЕ СТАНДАРТНОЙ ТЕРАПИИ С ИСПОЛЬЗОВАНИЕМ СТАНДАРТНОЙ ТЕРАПИИ ВМЕСТЕ С «СУПЕРИНДУКТИВНОЙ МАГНИТНОЙ СИСТЕМОЙ» ПРИ ЛЕЧЕНИИ СКЕЛЕТНО-МЫШЕЧНЫХ ТРАВМ

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Аннотация. Импульсное электромагнитное поле (ИМП) считается перспективным инновационным средством в физиотерапии и медицине. Метод имеет широкий спектр терапевтического воздействия, направленного главным образом на опорно-

двигательный аппарат и неврологические расстройства. Применение электромагнитных полей (ЭМП) в медицине имеет давнюю историю. Магнитные поля (МП) создавались пропусканием электрического тока через проволочную катушку, расположенную над переломом. Благодаря индукции Фарадея периодические изменения МП создавали соответствующее электрическое поле в кости [1]. Биологическое воздействие импульсного МП на нервную ткань было тщательно изучено в последние десятилетия [2]. Цель нашего исследования состояла в том, чтобы оценить эффективность у людей с мышечно-скелетной болью. Терапию с использованием Супериндуктивной Магнитной системы сравнивали со стандартной терапией. Статистический ана-лиз показал, что разница между группами была достоверной (p <0,001), что свидетельствует о большей эффективности тера-пии с Супериндуктивной Магнитной сис-темой по сравнению со стандартной терапией. Супериндуктивная Магнитная система является безопасным и эффективным методом лечения мышечно-скелетной боли. Необходимо провести дальнейшие исследования, чтобы получить более точные данные и оценить эффективность этого метода по сравнению с другими методами лечения.

Ключевые слова: *Супериндуктивная Магнитная система, импульсное электромагнитное поле, скелетно-мышечная боль, шкала VAS, стандартная терапия.*

DAYAQ-HƏRƏKƏT SİSTEMİNİN ZƏDƏLƏNMƏLƏRİNİN MÜALİCƏSİNDƏ STANDART TERAPİYA İLƏ STANDART TERAPİYA VƏ “SUPER İNDUKTİV MAQNETİK SİSTEM” TERAPİYASININ BİRLİKDƏ İSTİFADƏSİNİ MÜQAYİSƏ EDƏN RANDOMİZƏOLUNMUŞ KOHORT NƏZARƏT TƏDQİQATI

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Annotasiya. İmpulslu elektromaqnit sahəsi (İEMS) fizioterapiya və tibbdə perspektivli innovativ vasitə hesab olunur. Metod əsasən dayaq-hərəkət sistemi və nevroloji pozğunluqları əhatə edən geniş terapevtik təsirlərə malikdir. Elektromaqnit sahələrinin (EMS) tibbdə tətbiqi uzun tarixə malikdir. Maqnit sahələri (MF) sınıq sahəsindən üzərində yerləşdirilən naqilli sarğıdan elektrik cərəyanlarını keçirərək yaradılmışdır. Faradey induksiyası vasitəsilə MS-də dövri dəyişikliklər sümükdə müvafiq elektrik sahəsi yaratdı [1]. Son onilliklər ərzində impulslu maqnit sahəsinin sinir toxumasına bioloji təsirini öyrənən tədqiqatlar aparılmışdır [2]. Bizim apardığımız tədqiqatın məqsədi əzələ-skelet sistemində ağrısı olan insanlarda Super İnduktiv Maqnit sisteminin effektivliyini qiymətləndirmək idi. Super İnduktiv Maqnit sistemi ilə müalicə standart terapiya ilə müqayisə edilmişdir. Statistik təhlil qruplar arasında fərqin əhəmiyyətli olduğunu göstərdi ($p < 0.001$), bu, Super İnduktiv Maqnit Sisteminin standart terapiya ilə müqayisədə daha effektiv olduğunu sübut edir. Super İnduktiv Maqnit Sistemi dayaq-hərəkət ağrılarının müalicəsi üçün təhlükəsiz və effektiv üsuldur. Daha dəqiq məlumat əldə etmək və bu metodun digər müalicə üsulları ilə müqayisədə effektivliyini qiymətləndirmək üçün əlavə araşdırmalar aparılmalıdır.

Açar sözlər: *Super İnduktiv Maqnit Sistemi, impulslu elektromaqnit sahəsi, skelet-əzələ ağrıları, VAS şkalası, standart terapiya.*