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The Efficacy of Instrument-Assisted Soft Tissue Mobilization as an Adjunct to Therapeutic Exercise in Knee Osteoarthritis: A Parallel-Group Randomized Clinical Trial

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ABSTRACT

Background: In adults over 40, knee osteoarthritis (OA) commonly causes pain and dysfunction, often associated with tight soft tissues, quadriceps weakness, and limited range of motion. While therapeutic exercise is the main non-surgical treatment, its effectiveness can be limited by myofascial restriction. This study aimed to assess the effectiveness and safety of Instrument-Assisted Soft Tissue Mobilization (IASTM) combined with the exercise program compared with exercise alone in reducing pain, knee range of motion, and function in individuals with knee OA.

Methods: This is a parallel-group randomized trial with participant blinding, conducted over 12 months at two centers: Physio Care Center, Gujarat, and SK Physio OPD, Islamabad. Fifty patients with knee OA (Kellgren-Lawrence grade II-III) were randomly assigned to Group A (exercise + IASTM) or Group B (exercise only), with 25 patients in each group. All patients received 3 sessions per week for 6 weeks and were assessed at baseline and at 6 weeks using the Visual Analog Scale, Goniometry, and WOMAC index respectively.

Results: Both groups demonstrated improvement, with Group A (exercise + IASTM) demonstrating more pain reduction, knee flexion improvement, and residual effects compared to Group B (exercise only). All results in Group A were $p<0.01$ compared with Group B, which reduced extension deficits and showed better WOMAC scores.

Conclusion: The findings revealed that combining IASTM with therapeutic exercise yielded greater improvements in pain, knee mobility, and function than exercise alone in knee OA, making it a valuable complementary tool for traditional knee rehabilitation.

Keywords: *Exercise; Knee; Mobility; Osteoarthritis; Range of Motion.*

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INTRODUCTION

Osteoarthritis (OA) of the knee is a leading cause of persistent pain, disability, and reduced quality of life in adults over 401. According to the 2021 Global Burden of Disease, the number of people with knee OA exceeds 374 million, and its prevalence is projected to rise further until 2035 as the global population ages and expands[1]. This trajectory can further increase costs of care and productivity losses, leading to increasing significance of conservative treatments that are effective, affordable, and easily replicable[1].

Knee OA does not only involve loss of cartilage. The overall presentation is driven by synovium inflammation, sub-chondral bone remodeling, quadriceps weakness, and tightness of the fascia or myofascial tissue around the knee[2]. These alterations in soft tissues can perpetuate poor movement patterns, restrict joint mobility, and reduce the benefits of exercise training (3). This has led to an increased focus on rehabilitation strategies that address both the joint itself and the surrounding soft tissues.

This has led to increased interest in manual therapy techniques that directly address fascial restrictions to enhance outcomes from exercise-based therapy, especially when some stiffness and decreased mobility persist after routine care[3,4]. Instrument-Assisted Soft Tissue Mobilization (IASTM) is one such manual approach, in which purpose-built tools are used to deliver controlled mechanical force to areas of soft tissue restriction. Proposed mechanisms include greater tissue extensibility, release of fascial adhesions, and activation of local fibroblasts[5]. A growing set of trials has started evaluating IASTM specifically in people with knee OA, with reported benefits spanning gait-related muscle activity when paired with exercise,[5] improved clinical performance after iliotibial band treatment,[6] better gait kinetics,[7] gains in lower-limb strength and sit-to-stand ability,[8] and wider improvements in function and quality of life,[10], and a meta-analysis spanning several musculoskeletal conditions concluded that IASTM produces a meaningful improvement in range of motion[9]. Other early-stage work points the same way, describing symptom relief among knee OA patients who received IASTM[9,10].

That said, the existing literature varies considerably in treatment dose, comparison arms, and outcome measures, and relatively few studies have tested IASTM layered onto a standardized exercise protocol against exercise by itself within a tightly controlled, parallel-group design with concealed allocation. It is therefore unclear whether IASTM provides any additional efficacy beyond exercise therapy in patients with radiographically confirmed knee OA (Kellgren-Lawrence grade II-III)[11]. To address this disconnect, the present parallel-group randomized controlled trial was designed to examine the effects of IASTM, in addition to therapeutic exercise, on knee pain (VAS), ROM (goniometry), and functional performance (WOMAC) in individuals with knee OA, to generate evidence that can be directly applied to clinical practice.

METHODOLOGY

Study Design and Setting

The trial was a single-masked, two-arm, parallel-group Randomized Controlled Trial conducted at two sites, namely Physio Care Center, Gujarat, and SK Physio OPD, Islamabad, from January to December 2025. Patients with knee osteoarthritis (Kellgren-Lawrence II-III) were randomly allocated to two groups in equal numbers, with concealment achieved using sequentially numbered, sealed, opaque envelopes.

Sample Size

Sample size was determined with G*Power (version 3.1.9.4), drawing on figures from an earlier RCT titled “A comparative study of the efficacy of instrument-assisted soft tissue mobilization and massage techniques in patients with patellofemoral joint pain,”[12] which had reported post-treatment Numeric/Visual Analogue Scale (VAS) values of 2.25 ± 1.38 in the IASTM arm versus 3.58 ± 1.38 in the Tui-na arm. Based on these figures, the calculation indicated a minimum of roughly 17 participants per group would be needed. To guard against a type II error, allow for possible dropouts, and limit selection and attrition bias, the target was raised to 50 participants overall, with 25 randomly assigned to each of Group A and Group B.

Selection Criteria

Inclusion criteria: Participants were included if they (i) had a confirmed diagnosis of knee osteoarthritis (Kellgren-Lawrence grade II-III); (ii) were aged between 40 and 60 years; and (iii) were of either gender.

Exclusion criteria: Participants were excluded if they (i) did not meet the inclusion criteria, or (ii) had undergone recent lower-limb surgery.

Data Collection Procedure

Baseline testing took place in the week before treatment began. A trained assessor who did not know which group each participant belonged to recorded every outcome measure at baseline (Week 0) and again after treatment (Week 6).

- ***Visual Analogue Scale (VAS):*** Pain was rated on an 11-point scale from 0, meaning no pain, to 10, the worst pain imaginable, captured both while resting and during weight-bearing tasks such as climbing stairs; higher numbers reflected worse pain[13].
- ***Knee Range of Motion (Goniometry):*** This was measured by a standard universal goniometer at baseline and at six weeks. For extension, they were lying on their backs; for flexion, they were seated or lying on their stomachs with the knee free to hang. The fulcrum of the goniometer was placed over the lateral femoral epicondyle, the fixed arm over the greater trochanter, and the moving arm over the lateral malleolus. The knee should bend to 135°-140° and straighten completely to 0° (some individuals may have a small hyperextension of 5°-10°, which is normal for them). For mobility closer to these parameters, readings were considered good, whereas decreased flexion or inability to reach 0° extension indicated capsular or soft-tissue tightness[14].
- ***Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC):*** Function was assessed using the self-report questionnaire, the WOMAC index, which was validated specifically for people with OA. It includes 24 items divided into 3 domains: pain (5 items – walking, using stairs, resting in bed, sitting or lying,

and standing); stiffness (2 items – morning stiffness and stiffness later in the day); physical function (17 items – general day-to-day activities including walking, getting up from sitting, standing, bending, getting in and out of a car, shopping, dressing the feet, getting in and out of bed, bathing, sitting, using the toilet, and household activities of varying intensity). For each item, a Likert scale is used, ranging from “none” (0) to “extreme” (4), with a possible range of 0 to 96; higher scores indicate greater pain, stiffness, and disability, and lower scores indicate greater function[15].

Intervention Protocol

The duration of both study arms was six weeks, and the therapy sessions were 30 minutes in length, three times a week, on non-consecutive days (e.g., Monday, Wednesday, and Friday), supervised directly by a qualified physical therapist.

Group A: IASTM Combined with a Standardized Therapeutic Exercise Protocol

Each session opened with IASTM, delivered with a stainless-steel tool over the soft tissue surrounding the affected knee — the quadriceps (rectus femoris and vastus medialis/lateralis), iliotibial band, hamstrings, and peripatellar retinacular tissue. The therapist held the tool at roughly a 30°-60° angle against lightly lubricated skin, working proximal to distal with multi-directional sweeping strokes at a comfortable pressure for about 6-8 minutes, gradually increasing intensity over the six weeks based on how the tissue responded and the participant's pain tolerance. Exercise followed immediately after IASTM, using the same standardized protocol described below:

- **Quadriceps isometric/setting exercises, 3 sets of 10 repetitions, 5-10 second hold**
- **Straight leg raises, 3 sets of 10 repetitions**
- **Active-assisted knee flexion/extension range of motion exercises, 2 sets of 10 repetitions**
- **Hamstring stretching, 3 repetitions of 30-second static holds**
- **Terminal knee extension exercises using a resistance band, 3 sets of 10 repetitions**
- **Mini-squats/functional strengthening (as tolerated), 2 sets of 10 repetitions**

Group B: Therapeutic Exercise Protocol Alone

Group B followed the same exercise protocol (quadriceps setting, straight leg raises, active-assisted ROM work, hamstring stretching, terminal knee extension, and functional strengthening) at matching frequency, session length, and intensity progression, but skipped the IASTM step, filling the full 30 minutes with exercise alone, three times a week for six weeks.

Statistical Analysis

Analysis was carried out in SPSS version 25 (IBM Corp., USA). Normality of the data was checked with the Shapiro-Wilk test. Continuous variables are summarized as mean ± standard deviation, and categorical variables as counts and percentages. Paired-samples t-tests were used for within-group comparisons and independent-samples t-tests for between-group comparisons, with statistical significance set at $p < 0.05$.

Ethical Consideration

The approval was granted by the Institutional Ethical Review Committee at the Foundation of Medical Research and Lab (FMRL-IRB/2023/026) before the trial began, and every participant gave written informed consent prior to enrollment. The study followed Declaration of Helsinki principles and is registered on ClinicalTrials.gov under NCT07710209.

RESULTS

Fifty people with knee osteoarthritis were enrolled and split evenly into Group A (IASTM plus standardized exercise) and Group B (exercise only), 25 in each. No one dropped out over the six weeks, so all 50 completed both the baseline and post-intervention testing.

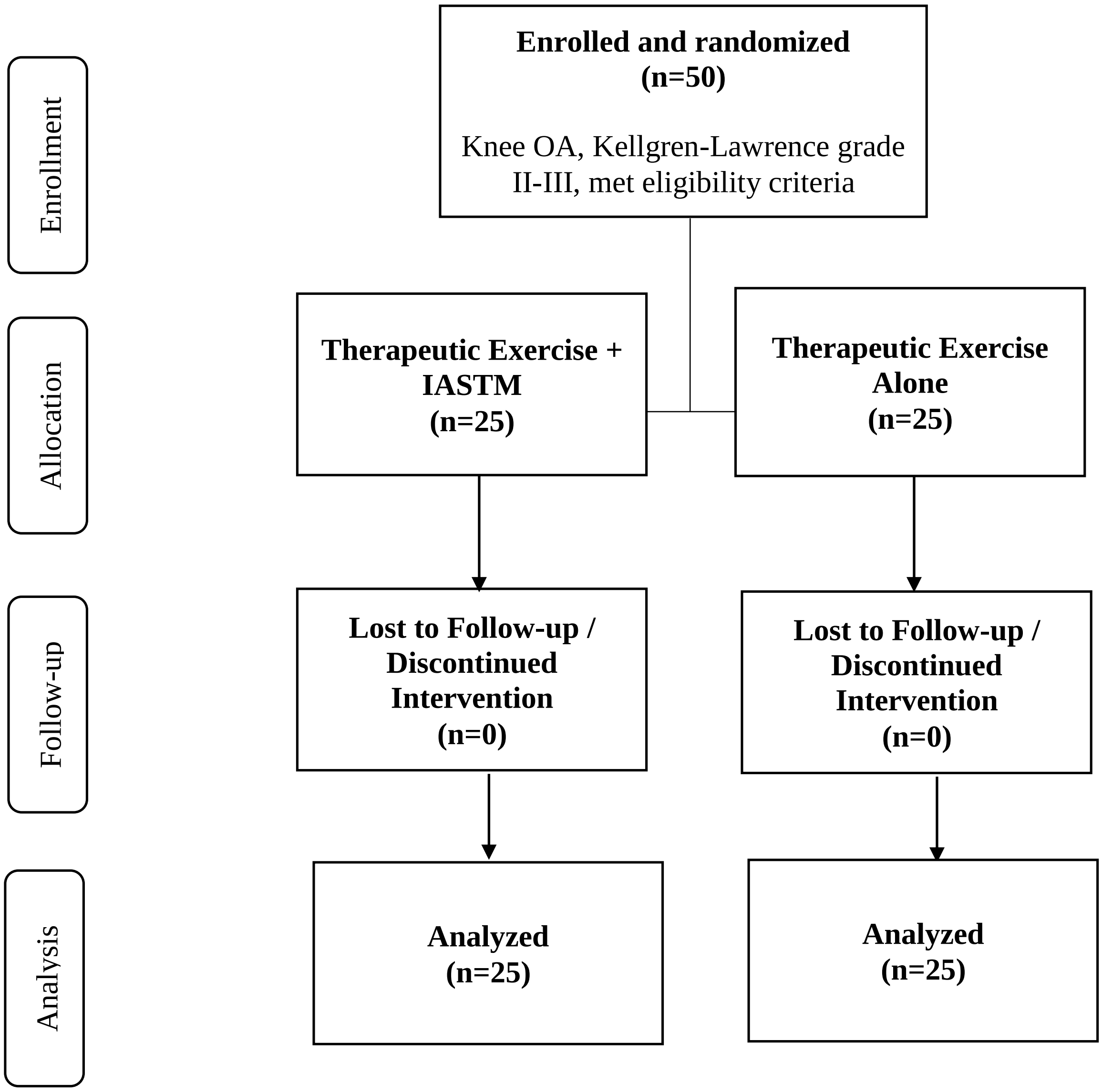

Figure 1. CONSORT flow diagram of participant enrollment, allocation, follow-up, and analysis

Each outcome variable was tested for normality using the Shapiro-Wilk test before running the main analyses. Most variables did ($p > 0.05$), both at baseline (WOMAC score, $p = 0.233$) and at Week 6 (WOMAC score, $p = 0.889$; knee flexion ROM, $p = 0.245$), with W-statistics of 0.949 and 0.980, respectively. With this in mind, throughout the data analysis, a parametric test, paired-samples t-test within groups and independent-samples t-test between groups, were used as planned.

Baseline demographics and clinical measures were compared across groups to check that randomization had worked as intended. Mean age was 48.44 ± 6.45 years in Group A versus 49.76 ± 6.31 years in Group B, a non-significant difference ($p = 0.468$), and the male-to-female split was similar between groups (10/15 in A, 11/14 in B; $p = 1.000$). None of the baseline outcome measures differed significantly either: VAS pain (7.16 ± 0.80 vs 6.84 ± 0.80, $p = 0.164$), knee flexion ROM (101.40° ± 6.24 vs 100.92° ± 6.98, $p = 0.799$), knee extension deficit (10.76° ± 3.02 vs 10.52° ± 3.20, $p = 0.786$), and WOMAC score (66.88 ± 7.79 vs 68.32 ± 7.30, $p = 0.503$), all $p > 0.05$ (Table 1). This supports attributing the post-intervention differences to treatment rather than to any starting imbalance between groups.

Group A's VAS score dropped from 7.16 ± 0.80 at baseline to 2.92 ± 1.15 by Week 6 ($p < 0.001$), while Group B's fell from 6.84 ± 0.80 to 4.12 ± 1.20 over the same period ($p < 0.001$). Comparing the two groups directly at Week 6, Group A's score was significantly lower than Group B's (2.92 ± 1.15 vs 4.12 ± 1.20; $p < 0.001$) — that is, pain relief was greater with IASTM added to exercise than with exercise on its own (Table 2).

Table 1. Baseline Demographic and Clinical Characteristics of Participants			
Variable	**Group A: IASTM + Exercise (n=25)**	**Group B: Exercise Only (n=25)**	**p-value**
Age (years)	48.44 ± 6.45	49.76 ± 6.31	0.468
Gender (Male/Female)	10 / 15	11 / 14	1.000
VAS Baseline	7.16 ± 0.80	6.84 ± 0.80	0.164
Knee Flexion ROM Baseline (°)	101.40 ± 6.24	100.92 ± 6.98	0.799
Knee Extension Deficit Baseline (°)	10.76 ± 3.02	10.52 ± 3.20	0.786
WOMAC Baseline	66.88 ± 7.79	68.32 ± 7.30	0.503

Values are presented as Mean ± SD or n. Between-group comparison by independent-samples t-test (gender by chi-square test). Significance set at p < 0.05

Table 2. Within- and Between-Group Comparison of Pain (Visual Analogue Scale)

Parameter	**Group A Baseline**	**Group A Week 6**	**Within-Group p**	**Group B Baseline**	**Group B Week 6**	**Within-Group p**	**Between-Group p (Week 6)**
VAS	7.16 ± 0.80	2.92 ± 1.15	<0.001	6.84 ± 0.80	4.12 ± 1.20	<0.001	<0.001

Data are expressed as Mean ± SD. Paired-samples t-test for within-group comparison and independent-samples t-test for between-group comparison. Significance set at p < 0.05.

Both groups gained knee flexion range: Group A moved from 101.40° ± 6.24 to 123.88° ± 6.92 ($p < 0.001$), and Group B from 100.92° ± 6.98 to 113.44° ± 7.48 ($p < 0.001$). Extension deficit shrank in both arms too, from 10.76° ± 3.02 to 4.12° ± 2.85 in Group A ($p < 0.001$) and from 10.52° ± 3.20 to 7.16° ± 3.75 in Group B ($p < 0.001$). At Week 6, Group A's flexion ROM was significantly greater than Group B's (123.88° ± 6.92 vs 113.44° ± 7.48; $p < 0.001$), and its residual extension deficit was significantly smaller (4.12° ± 2.85 vs 7.16° ± 3.75; $p = 0.002$), both findings favor the IASTM group (Table 3).

Table 3. Within- and Between-Group Comparison of Knee Range of Motion

Parameter	**Group A Baseline**	**Group A Week 6**	**Within-Group p**	**Group B Baseline**	**Group B Week 6**	**Within-Group p**	**Between-Group p (Week 6)**
Flexion ROM (°)	101.40 ± 6.24	123.88 ± 6.92	<0.001	100.92 ± 6.98	113.44 ± 7.48	<0.001	<0.001
Extension Deficit (°)	10.76 ± 3.02	4.12 ± 2.85	<0.001	10.52 ± 3.20	7.16 ± 3.75	<0.001	0.002

Values are presented as Mean ± SD. Within-group comparison by paired-samples t-test; between-group comparison by independent-samples t-test. Significance set at p < 0.05.

WOMAC scores also fell in both groups, Group A from 66.88 ± 7.79 to 33.96 ± 9.13 ($p < 0.001$), and Group B from 68.32 ± 7.30 to 50.32 ± 8.13 ($p < 0.001$). At Week 6, Group A's score was significantly better (lower) than Group B's (33.96 ± 9.13 vs 50.32 ± 8.13; $p < 0.001$), meaning the IASTM-plus-exercise combination produced a larger functional improvement than exercise alone (Table 4).

Table 4. Within- and Between-Group Comparison of Functional Status (WOMAC)

Parameter	**Group A Baseline**	**Group A Week 6**	**Within-Group p**	**Group B Baseline**	**Group B Week 6**	**Within-Group p**	**Between-Group p (Week 6)**
WOMAC Score	66.88 ± 7.79	33.96 ± 9.13	<0.001	68.32 ± 7.30	50.32 ± 8.13	<0.001	<0.001

Values are presented as Mean ± SD. Within-group comparison by paired-samples t-test; between-group comparison by independent-samples t-test. Significance set at p < 0.05.

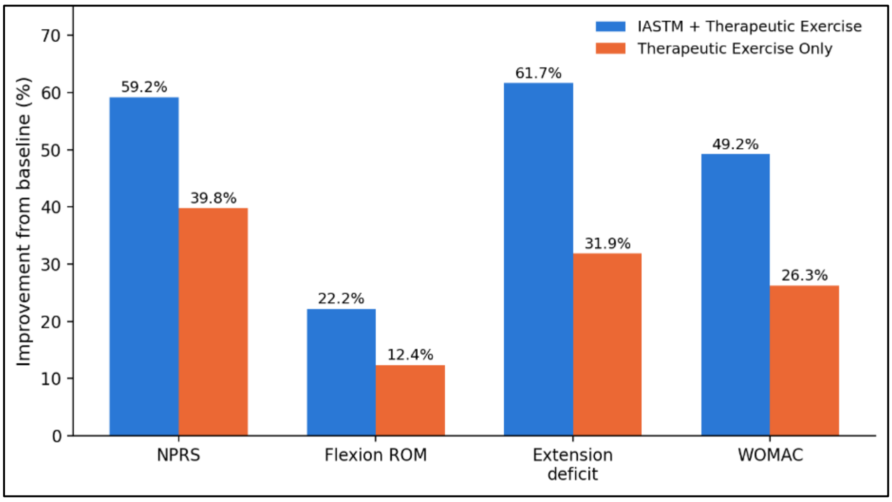

Figure 2. Percentage improvement in outcome measures at Week 6 by group.

Figure 2 shows the percent change from baseline for each outcome measure in both groups at Week 6. Group A's percentage improvements were greater than Group B's on all four parameters (pain (VAS), knee flexion ROM, extension deficit, and WOMAC score) and greatest on extension deficit (61.7% vs 31.9%) and pain (59.2% vs 39.8%).

DISCUSSION

The study found that combining IASTM with standard exercise yielded greater improvements in pain, knee mobility, and function compared with standard exercise alone in individuals with knee OA. This study's findings place IASTM in a clinically valuable position for use alongside regular exercise-based rehabilitation and support a growing IASTM literature base in the musculoskeletal and knee OA populations.

As it relates to pain, the VAS reduction was also significantly greater in Group A than in Group B, in line with the findings of Nazari et al.[16], which found that there was greater pain reduction in the combination group (ISTM + other active treatments) than in the active treatment group alone in upper-body, lower-body, and spinal conditions. The 2025 systematic review and meta-analysis by Tang et al.[17] also showed that combined interventions resulted in greater reductions in pain intensity and pain-pressure threshold than other interventions alone, supporting an additional pain-relieving effect of adding IASTM to other rehabilitation programs. In keeping with this, Gercek et al. [18], in a double-blind randomized controlled trial, showed that even a single IASTM session produced an immediate drop in pain and joint position error among patients with chronic neck pain — suggesting that mechanically desensitizing soft tissue can ease pain acutely after just one treatment, a mechanism that could plausibly contribute to the cumulative pain reduction seen in Group A over the six weeks of the present trial. This lines up with Cigdem-Karacay et al.,[19], whose randomized, blinded, sham-controlled study found IASTM outperformed a sham treatment for short-term pain relief in myofascial pain syndrome, weighing against a purely placebo-driven explanation.

The size of the range-of-motion gain seen in Group A tracks with what Wadhwa et al.[20] reported in their scoping review, namely that IASTM restores function in tight fascia and periarticular soft tissue and thereby boosts joint mobility, matching the sizable between-group gap in flexion ROM and extension deficit found here. The findings also match Gandotra et al.,[6], whose work on the iliotibial band and surrounding knee musculature showed improved clinical performance with IASTM, and Karimi Soloklo et al.,[7], whose work found improved gait kinetics after IASTM applied around the knee. The pattern also fits the meta-analysis by Tang et al.,[9], whose meta-analysis found that IASTM produces a meaningful improvement in range of motion across a range of joints and musculoskeletal conditions compared with exercise or no treatment. Collectively, this body of recent evidence points to soft tissue-directed intervention offering a mobility benefit beyond what exercise alone provides.

Group A's WOMAC gains also outpaced Group B's, matching Karimi Soloklo et al.,[8], who found larger gains in lower-limb muscle strength and sit-to-stand ability with IASTM in a comparable knee OA population, and Jafarsalehi et al.,[10], whose trial found greater gains in functional measures and quality of life when IASTM was added to knee OA treatment.

Additional support comes from the systematic review by Tsokanos et al.,[21], which concluded that both manual and instrument-based soft tissue techniques yield clinically meaningful gains in function and disability when added to exercise therapy for knee osteoarthritis. In a similar vein, Mutiara et al.[15] found that manual traction-based soft tissue work significantly improved WOMAC scores in knee OA patients, broadly matching the superior WOMAC gains seen in the IASTM-augmented group here. Taken together, these findings suggest soft tissue-directed adjuncts — whether manual or instrument-assisted — offer a consistent, incremental functional benefit beyond exercise alone.

A few physiological mechanisms may account for IASTM's superior results in this trial. Brandl et al.[22] used bioimpedance analysis to show that IASTM triggers measurable, immediate shifts in the fluid dynamics and hydration of myofascial tissue, alongside a rise in local tissue temperature consistent with better extensibility and less mechanical restriction. Nazari et al.[16] similarly proposed that IASTM's clinical value stems from a mix of local mechanical effects on fascia and connective tissue plus neurophysiological pain modulation. In a randomized controlled trial that paired targeted IASTM with neuromuscular exercise, Mylonas et al.[23] found that this combination led to significant gains in posture-related dysfunction and pain beyond exercise alone, a synergistic pattern similar to what this trial observed at the knee. These mechanistic and clinical results provide a compelling case for the incremental clinical value of treating periarticular soft tissue restriction in combination with therapeutic exercise rehabilitation in knee OA.

Several methodological details support the confidence in these results. The use of VAS for pain assessment is consistent with the previously mentioned study by Goudman et al.[13], in which the VAS was shown to agree well with the numerical rating scale for measuring pain intensity in adults with chronic pain. The report by Jayubo et al.14 also suggested that universal goniometer-based ROM measurement is reliable; this approach was used in the current study to measure knee flexion and extension. In this trial, which examined the reliability of clinicians' use of IASTM forces during simulated treatment, Duffy et al.[24] found acceptable reliability among trained clinicians, supporting the standardized IASTM approach performed by a single qualified physical therapist.

The strengths of this trial are the randomized parallel-group design, concealed allocation, blinded outcome assessment, and well-defined, repeatable IASTM and exercise protocols. A few limitations are worth flagging too. Because the design was single-blind, treating therapists knew each participant's group assignment, which may have introduced a degree of performance bias. Six weeks of follow-up, though standard for rehabilitation research, is too short to say anything about how long the benefits last, a shortfall also noted by Moore et al.[25] in their evidence-to-practice review, which pointed out a broader shortage of long-term follow-up data across the IASTM literature. Running the trial across two centers also helped feasibility, but it limits how far these results generalize to other clinical settings, patient groups, and age ranges.

CONCLUSION

Overall, adding IASTM to therapeutic exercise led to significantly greater reductions in pain and significantly larger gains in knee range of motion and function than exercise alone over six weeks of treatment for knee osteoarthritis. These results agree with, and add to, the IASTM literature published from 2020 to 2025, pointing to IASTM as a clinically useful and safe addition that fits readily into conventional exercise-based rehabilitation for knee OA. Clinicians treating knee osteoarthritis may want to consider pairing IASTM with therapeutic exercise, since it appears to deliver more pain relief and better restoration of joint mobility and function than exercise on its own. Further research with longer follow-up, recruitment across multiple centers, and blinded treatment providers would help confirm how durable and generalizable these findings are.

Author Contributions

Faiza Kalsoom conceived and designed the study, contributed to data collection, and supervised the research process. **Mehreen Ali** assisted in study design, data analysis, and interpretation of results. **Khakshan Taveel** contributed to the literature review, manuscript drafting, and critical revision. **Rabbia Irshad** assisted in data collection, manuscript editing, and data interpretation. **Zona Mehreen** contributed to manuscript preparation, critical revision, and final approval of the manuscript. All authors reviewed and approved the final manuscript.

Ethical Approval

The protocol was approved by the Institutional Ethical Review Committee at the Foundation of Medical Research and Lab (FMRL-IRB/2023/026).

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None.

Conflict of Interests

None.

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