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Ancillary Evaluation of Simultaneous Application of HIFEM and Synchronized Radiofrequency for Pain and Discomfort Reduction in the Upper and Lower Extremities

Jonathan Schoeff^{1*}, Mohamed Abdulhamid², Philip Saville³, Shawn Trokhan⁴, Pamela Levine⁵, Eugene Lou⁶

¹The Longevity Lab, E Prentice Ave Suite, Greenwood Village, CO, USA

²Royal Spine Surgery, E Bell Rd, Scottsdale, AZ, USA

³Saville Spine Institute, Village Square Crossing, Palm Beach Gardens, FL, USA

⁴Trokhan Orthopaedics LLC, Closter Dock Road, Closter, NJ, USA

⁵New York Orthopedic Hand Surgery, Prospect Park West, Brooklyn, NY, USA

⁶Southeast Texas Orthopedic Group, Gessner Road, Houston, TX, USA

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*Correspondence:

*Dr. Jonathan Schoeff, The Longevity Lab, E Prentice Ave Suite, Greenwood Village, CO, USA;
Email: jonschoeff@gmail.com

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Keywords

HIFEM

Synchronized RF

Pain Reduction

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WOMAC

DASH

Abstract

Background: Pain and discomfort in the extremities are common, yet current treatments often provide only temporary relief or are limited by adverse effects. Therapies utilizing electromagnetic field energy, with or without synchronized radiofrequency (RF), may offer a non-invasive alternative.

Methods: This ancillary, post hoc analysis combined data from two clinical studies originally designed to evaluate musculoskeletal outcomes. Fifty-seven participants (24 males, 33 females; age 23–78 years) underwent four weekly HIFEM or HIFEM+RF sessions targeting upper or lower extremities. Pain-related outcomes were assessed using the Subject Satisfaction Questionnaire (SSQ), WOMAC, and DASH at baseline, post-treatment, 1-month, and 3-month follow-ups.

Results: At 3 months post-treatment, 75% of participants reported reduced pain and 77% reduced discomfort on the SSQ. WOMAC pain scores decreased by 60% from baseline ($d = 1.24$ [95% CI: 0.43, 2.06], $p = 0.001$), and DASH pain scores by 45% ($d = 1.66$ [95% CI: 0.81, 2.51], $p < 0.001$), both representing large effect sizes. Notable improvements were observed in nocturnal pain and activity-related discomfort. Treatments were well tolerated, with 93% overall satisfaction and 91% reporting no procedural pain.

Conclusion: Clinically meaningful reductions in extremity pain and discomfort with large effect sizes, high patient satisfaction, and excellent tolerability were observed following the simultaneous HIFEM and synchronized RF treatment. These findings support further prospective evaluation of this combined non-invasive modality in musculoskeletal pain management.

Introduction

Pain and discomfort in the extremities constitute a significant clinical burden, affecting up to 31% of the population in the upper and 37% in the lower limbs¹. Conditions such as musculoskeletal disorders, post-surgical pain, and chronic neuropathic syndromes are prevalent and often lead to functional limitations, decreased mobility, and increased healthcare utilization^{2,3}. Apart from impairing physical function, pain of this nature is a multidimensional burden that further reduces the quality of life by causing psychological distress, disrupting social and familial roles, limiting work capacity, and creating economic hardship⁴. Current treatment options include pharmacological interventions, physical therapy, and invasive procedures. Providing variable relief, they are frequently associated

with adverse effects or limited long-term efficacy⁵⁻⁷. Thus, non-invasive non-pharmacological therapeutic strategies are of great clinical relevance, offering ease of administration and adaptability to individual patient circumstances and lifestyle by avoiding extended post-procedural downtime.

In the past decade, magnetic therapies have gained increasing attention and use in rehabilitation for musculoskeletal conditions, accompanied by a growing body of research investigating their analgesic and anti-nociceptive effects^{8,9}. The results and efficacy of these therapies appear to strongly depend on the type of electromagnetic field, its intensity, frequency, and the specific treatment protocol used¹⁰. These electromagnetic frequencies influence the cellular and neurological processes, modulate inflammation, and interact with endogenous bioelectrical activity, acting through a number of mechanisms¹¹. While conventional non-invasive approaches such as pulsed electromagnetic field (PEMF) therapy and transcutaneous electrical nerve stimulation (TENS) have demonstrated benefits in modulating pain and targeting superficial tissues or nerves, their effects are limited by lower field strengths (10 millitesla range) and penetration depths^{12,13}. To address these limitations, a novel functional wellness protocol integrating HIFEM technology has been developed. This approach employs shorter, low-intensity pulses at higher frequencies (up to 120 Hz), in contrast to the muscle-strengthening protocols used previously. HIFEM stimulation has been shown to activate satellite cells, promote muscle hypertrophy and hyperplasia, and enhance the function of connective tissues, offering a broader and deeper therapeutic effect^{14,15}.

The data presented and subsequently analyzed for pain reduction were collected from two separate studies^{16,17}. In both groups, subjects received HIFEM, and depending on individual circumstances, Synchronized Radiofrequency (RF) treatments. Synchronized RF complements the HIFEM treatment by providing increased circulation and accelerated tissue healing¹⁸. Although the parent studies were designed to evaluate primary outcomes adjacent to pain relief, self-reporting questionnaires contained several pain-related items. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaires, along with Subject Satisfaction Questionnaires (SSQ) and Therapy Comfort Questionnaires (TCQ), were administered to patients depending on the study. Combining data from these studies as an ancillary analysis provides a unique opportunity to investigate the analgesic effects of HIFEM and Synchronized RF therapies using an integrated platform.

Methods

This ancillary analysis compiles data from two studies investigating HIFEM stimulation in enhancing the musculoskeletal system function, as well as its procedural safety, therapy comfort, and participant satisfaction with outcomes. The present post hoc study evaluates the application of HIFEM and Synchronized Radiofrequency for pain and discomfort reduction in the upper and lower extremities by evaluating questionnaire pain-related items.

Participants were recruited into parent studies based on the following inclusion criteria: age over 21 years, body mass index (BMI) ≤ 35 kg/m², 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, drug pumps, pregnancy, postpartum or nursing status, hemorrhagic disorders, coagulation abnormalities, the use of anticoagulant medications, cardiovascular diseases, or acute inflammation. All participants were informed about the study procedures and provided written informed consent before enrollment. The parent studies were conducted in accordance with the Declaration of Helsinki and received Institutional Review Board approval. The studies were registered at the ClinicalTrials.gov site (Identifiers: NCT06703749 & NCT06677086). Participants received HIFEM & Synchronized RF treatments (Emsculpt NEO, BTL Industries Inc., Boston, MA, USA) targeting either the upper or lower extremities based on group assignment.

Participants

This ancillary analysis combined data from two independent clinical studies: one investigating musculoskeletal improvements in the upper and lower extremities, whereas the second study investigated the lower extremities only. In total, 57 patients (24 males, 33 females; age range: 23–78 years; BMI: 18.5–35.0 kg/m²) seeking enhancement of musculoskeletal function were included. Participants were allocated into two treatment groups based on their primary indication:

Joint group: 34 patients (9 males, 25 females; age range: 23–78 years; BMI: 18.5–32.7 kg/m²) targeting overall joint health and function.

Muscle group: 23 patients (15 males, 8 females; age range: 33–76 years; BMI: 19.5–35.0 kg/m²) targeting muscle atrophy and functional impairments.

A flow diagram is provided in Figure 1, illustrating participant enrollment, allocation, and questionnaire completion.

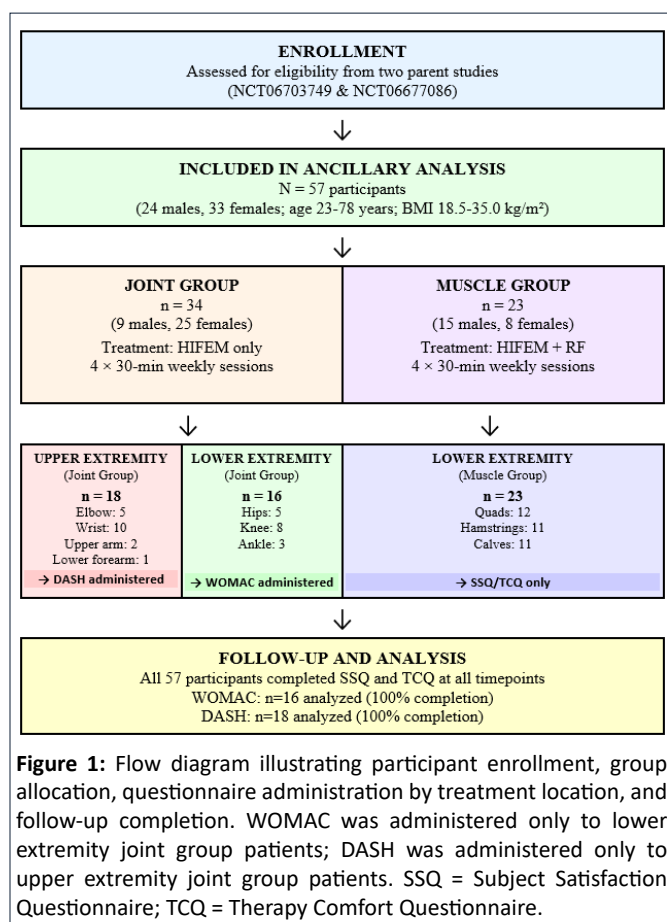


Figure 1: Flow diagram illustrating participant enrollment, group allocation, questionnaire administration by treatment location, and follow-up completion. WOMAC was administered only to lower extremity joint group patients; DASH was administered only to upper extremity joint group patients. SSQ = Subject Satisfaction Questionnaire; TCQ = Therapy Comfort Questionnaire.

Interventions

The joint group received four 30-minute HIFEM treatments, while the muscle group received four 30-minute combined HIFEM and Synchronized Radiofrequency (HIFEM+RF) treatments. All sessions were administered once weekly over a four-week period. Treatment intensity was individualized based on participant feedback, with a maximum of 100% intensity. Follow-up assessments were conducted at 1 month and 3 months post-treatment.

Outcome Measures

Patient-reported outcomes were assessed using the following self-reported questionnaires:

Subject Satisfaction Questionnaire (SSQ): Four pain-related items analyzed using a 5-point Likert scale (1 = Strongly disagree, 5 = Strongly agree).

Therapy Comfort Questionnaire (TCQ): Comfort assessed using a 5-point Likert scale, and pain in relation to therapy administration intensity evaluated using a visual analogue scale (VAS; 0 = none, 10 = worst possible pain).

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC): Administered to joint group patients treated for the lower extremities; included five pain-related items forming the Pain domain, rated on a 5-point scale (0 = none, 4 = extreme).

Disabilities of the Arm, Shoulder, and Hand (DASH): Administered to joint group patients treated for the upper extremities; included three pain-related items on sleeping difficulty due to pain, pain severity, and pain during specific activities, rated on a 5-point scale (1 = none, 5 = unable/extreme).

WOMAC was administered exclusively to joint group patients receiving lower extremity treatment (n = 16), while DASH was administered to joint group patients receiving upper extremity treatment (n = 18), reflecting the condition specificity of these validated instruments.

Follow-Up and Statistical Considerations

Follow-up assessments, including questionnaire administration, were conducted after the final treatment and at 1-month and 3-month post-treatment. Additionally, DASH and WOMAC questionnaires were administered at the baseline as well. All questionnaire results were compared against the earliest available time point, the baseline, or after the last therapy using the Wilcoxon signed-rank test. Effect sizes were calculated using Cohen's d with 95% confidence intervals. A p-value of <0.05 was considered statistically significant.

Results

The treatment was well tolerated, with no adverse effects reported. Fifty-seven patients (33 female, 24 male; mean age 51 ± 14 years, range 23–78) across both cohorts completed both the SSQ and TCQ. The joint group (n = 34) received treatment in the following areas: the elbow (n = 5), wrist (n = 10), upper arm (n = 2), lower forearm (n = 1), hips (n = 5), knee (n = 8), and ankle (n = 3). Pain in the treated area was self-reported by 28 participants in the joint group; 3 had a history of injury, and 4 had previous surgery in the same region. From the joint group, sixteen subjects have been identified to have completed the WOMAC questionnaire, along with eighteen subjects who have completed the DASH questionnaire. Within the muscle cohort, 23 patients were treated for muscle-related indications: 11 for a combined quadriceps–hamstrings condition, 1 for quadriceps only, and 11 for calves only. In total, this included 12 patients treated for quadriceps, 11 for hamstrings, and 11 for calves. Across both cohorts, 35 subjects underwent bilateral evaluation and treatment, whereas 22 were treated unilaterally (14 left and 8 right).

Subject Satisfaction and Treatment Comfort Questionnaires

At 3 months post-treatment, patient-reported outcomes demonstrated high levels of satisfaction and symptomatic improvement. Across the full cohort, 93% of patients reported that the treated area felt better, 77% indicated reduced discomfort, and 75% experienced a reduction in

pain. Summary of SSQ results regarding pain-related items is summarized in Figure 2. Overall treatment satisfaction was reported by 93% of participants. Treatment tolerability was also favorable, with 88% perceiving the therapy as comfortable and 91% reporting no pain during the procedure despite underlying musculoskeletal impairments, supported by low VAS scores of 0.4 (n = 57) in relation to therapy administration.

WOMAC

A total of sixteen (n = 16) joint group subjects who received lower extremity treatment completed the WOMAC questionnaire. The mean pain domain score of the WOMAC across all patients that completed the evaluation demonstrated a 60% reduction from the baseline to 3-month follow-up (p = 0.001), with a large effect size (d = 1.24 [95% CI: 0.43, 2.06]). Each item

within the domain has shown improvement, as illustrated in Table 1 and Figure 3.

Eleven subjects reported at least mild nocturnal pain at baseline, including five with moderate-to-severe difficulty. At 3 months post-treatment, 73% of these patients reported no nocturnal pain, with only two patients reporting mild and one patient reporting moderate symptoms. In total, 82% of these patients improved in this item. Nocturnal pain demonstrated the largest relative improvement (76% reduction) with a large effect size (d = 1.05).

Notably, a 50-year-old male participant who initially reported severe knee pain (WOMAC score ≥ 3) during stair climbing at baseline, along with moderate scores on three other pain-related items (nocturnal, rest, and weight-bearing), indicated no pain across all items at the 3-month follow-up.

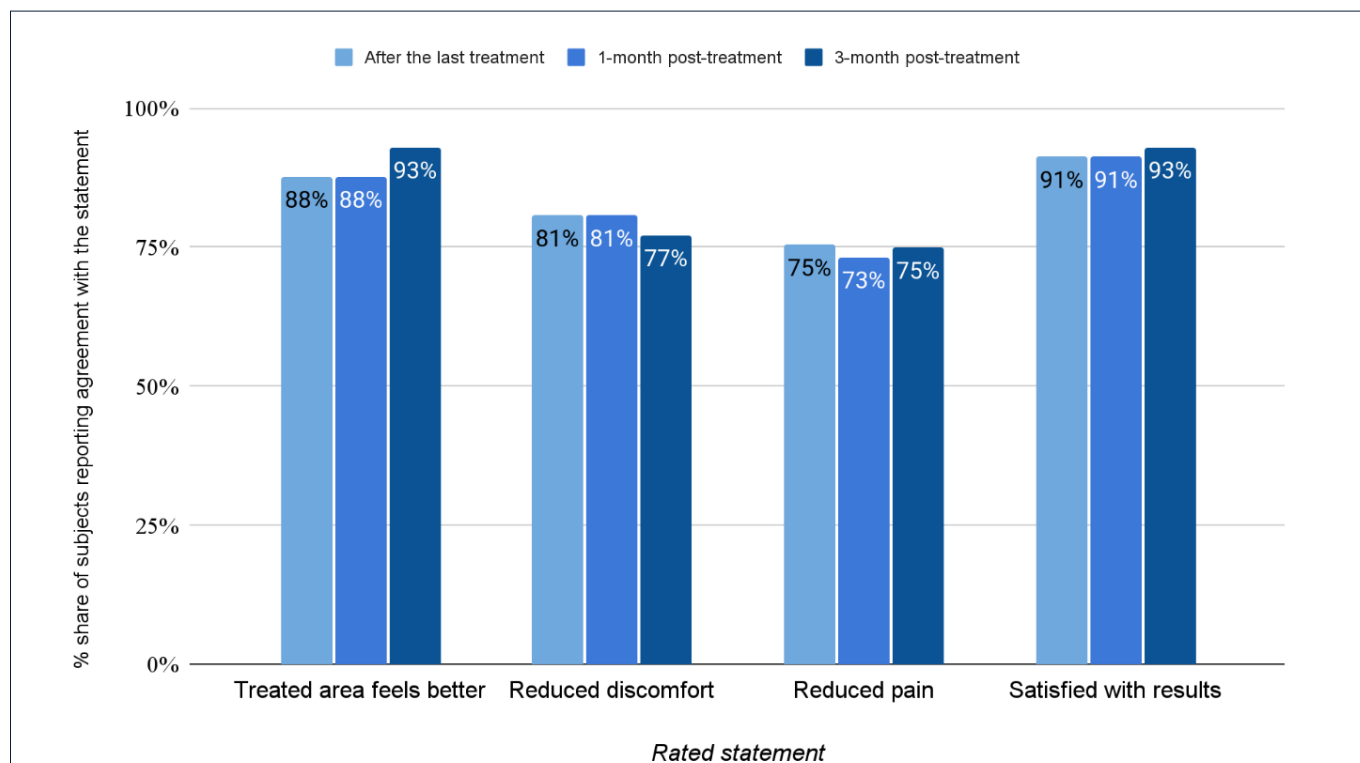


Figure 2: Subject Satisfaction Questionnaire (Pain-related Items)

Graphical representation of the SSQ outcomes covering data from all patients (n = 57, 100% of total participants) included in the ancillary study. SSQ was administered after the last treatment, 1-month post-treatment, and 3-month post-treatment follow-ups.

Table 1: WOMAC Pain Domains: Scores, Percent Change, and Effect Sizes at 3-Month Follow-Up (n = 16)

Pain Domain	Baseline Mean (SD)	3-Month Mean (SD)	Cohen's d [95% CI]	Magnitude	% Change	p-value
Walking	1.50 (1.21)	0.75 (1.29)	0.60 [-0.12, 1.32]	Medium	-50%	0.023
Stair climbing	2.06 (1.24)	0.81 (1.28)	0.99 [0.22, 1.77]	Large	-61%	0.004
Nocturnal	1.06 (0.93)	0.25 (0.58)	1.05 [0.27, 1.83]	Large	-76%	0.003
Rest	0.50 (0.82)	0.12 (0.34)	0.60 [-0.12, 1.32]	Medium	-75%	0.031
Weight bearing	1.38 (1.09)	0.69 (1.01)	0.65 [-0.08, 1.38]	Medium	-50%	0.020
Total Score	6.50 (2.90)	2.62 (3.32)	1.24 [0.43, 2.06]	Large	-60%	0.001

Note: Effect size interpretation per Cohen (1988): |d| < 0.2 = negligible, 0.2–0.5 = small, 0.5–0.8 = medium, ≥0.8 = large.

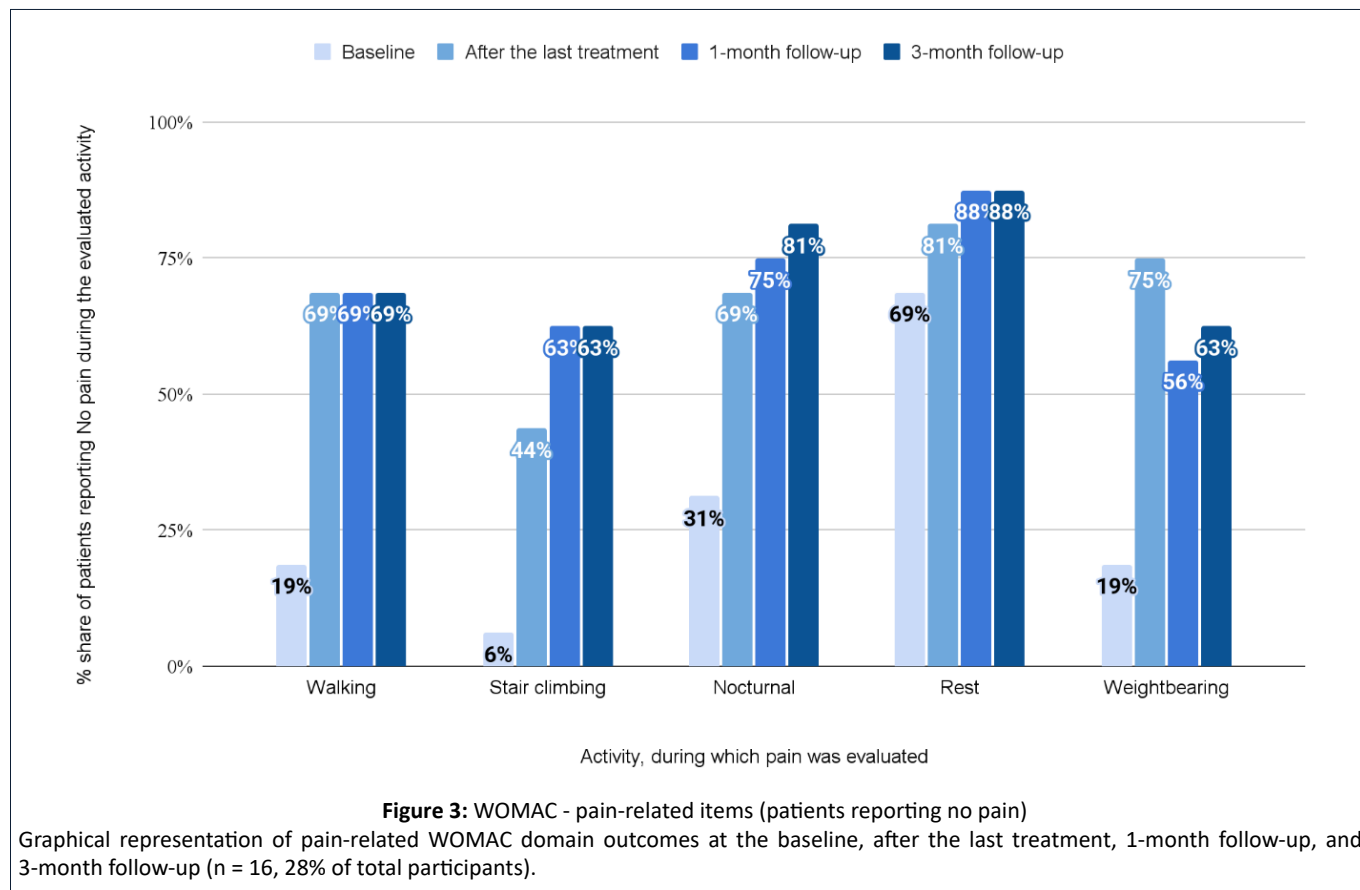


Table 2: DASH Pain Items: Scores, Percent Change, and Effect Sizes at 3-Month Follow-Up (n = 18)

Pain Item	Baseline Mean (SD)	3-Month Mean (SD)	Cohen's d [95% CI]	Magnitude	% Change	p-value
Sleep difficulty due to pain	2.89 (1.08)	1.33 (0.59)	1.79 [0.91, 2.66]	Large	-54%	<0.001
Pain	2.72 (1.02)	1.56 (0.70)	1.33 [0.55, 2.12]	Large	-43%	<0.001
Activity-specific pain	3.00 (1.03)	1.83 (0.86)	1.23 [0.46, 2.00]	Large	-39%	<0.001
Total Score	8.61 (2.66)	4.72 (1.96)	1.66 [0.81, 2.51]	Large	-45%	<0.001

Note: All individual items demonstrated large effect sizes (d > 0.8).

DASH

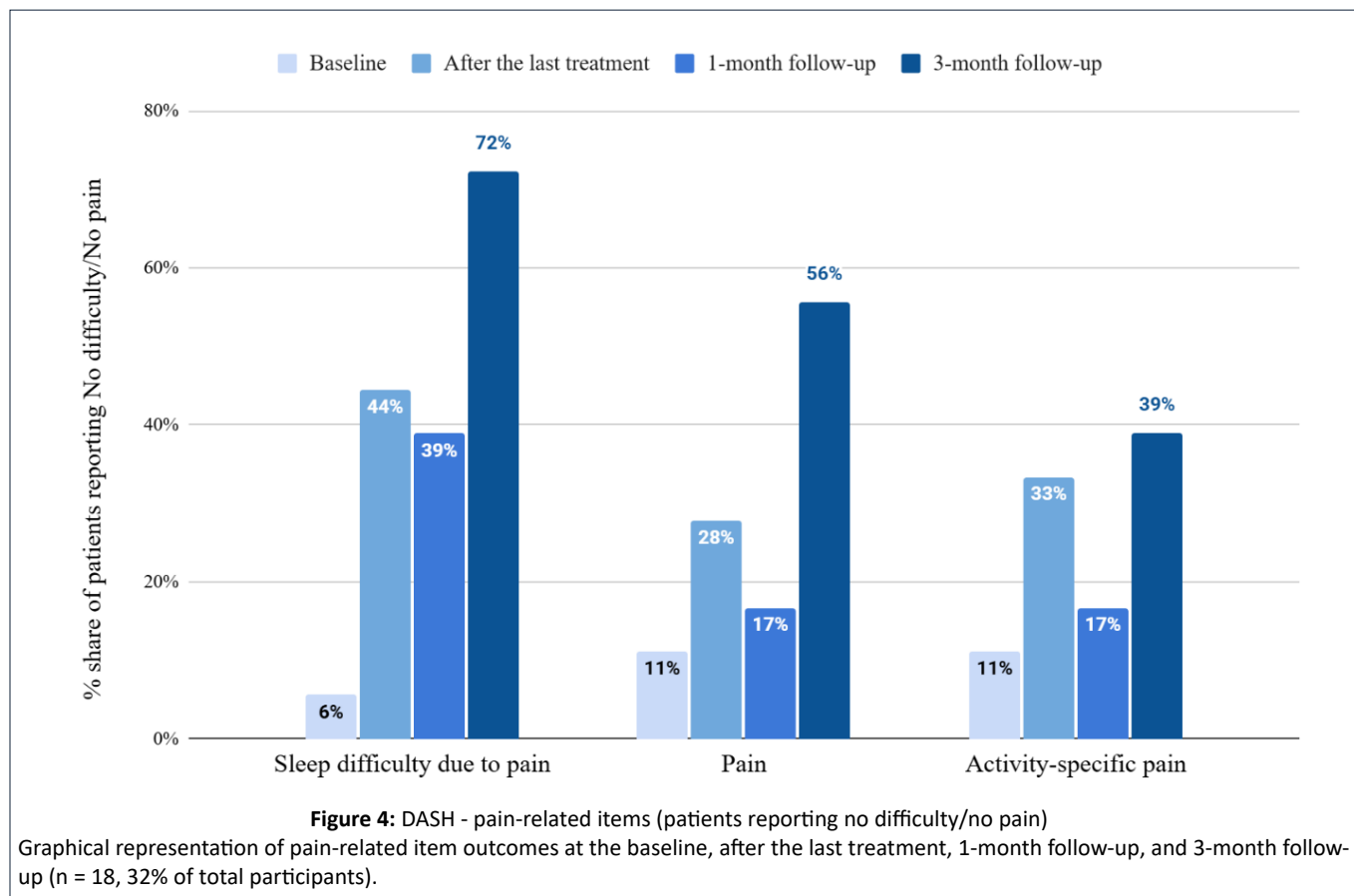
A total of eighteen (n = 18) joint group subjects who received upper extremity treatment completed the DASH questionnaire. The mean pain-related DASH item scores decreased by 45% (p < 0.001) from baseline, with a large effect size (d = 1.66 [95% CI: 0.81, 2.51]). (see Table 2), suggesting a marked reduction in pain affecting the arm, shoulder, or hand at the 3-month follow-up.

Furthermore, seventeen subjects reported at least mild difficulty sleeping due to pain in the arm, shoulder, or hand at baseline, with 4 reporting severe difficulty or being unable to do so. At 3 months post-treatment, 71% reported no difficulty sleeping (Figure 4), while the remainder experienced only mild-to-moderate difficulty. All patients who initially reported at least mild pain (n = 17) demonstrated improvement in this item. Sleep difficulty due to pain showed the largest effect size among DASH items (d = 1.79).

At the 3-month follow-up, a 49-year-old female reported being pain-free after receiving treatment for wrist pain. Initially, she had scored 4, 4, and 3 on a 5-point Likert scale for “Sleeping difficulty because of pain,” “Pain (general),” and “Pain when performing any specific activity”, respectively.

Discussion

This ancillary evaluation indicates that HIFEM therapy and HIFEM with Synchronized RF therapy is able to meaningfully reduce extremity pain and discomfort. Across both cohorts, patient-reported outcomes consistently improved. The WOMAC pain domain showed a 60% reduction with a large effect size (d = 1.24), and DASH pain items decreased by 45% with a large effect (d = 1.66) as well. The 95% confidence intervals for both total scores exclude zero, supporting the robustness of these findings despite the small sample sizes. Regarding the SSQ results, 77% of participants reported less discomfort, while 75%



experienced reduced pain (Figure 2). Although the data suggest immediate pain relief following the last treatment, the pain reduction scores peaked at the 3-month follow-up, indicating a gradual and durable effect with excellent tolerability; 91% of the patients described the procedures to be pain-free and comfortable despite previous musculoskeletal conditions. Finally, the SSQ reveals 93% of subjects were satisfied with the treatment at the 3-month follow-up.

The results align with the existing evidence that electromagnetic modalities reduce pain. Comparable trials of electromagnetic therapies frequently incorporate adjunctive interventions, including hot pack application, therapeutic ultrasound, or more invasive procedures such as intravenous infusion or electrode insertion¹⁹⁻²¹. These studies also tend to administer a greater number of therapy sessions, thus prolonging the treatment²². In contrast, the non-invasive HIFEM + Synchronized RF therapy has demonstrated comparable benefit with only four sessions. Clinically, these findings suggest that the modality could expand the management of musculoskeletal pain, particularly for patients with functional limitations or intolerance to pharmacological and invasive options. Improvements in nocturnal pain and activity-related discomfort (Figures 3 and 4) indicate a potential impact on the quality of life improvement.

Growing evidence demonstrates a strong association between muscle strengthening and pain reduction across a range of conditions²³. Regarding hip and knee osteoarthritis, resistance training has shown improved function and pain reduction²⁴. Similarly, eccentric and concentric strengthening of the wrist extensors has shown to reduce symptoms in elbow tendinopathy more effectively than passive treatments²⁵. Beyond joint mechanics, increases in skeletal muscle mass correlate with reduced hyperalgesia and reported pain, indicating further analgesic benefits of strength training²⁶. Findings of a meta-analysis imply neurobiological modulation as an effect of exercise, leading to the lowering of the nociceptive threshold and inhibitory mechanism adaptation²⁷. Parent study primary outcomes of this ancillary analysis have indeed focused on muscle strengthening via HIFEM technology in a rehabilitative context. Furthermore, diathermic effects of RF have been established to reduce pain through deep tissue heating, vasodilation, enhanced blood flow, and modulation in nociceptive signaling²⁸. Thus, it is unsurprising to observe pain reduction across the cohorts. Nonetheless, it would be of interest to investigate the specific mechanisms by which HIFEM contributes to pain relief, both independent of and in conjunction with the muscle-strengthening effects.

As a post hoc analysis, pain outcomes were not prospectively powered primary endpoints. The parent

studies were designed to assess muscle function and musculoskeletal outcomes rather than pain efficacy; pain data were collected via validated instruments as secondary measures. Sample sizes were modest ($n = 16$ for WOMAC, $n = 18$ for DASH), though the 95% confidence intervals for total scores remained above zero, supporting the robustness of the large effect sizes observed.

The single-arm design of the pooled analysis precludes definitive causal attribution; while the magnitude and consistency of improvements across validated instruments like WOMAC and DASH provide supportive evidence, contributions from placebo response cannot be excluded. Follow-up was limited to 3 months; longer-term durability data would strengthen conclusions about sustained efficacy.

Future directions should include prospective, randomized controlled trials with pain intensity as a primary endpoint, comparative studies against standard modalities, mechanistic evaluations of neuromuscular and connective tissue pathways, and extended follow-up periods. While the therapy offers the advantage of individualized settings, further protocol optimization for analgesia would be of great interest.

Conclusion

This ancillary evaluation provides novel insights into the potential of simultaneous HIFEM and synchronized RF therapy for alleviating extremity pain and discomfort. Although the parent studies were not primarily designed to assess analgesic outcomes, post hoc analysis of patient-reported measures revealed consistent improvements across multiple instruments with large effect sizes (WOMAC $d = 1.24$; DASH $d = 1.66$). At three months post-treatment, most patients reported reductions in pain and discomfort alongside enhanced satisfaction and comfort. Taken together, these findings suggest that combined HIFEM and synchronized RF therapy confers clinically relevant, well-tolerated reductions in extremity pain. They justify further prospective evaluation.

Declaration of Interests

All authors are clinical investigators and speakers for BTL Industries, the sponsor of the clinical trial.

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