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Non-invasive HIFEM technology for musculoskeletal system enhancement

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ABSTRACT

Background: Musculoskeletal conditions are a leading cause of disability and their prevalence is expected to further rise. Current treatment approaches are often associated with significant adverse effects or high dropout rates, highlighting the need for alternative solutions that are both effective and well-tolerated. This study aims to evaluate the efficacy of HIFEM stimulation in enhancing the musculoskeletal system function, as well as its procedural safety, therapy comfort, and participant satisfaction with outcomes.

Methods: A total of 36 subjects were enrolled. Four HIFEM treatments were delivered to the upper or lower extremities, 5–10 days apart. Follow-up visits were scheduled 1 month and 3 months post-treatment. The Western Ontario and McMaster Universities Arthritis Index (WOMAC) was used for assessment of change in the condition of subjects treated on the lower extremity, while the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire was utilized for subjects treated on the upper extremity. Subject satisfaction, therapy comfort, and safety were additionally assessed. Changes in WOMAC and DASH scores were analyzed using Friedman's test to assess statistical significance. Post-hoc Dunn's test was performed for multiple comparisons of total scores across time points.

Results: The WOMAC scores improved ($p < 0.05$) by 62.0 % on average after the final treatment, by 65.1 % at 1 month, and increased to 68.3 % at 3 months. The DASH scores were improved ($p < 0.05$) on average by 49.0 % after the final treatment, by 46.6 % at 1 month, peaking at 3 months with 67.7 % score reduction. 91 % of participants were satisfied with results and found the treatments comfortable. 97.1 % reported their treated joints felt better and 91.2 % that their range of motion had improved. Additionally, 82.4 % reported increased mobility, and 76.5 % experienced enhanced flexibility. No side effects or adverse events occurred throughout the study.

Conclusion: These results support HIFEM as a safe and effective approach for enhancing musculoskeletal conditions as an independent modality or adjunctive to traditional treatments.

1. Introduction[d]

Musculoskeletal conditions are a leading cause of disability, and their prevalence is expected to increase due to longer life expectancy, rising obesity rates, and more sedentary lifestyles.[1] A national survey in the United States found that approximately 47.8 % of adults had a history of chronic musculoskeletal conditions or related abnormalities and are the most common cause of long-term pain and physical disability.[1,2] With an estimated 1.3 billion cases worldwide,[3] musculoskeletal conditions pose a significant global health burden. Common symptoms include pain, stiffness, and reduced mobility, all of which negatively impact an individual's physical, mental, and social well-being.[1]

Treatment strategies vary depending on the specific condition, but typically begin with physical therapy as the first-line intervention. Despite its early use, physical therapy often suffers from low participation and high dropout rates due to time constraints, session-related discomfort, or poor patient compliance, and may fail to address the underlying cause of symptoms, especially in degenerative conditions.[4–6] If physical therapy is not suitable or proves insufficient, treatment may progress to analgesics or disease-modifying drugs; however,

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[d] Abbreviations: DASH - Disabilities of the Arm, Shoulder, and Hand Questionnaire, MCID - Minimal Clinically Important Difference, NRS - Numerical Rating Scale, SSQ - Subject Satisfaction Questionnaire, TCQ - Therapy Comfort Questionnaire, WOMAC - Western Ontario and McMaster Universities Arthritis Index.

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pharmacological options are generally unsuitable for long-term use due to the risk of adverse effects such as gastric ulcers, renal dysfunction, bleeding complications, and hepatotoxicity, particularly with the commonly prescribed non-steroidal anti-inflammatory drugs (NSAIDs).[7] In more severe or refractory cases, surgical intervention may be required. However, surgery carries significant risks, including blood clots, infection, nerve or surrounding tissue damage, wound break-down, and loosening or malalignment of the prosthetic component.[8] It is reported that over half of patients after a knee replacement surgery experienced at least one complication.[9] Furthermore, surgeries require hospitalization, long downtime periods and are followed by rehabilitation, substantially affecting patients' lives.[6]

Therefore, there is a need for alternative approaches. To address this, a novel therapy protocol integrating HIFEM technology was developed. HIFEM, a trademarked electromagnetic stimulation technology, has previously demonstrated effectiveness in enhancing muscle quality and tone, contributing to improved physical function and quality of life in elderly patients and postpartum women.[10,11] Unlike earlier body-sculpting protocols that induced supramaximal muscle contractions in targeted muscle groups, this new functional wellness protocol for musculoskeletal enhancement employs shorter electromagnetic pulses at lower intensity and higher frequency. The shorter pulses facilitate rapid, controlled muscle contractions, minimizing the risk of overloading or fatiguing compromised muscle tissue. The low-intensity stimulation ensures a gentler treatment, while the higher frequency stimulation (up to 120 Hz) supports tissue regeneration.[12,13] Electromagnetic stimulation has been shown to slow degenerative processes and promote the repair and regeneration of various musculoskeletal tissues, including muscle, bone, tendons, ligaments, and joint cartilage, by modulating complex intracellular pathways.[14] Specifically, HIFEM technology has been found to activate satellite cells, the stem cells of muscle tissue, leading to muscle hypertrophy and hyperplasia.[15]

2. Methods

This study aims to evaluate the efficacy of HIFEM stimulation in enhancing the musculoskeletal system function, as well its procedural safety, therapy comfort, and participant satisfaction with outcomes.

This was a prospective, interventional, multi-center, open-label study. Participants were recruited based on the following inclusion criteria: age over 21 years, body mass index (BMI)$\leq$35 kg/m^2, use of birth control for women of childbearing potential, willingness to abstain from any treatments other than the prescribed pre-procedure and study protocols for musculoskeletal improvement, and the ability and commitment to maintain their pre-study diet, exercise, and therapy routines. Exclusion criteria included contraindications to electromagnetic field exposure, such as the presence of electronic or metal implants, pregnancy, postpartum or nursing status, hemorrhagic disorders, coagulation abnormalities, or the use of anticoagulant medications. All participants were informed about the study procedures and provided written informed consent. The study was conducted in accordance with the Declaration of Helsinki, received Institutional Review Board approval (Advarra, Pro00075291), and was retrospectively registered at ClinicalTrials.gov (NCT06677086).

Participants received four HIFEM treatments (Emsculpt NEO, BTL Industries Inc., Boston, MA, USA) targeting either the upper or lower extremities. Treatment intensity was individualized based on participant feedback, with a maximum of 100 % intensity. Each session lasted 30 min and was spaced 5–10 days apart. Follow-up assessments were conducted at 1 month and 3 months post-treatment.

Lower extremity outcomes were measured using the Western Ontario and McMaster Universities Arthritis Index (WOMAC), a 24-item questionnaire assessing pain, stiffness, and functional limitation. Each item is scored from 0 (none) to 4 (extreme), with a total possible score of 0–96. Higher scores indicate greater impairment. Improvement was defined as a reduction in the total score and minimal clinically important difference (MCID) as a reduction of $\geq$22 % from baseline.[16]

Upper extremity condition was evaluated using the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire. This 30-item instrument measures functional limitation and symptoms in patients with one or several musculoskeletal conditions of the upper limb. Each item is scored on a scale of 0 (none) to 5 (unable/very severe), with higher scores reflecting worse symptoms and function. The total score is calculated based on the following formula: ([(sum of n responses)/n] −1)*(25), where n represents the number of completed items. Improvement was defined as a reduction in the total score and MCID as a reduction of $\geq$10 points from baseline.[17]

Both the WOMAC and DASH questionnaires were administered at baseline, after the final treatment session, and at both follow-up visits.

Outcome satisfaction was measured using the Subject Satisfaction Questionnaire (SSQ), administered after the final treatment and at both follow-ups. Treatment comfort was evaluated using the Therapy Comfort Questionnaire (TCQ), completed after the final treatment. Both instruments used a 5-point Likert scale (0 = strongly disagree, 5 = strongly agree). The TCQ also included a Numerical Rating Scale (NRS) for pain, where participants rated discomfort from 0 (no pain) to 10 (worst possible pain).

Relative differences to baseline total scores were calculated for each subject individually, and then averaged across participants for each time point. Mean scores for pain (5 items), stiffness (2 items) and functional limitation (17 items) of WOMAC subscales were assessed, as well as symptoms (5 items regarding pain, stiffness, weakness and tingling), functional limitation (22 items), sleep difficulty (1 item), social (1 item) and work limitation (1 item) components of the DASH questionnaire. Changes in WOMAC and DASH scores were analyzed using Friedman's test to assess statistical significance. Post-hoc Dunn's test was performed for multiple comparisons of total scores across time points. Data from the subjects lost to follow-up was not included in the statistical analysis due to missing values. All analyses were conducted using GraphPad Prism (GraphPad Software, Boston, MA), with a significance level set at $\alpha = 0.05$.

3. Results

Thirty-six subjects (n = 36; 9 males, 27 females; mean age 50.8 ± 14.4 years; BMI 24.8 ± 4.0 kg/m^2) were enrolled in the study. One participant (n = 1) withdrew from the treatment before completing it without providing a reason and was excluded from the evaluation. Another subject (n = 1) was lost to follow-up at both the 1-month and 3-month assessments.

As a result, post-treatment data were evaluated for 35 subjects (n = 35; mean age 51.2 ± 14.4 years; 9 males, 26 females; BMI 24.9 ± 4.0 kg/m^2), and follow-up data were available for 34 participants (n = 34; mean age 50.7 ± 14.3 years; 9 males, 25 females; BMI 24.8 ± 4.1 kg/m^2).

Treatment areas included the elbow (n = 5), wrist (n = 10), upper arm (n = 2), lower forearm (n = 1), hips (n = 5), knee (n = 9), and ankle (n = 3). Twenty-eight subjects reported pain in the treated area, three had a history of injury, and four had a history of surgery in the treated region. Twenty-five participants received bilateral treatment, while five were treated on the left extremity and five on the right.

3.1. Western Ontario and McMaster Universities Arthritis Index (WOMAC)

The WOMAC was used to evaluate seventeen participants. At baseline, the mean total WOMAC score was 32.3 ± 15.9. Following the final treatment session, the score significantly decreased to 14.9 ± 15.5 ($p = 0.004$), representing a 62.0 % reduction. Further reductions were observed at follow-up, with scores declining to 13.2 ± 17.7 at 1 month ($p = 0.002$, representing a 65.1 % reduction) and 11.3 ± 14.7 at 3 months ($p < 0.001$, representing a 68.3 % reduction).

The proportion of participants reaching MCID was 88.2 % after the final treatment, 81.3 % at 1 month, and 87.5 % at 3 months.

Analysis of WOMAC subscales revealed consistent improvements across all domains. The pain subscale score decreased by 54.3 % after the final treatment, 57.9 % at 1 month, and 61.5 % at 3 months. Stiffness showed a 50.8 % reduction after the final treatment, 61.7 % at 1 month, and 51.2 % at 3 months. Although the greatest improvement in stiffness occurred at 1 month, the reduction in severity, from moderate at baseline to slight, was sustained at 3 months. The functional limitation subscale improved by 54.0 % post-treatment, 59.2 % at 1 month, and 68.3 % at 3 months. These trends are illustrated in Fig. 1, and mean subscale scores are summarized in Table 1.

3.2. Disabilities of the arm, shoulder, and hand (DASH) questionnaire

Eighteen participants who received treatment for upper extremity conditions were assessed using the DASH questionnaire. The mean baseline score was 32.1 ± 21.0. This decreased significantly to 16.8 ± 14.7 after the final treatment ($p = 0.005$), reflecting a 15.3 ± 10.3 or 49.0 % reduction. Continued improvement was observed at follow-up, with scores of 14.7 ± 12.4 at 1 month ($p < 0.001$, 17.4 ± 12.9 or 46.6 % reduction) and 8.9 ± 10.8 at 3 months ($p < 0.001$, 23.2 ± 18.9 or 67.7 % reduction).

The proportion of subjects reaching MCID was 66.7 % after the final treatment, increasing to 77.8 % at 1 month, which was sustained at 3 months.

Similar to the WOMAC subscales, DASH components showed continuous improvement. Functional limitation improved by 23.0 % following the final treatment, increasing to 28.0 % at 1 month and 37.8 % at 3 months. Symptom severity decreased by 34.0 %, 35.2 %, and 45.3 %, respectively, across the same intervals. Social limitation was reduced by 35.6 % after the final treatment and at 1 month, and by 44.4 % at 3 months. Limitation related to work decreased by 25.6 % post-treatment, 34.9 % at 1 month, and 46.5 % at 3 months. Sleep difficulty improved by 44.2 % after the final treatment, 40.4 % at 1 month, and 53.8 % at 3 months. These results are illustrated in Fig. 2, and mean subscale scores are presented in Table 2.

3.3. Patient cases

A 62-year-old male patient presented with persistent left knee pain that had not improved despite previous physical therapy. In the initial WOMAC evaluation, he reported extreme difficulty with heavy domestic duties, severe pain when climbing stairs, and severe discomfort while lying in bed. His total WOMAC score at baseline was 44. After three months, the patient noted improvements, based on the SSQ: he had begun exercising, experienced better mobility and range of motion, and reported less discomfort. His WOMAC score improved by 81.8 %.

In another case, a 26-year-old female patient reported bilateral wrist pain that had persisted for six months. Her baseline DASH score was 37.5 points. After three months, all her symptoms had resolved, and her DASH score had improved to 0, signifying a complete recovery.

Table 1
Mean scores of WOMAC subscales across time points.

WOMAC Subscale	Baseline	Final Treatment	1 Month	3 Months
Pain	1.365	0.624	0.575	0.525
Stiffness	1.794	0.882	0.688	0.875
Functional Limitation	1.287	0.592	0.526	0.408

3.4. Subject Satisfaction Questionnaire (SSQ)

The average Subject Satisfaction Questionnaire score across all participants and questions was 4.0 ± 0.7 after the final treatment, 4.1 ± 0.7 at 1 month, increasing to 4.2 ± 0.8 at 3 months. 91.2 % of participants reported satisfaction with the outcomes and that their range of motion had improved, and 97.1 % noted that their treated joints felt better. Furthermore, 82.4 % reported increased mobility, and 76.5 % experienced enhanced flexibility. The percent of subjects in agreement with each SSQ statement is described in Table 3.

3.5. Safety and Therapy Comfort Questionnaire

No adverse event or side effect occurred throughout the study. According to the Therapy Comfort Questionnaire, 91.4 % of participants found the treatments comfortable. The mean reported score on the NRS was 0.3 ± 1.0 points.

4. Discussion

This study evaluated the efficacy of HIFEM stimulation in enhancing the musculoskeletal system function. The desired outcomes were reflected in significant improvements in both WOMAC and DASH scores, with reductions peaking at 68 % three months post-treatment. Participants rated the outcomes positively, giving an average score of 4.2 out of 5 at the 3-month follow-up. Additionally, 91.4 % of participants found the treatments comfortable. A low NRS score of 0.3 out of 10 indicated that the stimulations were painless. Absence of adverse events or side effects supports the safety of the treatments.

The majority of participants achieved the MCID at three months post-treatment (87.5 % for WOMAC scores and 77.8 % for DASH scores). The MCID represents a change following an intervention that is considered meaningful to the patient. For DASH, the MCID was defined as an improvement of ≥10 points, and for WOMAC, a relative improvement of ≥22 %, based on thresholds established for surgical procedures,[16,17] as cut-offs were not estimated for electromagnetic stimulations yet. Immediately after the final treatment, the mean improvements substantially exceeded these MCID thresholds.

Furthermore, these changes were comparable to improvements observed after surgical procedures. In a study by Gummesson et al.,[18] the mean baseline DASH score was 35 ± 22 (compared to 32 ± 21 in the

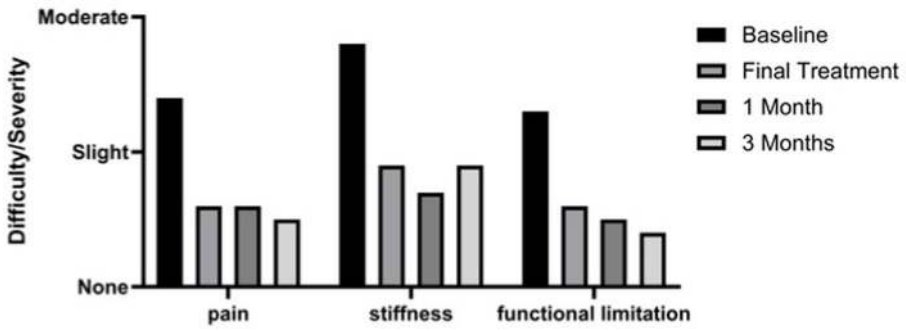

Fig. 1. Graphical illustration of the change in difficulty/severity of WOMAC subscales over time.

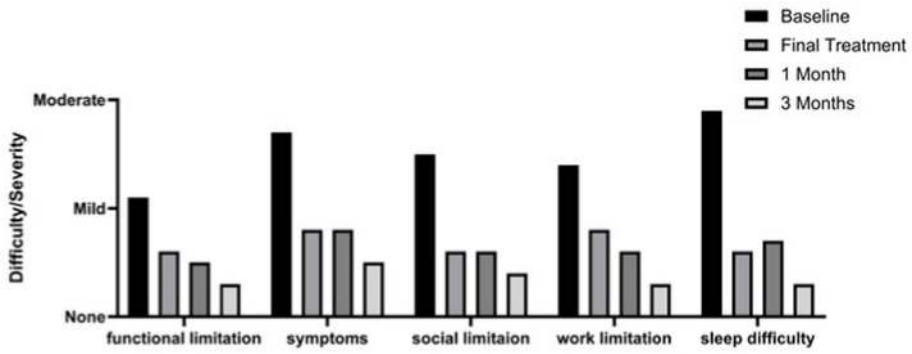

Fig. 2. Graphical illustration of the change in difficulty/severity of DASH components over time.

Table 2
Mean scores of DASH subscales across time points. Notably, sleep difficulty improved from moderate severity at baseline to minimal levels at the 3-month follow-up.

DASH Component	Baseline	Final Treatment	1 Month	3 Months
Functional Limitation	2.122	1.634	1.528	1.320
Symptoms	2.744	1.811	1.778	1.500
Social Limitation	2.500	1.611	1.611	1.389
Work Limitation	2.389	1.778	1.556	1.278
Sleep Difficulty	2.889	1.611	1.722	1.333

Table 3
The percentage of subjects in agreement with each statement from the Subject Satisfaction Questionnaire.

	Final Treatment	1 Month	3 Months
The range of motion in the treated joints has improved after the treatments.	80.0 %	88.2 %	91.2 %
The stiffness in the treated joints has improved after the treatments.	91.4 %	91.2 %	85.3 %
The treated joints feel better after the treatments.	91.4 %	91.2 %	97.1 %
The mobility of the treated joints has improved after the treatments.	88.6 %	85.3 %	82.4 %
The flexibility of the joints has improved after the treatments.	68.6 %	79.4 %	76.5 %
The discomfort in the treated joint has reduced after the treatment.	88.6 %	91.2 %	85.3 %
The pain in the treated joint has reduced after the treatment.	85.7 %	85.3 %	79.4 %
I feel more comfortable and confident during physical activities after the treatments.	88.6 %	73.5 %	76.5 %
The treated joints feel less fragile after the treatments.	82.9 %	73.5 %	82.4 %
I am satisfied with the treatment results.	88.6 %	88.2 %	91.2 %

present study). Following upper extremity surgery, the DASH score decreased by 15 ± 13 points, whereas in the present study, the reduction was 15 ± 10 points immediately post-treatment and 23 ± 19 points at three months. Similarly, in an analysis of WOMAC score change one year after osteoplasty, Bachmeier et al. found a 53 % reduction in pain, a 43 % reduction in stiffness, and a 43 % improvement in physical function,[19] while this study observed a 61.5 % pain reduction, 51.2 % stiffness reduction, and 68.3 % physical functioning improvement at three months. Notably, the present procedure also outperformed results reported in a review article, where other electromagnetic stimulation approaches led to a 42 % improvement in WOMAC scores.[20] These findings suggest that meaningful change comparable to surgical interventions can be achieved after four stimulation sessions, with further improvements observed over time.

Changes observed in DASH and WOMAC scores were consistent with participants' responses on the Subject Satisfaction Questionnaire, which addressed additional aspects not captured by these standardized tools, observing further beneficial effects on range of motion, mobility, and flexibility.

Unlike pharmacological treatments, which may carry the risk of adverse events,[6] HIFEM procedures were well tolerated and associated with no reported side effects. Compared to physical therapy, which is typically the first-line treatment, the HIFEM approach involves only four high-comfort sessions and may be particularly suitable for patients who avoid physical therapy due to scheduling conflicts, limited mobility, or previous painful experience. Additionally, HIFEM may go beyond symptom relief by targeting the underlying source of symptoms, promoting tissue regeneration,[15,21] as discussed above, potentially contributing to longer-lasting clinical improvements. Further research is, however, needed to confirm this hypothesis.

Despite the promising findings, the limitations of the study should be acknowledged. Firstly, although the sample size was sufficient to detect statistically significant changes, it remained relatively small. Secondly, the follow-up period of three months limited the assessment of long-term outcome sustainability. Lastly, the absence of a control or sham group restricts the ability to attribute improvements specifically to the HIFEM treatment, as opposed to placebo effects or natural progression.

Nonetheless, the study also has several notable strengths. By including treatment across multiple anatomical areas, the applicability and generalizability of the findings were broadened to encompass various musculoskeletal conditions. The use of validated, change-sensitive instruments ensured reliable and accurate outcome assessments. Additionally, incorporating self-reported measures provided valuable insights into patients' subjective experiences and perceived benefits of the treatment.

5. Conclusions

Non-invasive HIFEM treatments led to an average of 68 % improvement in both WOMAC and DASH scores, reflecting significant reductions in pain and stiffness alongside enhanced physical function. Patients also reported greater mobility, improved range of motion, and less discomfort. These results support HIFEM as a safe and effective approach for enhancing musculoskeletal conditions as an independent modality or adjunctive to traditional treatments.

CRediT authorship contribution statement

Eugune Lou: Investigation, Project administration, Writing - original draft; Shawn Trokhan: Investigation, Project administration, Writing - review & editing; Pamela Levine: Investigation, Project administration, Formal analysis, Writing - review & editing; All authors have read and agreed to the published version of the manuscript.

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki, and was approved by the Institutional Review Board Advarra (ID: Pro00075291). Each subject was informed about the study procedures, and signed a written informed consent form.

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