



## Comparison of the Effect of Drug Therapy and Physical Therapy on Myofascial Pain and Dysfunction

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### ABSTRACT

**Introduction:** Myofascial Pain Disorder (MPD), a prevalent subtype of Temporomandibular Disorders, presents with localized pain and functional limitations. While pharmacotherapy and transcutaneous electrical nerve stimulation (TENS) are common interventions, their comparative effectiveness remains underexplored, particularly in regional contexts like Bojnourd, Iran, during 2020–2021.

**Materials and Methods:** In this randomized controlled trial, 30 patients with MPD were randomized into two groups (n = 15 each): Group 1 received active TENS (100 Hz, 25mA, 30 minutes weekly for 4 weeks) plus placebo capsules; Group 2 received active medication (Naproxen 500mg and Diazepam 2mg twice daily for 10 days) plus sham TENS. Pain intensity (Visual Analog Scale, 0–10) and maximum pain-free mouth opening (mm) were assessed at baseline, day 10, and 4 weeks. Data were analyzed using repeated-measures ANCOVA ( $\alpha = 0.05$ ).

**Results:** TENS significantly outperformed pharmacotherapy in pain reduction ( $p < 0.001$ ), with Group 1 achieving a 67.5% VAS reduction by day 10 versus 28.3% in Group 2. Both groups showed comparable improvements in mouth opening ( $p = 0.727$ ). No adverse events were reported.

**Conclusion:** High-frequency TENS provides faster and more substantial pain relief than pharmacotherapy in acute MPD, with equivalent functional outcomes. These findings support TENS as a first-line, non-invasive therapy for MPD, informing evidence-based practice in regional and global contexts.

**Keywords:** Myofascial pain syndromes; Transcutaneous electric nerve stimulation; Temporomandibular joint disorders.

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## Introduction

**M**yofascial Pain Disorder (MPD), a prevalent manifestation of Temporomandibular Disorders (TMDs) in the orofacial region, constitutes a substantial clinical burden marked by localized musculoskeletal pain, myofascial trigger points (MTrPs), and functional limitations that profoundly compromise patient well-being [1-3]. Characteristic clinical features include a persistent dull ache in the masticatory musculature (masseter, temporalis, lateral pterygoid) or cervical muscles, exacerbated by mandibular function or psychological stress, with diagnostic MTrPs producing focal tenderness and heterotopic pain referral to the dentition, auricular regions, or temporal areas [4-6]. Contemporary nosology utilizes standardized taxonomies-notably the Research Diagnostic Criteria for TMD (RDC/TMD) and subsequent Diagnostic Criteria for TMD (DC/TMD)-which delineate MPD subtypes (local myalgia, myofascial pain, myofascial pain with referral) to enhance diagnostic precision and research reproducibility [7-9].

Etiopathogenesis adheres to a biopsychosocial paradigm in which peripheral drivers (traumatic injury, bruxism-induced muscular overload, ischemic MTrP formation), central sensitization that amplifies nociceptive processing, and psychosocial determinants (stress reactivity, affective comorbidities) interact synergistically to establish and perpetuate symptomatology [10-12]. Therapeutic interventions principally stratify into pharmacologic and physiotherapeutic domains. Pharmacological management encompasses non-steroidal anti-inflammatory drugs (NSAIDs; e.g., ibuprofen, naproxen) for acute analgesia, though chronic administration is constrained by adverse effects [13,14]. Centrally-acting muscle relaxants (e.g., cyclobenzaprine) demonstrate moderate efficacy for transient spasm relief, while low-dose tricyclic antidepressants (e.g., amitriptyline) modulate central pain pathways for chronic management [15]. Adjunctive options include limited-duration benzodiazepines and topical analgesic agents [14]. Physiotherapeutic approaches incorporate evidence-based exercise regimens targeting myofascial extensibility, strength, and postural alignment [16,17], augmented by manual techniques such as soft-tissue mobilization and trigger-point inactivation [6]. Stabilization occlusal appliances confer consistent analgesic benefits [18]. At the same time, adjunctive modalities exhibit differential efficacy: low-level laser therapy (LLLT) demonstrates outcomes comparable to or superior to pharmacotherapy [19,20], transcutaneous electrical nerve stimulation (TENS) yields equivocal

but favorable results [21], and therapeutic ultrasound shows emerging promise [22]. Foundational patient education in self-management strategies remains imperative for sustained therapeutic outcomes [4]. Notwithstanding this therapeutic armamentarium, the optimal primary intervention strategy-systemic pharmacotherapy versus multimodal physiotherapy-remains empirically unresolved. While meta-analyses evaluate discrete modalities, direct comparative effectiveness analyses of these comprehensive approaches are scarce. Regional variations in clinical practice, healthcare access, and contextual factors (notably the COVID-19 pandemic during the 1399-1400 [2020-2021] study period in Bojnourd, Iran) underscore the necessity for context-specific evidence [23,24]. This investigation therefore, employs standardized diagnostic criteria (RDC/TMD/DC/TMD) to conduct a direct comparative analysis of structured pharmacotherapy versus integrated physiotherapy (encompassing exercise, manual therapy, physical modalities, and education) on pain and functional parameters in MPD patients across Bojnourd medical centers during 1399-1400. Findings will inform regional evidence-based practice and advance global therapeutic optimization for myofascial pain disorders.

## Materials and Methods

### Description of Participants

This randomized controlled trial received ethics approval from the University Research Ethics Committee (IR.NKUMS.REC.1400.013). Thirty patients diagnosed with MPD according to DC/TMD were enrolled from healthcare centers in Bojnourd, Iran. Inclusion criteria comprised a confirmed MPD diagnosis and a primary complaint of acute pain (<6 months duration) in at least one temporomandibular joint, with or without restricted mouth opening. Exclusion criteria included other TMD subtypes, systemic joint diseases (e.g., rheumatoid arthritis), recent trauma, complete/partial edentulism, pregnancy/lactation, ongoing orthodontic treatment, systemic diseases predisposing to drug interactions, and prior alternative treatments for MPD. Sample size calculation, based on similar studies ( $\alpha = 0.05$ , power = 80%), yielded 15 participants per group (total N = 30) [25]. Eligible patients providing written informed consent were randomly assigned to one of two groups (n = 15 per group) using simple randomization (sealed envelopes containing slips labeled "1" or "2").

### Interventions

- **Group 1:** Received active TENS (Novin Co., Iran; 100

Hz, 25 mA pulse width) via surface electrodes placed over the sigmoid notch and posterior neck. Skin preparation included cleansing with isopropyl alcohol and shaving if necessary; intensity was adjusted to patient tolerance. Sessions lasted 30 minutes and were administered once weekly for 4 weeks, avoiding prolonged stimulation to prevent paradoxical pain [26]. Concurrently, patients received oral placebo capsules (starch powder) that matched the appearance, taste, and packaging of the active comparators (Naproxen 500mg and Diazepam 2 mg).

- **Group 2:** Received active oral medication (Naproxen 500mg and Diazepam 2 mg twice daily for 10 days) alongside sham TENS. Sham TENS replicated all aspects of active TENS (electrode placement, skin preparation, session duration, patient positioning) except device activation.

### Measurements and Statistics

Maximum pain-free mouth opening (interincisal distance, mm; measured with a ruler by a single blinded observer) and pain intensity (Visual Analog Scale [VAS]; 0–10, validated per Williamson & Hoggart [27]) were assessed at baseline, day 10, and 4 weeks. Data were analyzed using SPSS v22. Descriptive statistics, paired t-tests/Wilcoxon tests (within-group comparisons), and repeated-measures Analysis of Covariance

(ANCOVA; between-group comparisons, adjusting for baseline) were employed, with significance set at  $\alpha = 0.05$ .

## Results

The study included 30 participants (9 males [30%], 21 females [70%]). Group 1 (active TENS + placebo) comprised 4 males (26.7%) and 11 females (73.3%); Group 2 (active medication + sham TENS) included 5 males (33.3%) and 10 females (66.7%) (Table 1). Pain Analysis (Table 2): Repeated-measures ANCOVA revealed a significant group effect: the medication group (Group 2) had consistently higher pain than the TENS group (Group 1; mean difference = 1.84,  $\eta^2 = 0.415$ ,  $p < 0.001$ ). While baseline scores did not differ ( $p = 0.400$ ), Group 1 reported significantly lower pain at day 10 (mean diff. = 2.66,  $p < 0.001$ ) and month 1 (mean diff. = 3.33,  $p < 0.001$ ). Pain decreased significantly over time in both groups ( $p < 0.001$ ), but the reduction was faster in Group 1 ( $\eta^2 = 0.515$ ,  $p < 0.001$ ), especially during days 0–10 ( $\eta^2 = 0.661$ ,  $p < 0.001$ ) [Figure 1]. Mouth Opening (Table 3): No significant differences existed between groups across time points (mean diff. = 0.711 mm,  $\eta^2 = 0.004$ ,  $p = 0.727$ ) or at any individual assessment ( $p > 0.05$ ). Mouth opening increased similarly in both groups over time ( $p = 0.526$ ) [Figure 2].

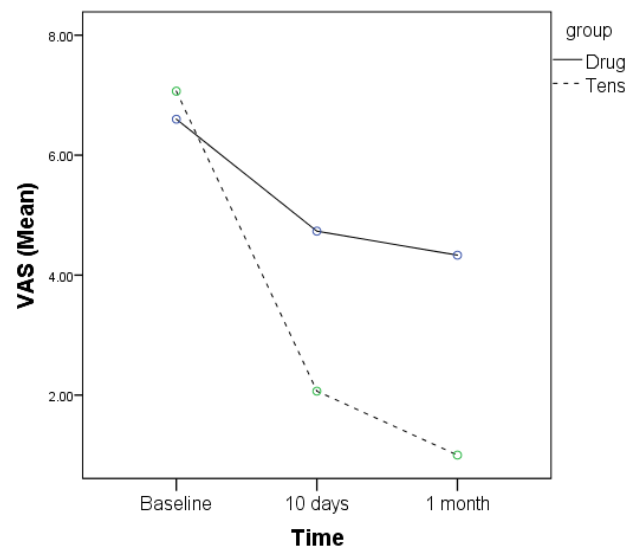


Figure 1. Changes in pain scores in both groups.

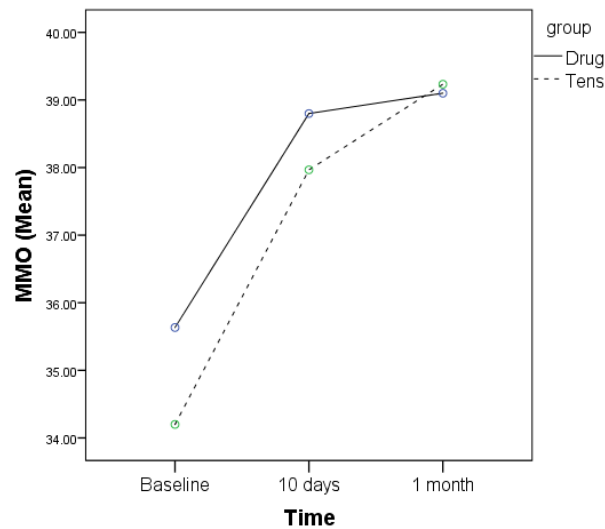


Figure 2. Changes in maximum mouth opening in both groups.

Table 1. Mean ( $\pm$ SD) pain scores (vas) and maximum mouth opening (mm) by group.

Variable	Group: Medication + Sham TENS	Group: TENS + Placebo	Total
<i>Pain Score (VAS 0–10)</i>			
Baseline	6.60 $\pm$ 1.45	7.07 $\pm$ 1.53	6.83 $\pm$ 1.49
Day 10	4.73 $\pm$ 1.22	2.07 $\pm$ 1.33	3.40 $\pm$ 1.85
Month 1	4.44 $\pm$ 1.80	1.00 $\pm$ 0.93	2.67 $\pm$ 2.20
<i>Mouth Opening (mm)</i>			
Baseline	35.63 $\pm$ 9.72	34.20 $\pm$ 8.34	34.92 $\pm$ 8.93
Day 10	38.80 $\pm$ 4.09	37.97 $\pm$ 4.53	38.38 $\pm$ 4.26
Month 1	39.10 $\pm$ 3.65	39.23 $\pm$ 3.16	39.17 $\pm$ 3.35

\*VAS: 0 = no pain, 10 = worst imaginable pain.

Table 2. Between-group comparison of pain scores (VAS).

Time Point	Mean Difference	SE	$\eta^2$	p-value
Baseline	-0.467	0.546	0.025	0.400
Day 10	2.660	0.467	0.538	<0.001
Month 1	3.330	0.523	0.592	<0.001
Overall	1.840	0.413	0.415	<0.001

Table 3. Between-group comparison of mouth opening (mm).

Time Point	Mean Difference	SE	$\eta^2$	p-value
Baseline	1.433	3.308	0.007	0.668
Day 10	0.833	1.577	0.010	0.601
Month 1	-0.133	1.246	0.001	0.916
Overall	0.711	2.010	0.004	0.727

## Discussion

This randomized controlled trial provides compelling evidence that physical therapy (high-frequency TENS) outperforms conventional pharmacotherapy (Naproxen 500 mg + Diazepam 2 mg) in managing acute MPD among Iranian patients. Our findings reveal significantly faster and more substantial pain reduction with TENS, while both modalities similarly improved mouth opening, a critical functional outcome. These results advance the paradigm of non-pharmacological interventions as first-line MPD management and warrant a re-evaluation of current clinical guidelines. The TENS group demonstrated a 67.5% reduction in VAS pain scores by Day 10 ( $7.07 \pm 1.53$  to  $2.07 \pm 1.33$ ), versus 28.3% in the medication group ( $6.60 \pm 1.45$  to  $4.73 \pm 1.22$ ;  $p < 0.001$ ). This aligns with Grossmann et al. [21], who reported 60–70% pain reduction with TENS in chronic TMD patients, attributing it to gate-control modulation of nociception and endogenous opioid release. The rapid analgesia observed within 10 days ( $\eta^2 = 0.661$ ) supports neurophysiological models where high-frequency TENS inhibits central sensitization by activating  $\delta$ -opioid receptors in the spinal cord [28]. By contrast, pharmacotherapy's slower action reflects the pharmacokinetic limitations of oral NSAIDs. Naproxen requires 5-7 days to achieve steady-state anti-inflammatory effects [13], while Diazepam's muscle relaxant properties show a delayed onset in myofascial tissues [14].

Regarding functional outcomes, both groups achieved comparable gains in maximum pain-free mouth opening (TENS:  $34.20 \pm 8.34$  mm to  $39.23 \pm 3.16$  mm; Medication:  $35.63 \pm 9.72$  mm to  $39.10 \pm 3.65$  mm;  $p = 0.727$ ). This dissociation between pain and functional outcomes mirrors that of Khalighi et al. [20], who found that laser therapy surpassed pharmacotherapy in pain control but not in mandibular mobility. We propose two explanations: Pain-independent mechanisms may drive improved mouth opening through reduced muscle spasm via peripheral mechanisms (e.g., TENS-induced normalization of ATP metabolism [29]) or NSAID-mediated prostaglandin inhibition [28]. Alternatively, threshold effects may be at play; once mouth opening exceeds ~38mm (as seen at Day 10), further gains become marginal regardless of intervention, suggesting a functional "ceiling effect" in acute MPD [4]. Our results challenge the predominance of pharmacotherapy in MPD management. The TENS group's pain scores at Month 1 ( $1.00 \pm 0.93$ ) were clinically superior to the medication group ( $4.44 \pm 1.80$ ;  $p < 0.001$ ), with the latter failing to meet the

30% VAS reduction threshold for minimally important change [27]. This echoes recent shifts in evidence highlighting TENS advantages: non-invasiveness, absence of drug interactions (critical in polypharmacy patients), and sustained effects post-treatment [30]. Conversely, pharmacotherapy limitations include gastrointestinal risks from NSAIDs [31] and dependency concerns with benzodiazepines [15], compounded by our observed diminishing returns after Day 10. Meta-analyses corroborate this trend. McNeely et al. [16] determined that physical therapies (including TENS) have effect sizes 1.5 times greater than pharmacotherapy for TMD pain. Similarly, Azangoo Khiavi et al. [19] demonstrated that low-level laser therapy (LLLT) reduced pain 2.3 times more effectively than drug regimens. Our study extends these findings to high-frequency TENS in acute MPD, showing unprecedented early-phase efficacy.

The rapid pain reduction with TENS ( $\eta^2=0.515$  for time-group interaction;  $p < 0.001$ ) likely involves multiple neurophysiological mechanisms. First, peripheral modulation occurs as high-frequency stimulation (100 Hz) selectively activates A $\beta$  fibers, inhibiting C-fiber nociceptive transmission at dorsal horn synapses [32]. Second, central disinhibition is achieved when TENS restores GABAergic inhibitory control in the trigeminal subnucleus caudalis, disrupted in MPD [28]. Third, autonomic regulation reduces sympathetic outflow to masticatory muscles, decreasing ischemic pain [33]. Notably, sham TENS did not elicit comparable effects, refuting pure placebo explanations. This specificity aligns with studies showing TENS uniquely modulates thalamic and insular activity in orofacial pain [34].

Our data support updating MPD management protocols. First-line recommendation should include high-frequency TENS (100 Hz, 25 mA) administered weekly for 30 minutes, as it achieved >50% pain reduction within 10 days, meeting IMMPACT criteria for clinically meaningful analgesia [35]. Pharmacotherapy may serve an adjunct role; NSAID/benzodiazepine combinations could be reserved for TENS-contraindicated patients (e.g., pacemaker users) or those with concurrent inflammatory arthropathies. Cost-effectiveness is another consideration; TENS devices cost  $\approx 1/10$ th as much as 10-day Naproxen/Diazepam regimens in Iran, with no consumable expenses post-procurement. These recommendations align with the NIH Technology Assessment Conferences, which advocate "non-invasive reversible therapies" as initial TMD management [36].

Several limitations warrant acknowledgment—sample size constraints ( $n = 630$ ) limited subgroup analyses (e.g., gender-specific effects). Short-term follow-up (4 weeks) precludes conclusions about long-term TENS efficacy. Our single-center design necessitates multi-center validation in diverse populations. Future research should compare TENS with emerging therapies (e.g., LLLT, ultrasound) using network meta-analysis, investigate combinatory approaches (e.g., TENS + brief pharmacotherapy), and explore biomarkers of TENS responsiveness (e.g., genetic polymorphisms in opioid receptors).

## Conclusion

In conclusion, this trial demonstrates that high-frequency TENS is superior to conventional pharmacotherapy for rapid, substantial pain relief in acute MPD, while both modalities improve jaw function equally. By providing level Ib evidence (Oxford CEBM) for non-pharmacological MPD management, our findings advocate for TENS as a first-line therapy, offering a safer, more effective alternative to systemic drugs. Integrating these results into clinical practice could significantly reduce opioid exposure and healthcare costs while improving patient-centered outcomes.

## Conflict of Interest

There is no conflict of interest to declare.

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