1 Efficacy of Transcutaneous Electrical Nerve Stimulation and Soft Splint Therapy in the Treatment of

2 Patients with Temporomandibular Joint Disc Displacement with Reduction – A Comparative Study

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4 Abstract:

5 Background: The variability in treatment approaches for temporomandibular disc displacement with 6 reduction underscores the pressing need for this study. With disparate clinical practices, there is a 7 critical gap in establishing the most effective treatment. Addressing this gap will optimize patient care 8 and minimize the risk of suboptimal treatment outcomes.

9 Aims: The study aimed to compare the effectiveness of Transcutaneous Electrical Nerve Stimulation 10 and splint therapy in managing temporomandibular joint disc displacement with reduction by 11 evaluating pain intensity, mouth opening, and masticatory muscle tenderness post-treatment.

Settings and Design: A randomized controlled trial was conducted in patients with temporomandibular joint disc displacement with reduction. Patients were randomly assigned to receive either TENS therapy or splint therapy.

Methods and Material: Baseline assessments of pain intensity, maximum mouth opening, and masticatory muscle tenderness were recorded preoperatively. Treatment was administered over four weeks, with weekly evaluations to monitor efficacy.

Statistical analysis used: Inter-group analysis was done using independent t-tests, and intra-group analysis was done using ANOVA tests to evaluate the efficacy of each treatment.

Results: In the TENS group, there were notable reductions in pain intensity and masticatory muscle tenderness, accompanied by an improvement in mouth opening over the four weeks. Conversely, the splint therapy group showed minimal changes in these parameters.

Conclusions: TENS therapy shows promise as an effective treatment modality for temporomandibular
 joint disc displacement with reduction. The significant improvements observed in pain intensity,
 muscle tenderness, and mouth opening highlight TENS therapy's potential to alleviate symptoms of
 DDWR.

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Key-words: Temporomandibular joint disc displacement with reduction, Trans electronic nerve
 stimulation, Soft Splint therapy, Temporomandibular disorders

UNDER REFERENCE

32 Introduction:

Orofacial pain commonly stems from temporomandibular disorders (TMDs), which typically have origins beyond dental concerns. They encompass various conditions affecting the temporomandibular joint and jaw muscles. Symptoms include pain in the auricular, temporomandibular joint, or masticatory muscles, restricted jaw movement, and clicking sounds during jaw movement.<sup>1</sup> Interestingly, only a quarter of individuals with TMD recognize or report their symptoms, despite 70% of the general population exibits signs of the disorder.<sup>2</sup>

Research indicates a TMD prevalence of 40% to 75%. For instance, Solberg et al. found 76% of individuals aged 18 to 25 displayed TMD signs, with 26% experiencing associated symptoms. While half of TMD patients may exhibit jaw sounds or deviation upon opening, only a tiny fraction seek treatment.<sup>3</sup> The most TMDs involve anterior disc displacement, which can be classified into disc displacement with and without reduction.<sup>4</sup>

Treatment modalities range from non-invasive options like physical, exercise, and thermal therapies, acupuncture, occlusal splint, and Transcutaneous Electric Nerve Stimulation therapy (TENS), to invasive options like arthrocentesis, arthroscopy, joint reconstructive surgery, and condylotomy. Among these, TENS and occlusal splint therapy are most commonly used. TENS delivers pulsed biphasic electrical waves through skin-surface electrodes to manage pain by promoting muscle relaxation and neuromuscular stimulation. Occlusal splint therapy, involving bite guards, protects teeth from excessive forces during clenching or grinding, reducing TMJ stress and muscle pain.<sup>2</sup>

51 Due to the varied treatment options for temporomandibular disc displacement with reduction, 52 consensus on the most effective approach is lacking, leading to varied clinical practices and potential 53 suboptimal outcomes.

This study aims to assess and compare the effectiveness of TENS therapy versus soft splint therapy in managing temporomandibular disc displacement with reduction by evaluating the intensity of pain, maximum mouth opening, and masticatory muscle tenderness post-treatment.

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58 Subjects and Methods:

59 Study Population:

The study was conducted in the Outpatient Department of Oral and Maxillofacial Surgery at GITAM Dental College and Hospital, Visakhapatnam. Patients diagnosed with temporomandibular disc displacement with reduction were enrolled. Patients were randomly selected and voluntarily participated by signing informed consent forms. The study was approved by the institutional review board, and ethical clearance was obtained from the institutional ethical committee.

The inclusion criteria were patients aged 16 to 50 years, no gender predisposition, patients no predisposing medical history, class I occlusion and no requirement for orthodontic intervention, and diagnosed with temporomandibular disc displacement with reduction. Diagnosis was made solely through clinical examination, without radiographs. Selected patients exhibited a clicking sound, masticatory muscle tenderness, temporomandibular joint pain upon palpation.

The exclusion criteria were patients with systemic diseases or dentofacial anomalies, ongoing medical or psychological treatments, history of temporomandibular joint surgery or trauma, parafunctional habits like bruxism and/or clenching, refusal to participate, edentulous or partially edentulous patients, those with cardiac pacemakers, and epileptic patients.

A randomized controlled study involving 40 patients diagnosed with temporomandibular disc displacement with reduction was conducted. Patients were informed about clinical research's nature and purpose, and their informed consent was obtained. Ethical clearance was diligently obtained from the Institutional Ethical Committee, ensuring compliance with ethical standards. A double-blinding protocol was implemented. Participant Blinding involved not informing patients of their assigned treatment group (TENS or Splint), and researcher blinding ensured that the researchers were unaware of each participant's treatment allocation.

81 The study parameters included the intensity of pain, mouth opening, and masticatory muscle 82 tenderness, evaluated initially pre-treatment as baseline data and then weekly for four weeks post-83 treatment. Pain intensity was measured using the Visual Analogue Scale (VAS), where patients 84 marked their pain level on a 10 cm line ranging from 0 (no pain) to 10 (worst possible pain). Mouth 85 opening was measured by the distance between the incisal edges of the upper and lower central 86 incisors using a divider. Masticatory muscle tenderness was evaluated by manually palpating the 87 temporalis, masseter, lateral and medial pterygoid muscles bilaterally with firm yet gentle and 88 constant pressure (Figure 1). The tenderness assessment also utilized the Visual Analogue Scale,

with patients marking their pain level on a 10 cm line from 0 (no pain) to 10 (worst possible pain).
These assessments were conducted weekly for four consecutive weeks following treatment initiation.

In the TENS Group, patients received treatment with transcutaneous electric nerve stimulation therapy using a TENS device (PHYSIO TENS, manufactured by Scientific Medical Systems). The active electrode was positioned between the temporomandibular joint (TMJ) and coronoid process to ensure the stimulus reached the trigeminal and facial nerves, while the control electrode was placed at the back of the neck. The therapy was administered at a frequency of 50 Hz, a pulse width of 0.5 msec, and an intensity ranging from 0 to 60 mA for 20 minutes per session, conducted weekly intervals for four consecutive weeks. (Figure 2)

98 In the Splint Group, patients underwent soft splint therapy. Impressions were made, and a 2mm thick 99 rubber sheet was vacuum-formed using a BIOSTAR vacuum former to fabricate the soft splint. After 100 cooling, the splint was trimmed to shape and checked for retention and occlusal interferences. 101 Patients were instructed to wear the splint continuously for 24 hours daily. Follow-up assessments 102 were conducted for four weeks. Pain score, maximum mouth opening, and masticatory muscle 103 tenderness were reassessed and recorded at each follow-up. (Figure 3) Depending on the patients' 104 tolerance levels, analgesics were prescribed as needed for pain management. During each visit, 105 patients were asked to report if their pain was intolerable and if they required medication. Patients 106 who required additional analgesics were excluded from the study. Only those not taking additional 107 pain medication were included in the final analysis.

In the TENS Group (A) and Splint group (B), baseline data for pain (PQ), mouth opening (OQ), and muscle tenderness (TQ) were recorded, followed by weekly evaluations pain (P1- P4), mouth opening (O1- O4), and muscle tenderness (T1 - T4). This systematic approach ensured comprehensive monitoring of treatment outcomes.

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113 Statistical analysis:

Data analysis was conducted using SPSS version 15.0. The Independent t-test compared data between the TENS and SPLINT groups weekly and ANOVA tests analyzed data across consecutive weeks for both groups.

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118 Results:

The mean and standard deviation scores for pain intensity, mouth opening, and muscle tendernesswere recorded weekly for both groups.

Pain intensity and masticatory muscle tenderness were consistently higher in the SPLINT group compared to the TENS group. In the SPLINT Group, the mean pain score slightly decreased from 6.15 in the first week and 5.15 at the end of the fourth week. In contrast, the TENS group showed a significant reduction in pain scores, from 5.80 in the first week to 1.20 at the end of the fourth week.

125 (Graph 1)

Similarly, the mean masticatory muscle tenderness scores in the SPLINT group showed only 1.1 variation from 6.90 in the first week to 5.80 at the end of the fourth week. However, the TENS group experienced a significant decrease, from 6.65 in the first week to 1.50 at the end of the fourth week.

129 (Graph 2)

Regarding mouth opening, the SPLINT group showed a slight increase the measurements showed an increase from 38.85 mm in the first week to 39.69 mm at the end of the fourth week. In contrast, the TENS group saw a substantial increase from 39.90 mm in the first week to 50.22 mm at the end of the fourth week. (Graph 3)

Inter-group and intra-group analyses were conducted to evaluate the efficacy of each treatment.
Independent t-test evaluations revealed significant differences (p-value < 0.05) in all three</p>
parameters. The intensity of pain and masticatory muscle tenderness significantly decreased in the
TENS group, while mouth opening significantly increased compared to the SPLINT group (Table 1).

Furthermore, the parameters were compared to baseline data each week. In the TENS group, there was a notable decrease in the intensity of pain and muscle tenderness and a marked increase in mouth opening with each consecutive measurement. These differences were statistically significant (p-value < 0.05) across all three parameters, as analyzed by the ANOVA test.

In contrast, the SPLINT group showed only minor variations from baseline data for all parameters,
with no statistical significance in the scores between baseline and subsequent weeks as revealed by
the ANOVA test (Table 2).

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146 Discussion:

147 The temporomandibular joint (TMJ) is often affected by pain-related and intraarticular conditions, with 148 anterior disc displacement being the most common type of TMJ arthropathy. Anterior disc 149 displacement with reduction (DDWR) accounts 41% of clinical TMJ disorder diagnoses, as highlighted 150 Poluha et al.<sup>5</sup> In DDWR, the articular disc displaces when the mouth is closed and repositions 151 between the condyle and articular tubercle upon opening. Misalignment of the condyle-disc complex 152 is attributed to factors like elongation of discal collateral ligaments, thinning of the posterior disc 153 border, and condule resting on posterior disc regions, leading to abnormal condule movement over 154 the disc's posterior border during the opening, defining the DDWR stage.<sup>5</sup>

155 Disc displacement involves abnormal disc positioning to the mandibular condyle and articular 156 eminence. Mild disc displacement may initially manifest as occasional painful clicking, intermittent 157 locking, and headaches. As the displacement worsens, symptoms often include joint pain and 158 tenderness, locking, and a restricted mandibular motion range. Severe displacement can lead to disc 159 deformation, degeneration of osseous components, deterioration of articular cartilage and disc 160 surface, and bone remodelling. In this study, the diagnosis of DDWR was made solely through clinical 161 findings of patients with clicking sounds, TMJ pain, and tenderness of masticatory muscles on 162 palpation. Radiographs or MRI scans were not used due to ethical concerns regarding radiation 163 exposure and cost-effectiveness.

164 The three most common symptoms of DDWR, i.e., pain intensity, mouth opening, and masticatory 165 muscle tenderness were selected for evaluation in this study. Treatment options for TMJ internal 166 derangement are categorized into non-invasive, minimally invasive, and invasive management. The 167 initial approach prioritizes the least invasive and reversible treatments, reserving more invasive 168 options for cases where initial treatments fail to alleviate the symptoms. Non-invasive treatment 169 modalities include pharmacotherapy, physical therapy, exercise therapy, thermal therapy, 170 acupuncture, occlusal splint therapy, and TENS therapy. Disorders of articular or muscular origin, 171 typically respond well to non-invasive interventions like TENS and occlusal splint therapy.<sup>6,7</sup> 172 Therefore, this study compared these two treatment modalities for effectiveness. Additionally, 173 analgesics were prescribed as needed, but patients requiring additional medication were excluded, 174 ensuring only those not taking extra pain medication were included in the final analysis.

Occlusal splint therapy aims to establish neuromuscular harmony in the masticatory system by using removable appliances to create a mechanical disadvantage against parafunctional forces. These 177 splints serve various purposes, including muscle relaxation, condylar positioning, diagnostic aid, 178 protection against bruxism, and reduce cellular hypoxia levels.<sup>7</sup> TENS therapy, a non-invasive and 179 cost-effective modality, effectively controls chronic and acute pain by activating the descending 180 inhibitory system. According to the gate control theory, TENS modulates pain perception by recruiting 181 A-beta afferent fibers and inhibiting pain impulse transmission. TENS units consist of a TENS unit, 182 lead wires, and electrodes, and are classified into high-frequency (>50 Hz) and low-frequency (<10 183 Hz), with advantages including safety, self-administration, and muscle relaxation.<sup>8, 9, 10</sup>

184 In our study, the TENS group showed significantly lower pain intensity and masticatory muscle 185 tenderness scores along significant increase in mouth opening, compared to the splint group. These 186 findings align with other studies by Nunez et al. and Kota et al., which demonstrated significant improvements in mouth opening with TENS therapy.<sup>11,12</sup> Contradictory findings from Farheen Jahan et 187 188 al. suggest higher post-intervention pain scores in the TENS group compared to ultrasound and splint 189 groups when observed for four weeks.<sup>9</sup> Therefore, the observation period in this study was 190 standardized to four weeks for consistency in the outcomes assessment. TENS therapy yielded a 191 more pronounced reduction in pain scores over one month than splint interventions.

Blinding procedures were rigorously employed in this study, to mitigate potential sources of bias, particularly regarding subjective assessment of treatment outcomes. A double-blinding protocol was implemented, as both the participants and researchers were unaware of the treatment allocation for each participant. This ensured participants' expectations or perceptions did not influence reported outcomes researchers' judgments and interpretations remained unbiased throughout the study.

197 A notable reduction in masticatory muscle tenderness was observed in the TENS group compared to 198 the Splint group, with statistical significance (p < 0.05). This aligns with the findings by A. Monaco et 199 al., who demonstrated that a single 60-minute TENS session application effectively diminished 200 masticatory muscle tenderness, while increasing interocclusal distance.<sup>13</sup> Furthermore, the results 201 from Siefi et al.'s study further support our findings. Their investigation revealed a substantial 53.88% 202 decrease in masticatory muscle tenderness among TENS therapy participants.<sup>14</sup> In a randomized 203 controlled study by Ana Paula de Lima Ferreira et al., it was found that transcutaneous electrical 204 nerve stimulation (TENS) could effectively increase the pressure pain threshold (PPT) of masticatory 205 muscles.<sup>15</sup> Moreover, Remi Escassan et al. suggested that an optimal application of ultra-low 206 frequency TENS (ULF-TENS) for 40 minutes is necessary to achieve adequate muscle relaxation. This recommendation aligns with our study's findings regarding the efficacy of TENS in reducing masticatory muscle tenderness.<sup>16</sup> These collective findings emphasize the efficacy of TENS in alleviating muscle tenderness associated with TMDs, underscoring its potential as a valuable treatment modality.

211 In the TENS group, consecutive weekly treatment led to a significant decrease in pain intensity, 212 masticatory muscle tenderness, and a notable increase in mouth opening. In contrast, such 213 improvements were not observed in the SPLINT group. This finding aligns with previous research by 214 Farheen Jahan et al., which also demonstrated significant reductions in muscle tenderness and 215 temporomandibular joint (TMJ) pain with TENS therapy over consecutive weeks.<sup>9</sup> Conversely, the 216 SPLINT group did not show significant improvements in pain intensity, mouth opening, or muscle 217 tenderness over consecutive weeks, likely due to the longer time required for clinical symptom 218 reduction with splint therapy. Studies by Tecco et al. and Malgorzata Pihut et al. support this, indicating that patients treated with splints experienced reduced pain levels over months.<sup>17,18</sup> 219

TENS therapy offers additional advantages, including its applicability for needle-phobic patients, absence of post-operative anaesthesia, and the ability for patients to self-administer treatment and adjust dosage as needed, leading to positive patient acceptance. Furthermore, TENS helps relax hyperactive muscles and acts as a neuromuscular stimulator.<sup>19</sup> On the other hand, occlusal splint therapy has limitations, including dependence on patient compliance for wearing the splint, interference with finding the patient's usual occlusion, and longer treatment duration required for therapeutic outcomes.<sup>20</sup>

The study's limitations include a relatively small sample size, a brief four-week treatment duration, and a lack of long-term follow-up. The short treatment duration in this study may not fully capture the benefits of occlusal splint, which typically requires longer application periods.

Despite these limitations, our study indicates that TENS therapy is more effective than occlusal splint therapy for managing TMJ-DDWR. Over the 4-week period, TENS therapy significantly reduced pain intensity and masticatory muscle tenderness and improved mouth opening compared to occlusal splint therapy. Further research with larger sample sizes and extended treatment durations is needed for more comprehensive results.

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- 326 Graphs:
  - PAIN INTENSITY
- 327 Graph 1: Comparison of mean value of pain between TENS group and SPLINT group at initial

328 assessment and after treatment during the 1st, 2nd, 3rd, 4th consecutive weeks.

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338 Graph 2: Comparison of mean value of masticatory muscle tenderness between TENS group and
339 SPLINT group at initial assessment and after treatment during the 1st, 2nd, 3rd, 4th consecutive
340 weeks.



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- 380 Tables:

381 Table 1: Inter-group analysis of three parameters between TENS and Soft Splint therapy by

et est

382 independent t-test

Parameters	Examined at	TENS (A)		SPLINT (B)		p-value
		Mean	SD	Mean	SD	(t-test)
Pain	Initial (P <sub>Q</sub> )	5.80	1.24	6.15	1.09	0.35
	1st week (P1)	4.50	1.15	6.15	1.09	0.000*
	2nd week (P <sub>2</sub> )	3.35	1.18	5.80	1.06	0.000*
	3rd week (P <sub>3</sub> )	2.35	1.09	5.35	0.99	0.000*
	4th week (P <sub>4</sub> )	1.20	1.11	5.15	1.09	0.000*
Mouth Opening	Initial (O <sub>Q</sub> )	39.90	3.93	38.85	3.36	0.369
	1st week (O <sub>1</sub> )	42.89	4.05	39.07	3.36	0.002*
	2nd week (O <sub>2</sub> )	45.55	3.80	39.29	3.34	0.000*
	3rd week (O <sub>3</sub> )	48.14	3.16	39.48	3.34	0.000*
	4th week (O <sub>4</sub> )	50.22	2.98	39.69	3.34	0.000*
Masticatory Muscle Tenderness	Initial (T <sub>Q</sub> )	6.65	1.18	6.90	1.12	0.496
	1st week (T1)	5.20	1.40	6.90	1.12	0.000*
	2nd week (T <sub>2</sub> )	3.80	1.28	6.35	1.04	0.000*
	3rd week (T <sub>3</sub> )	2.40	1.31	5.95	1.10	0.000*
	4th week (T <sub>4</sub> )	1.50	0.76	5.80	1.01	0.000*

- 384 Table 2: Intra-group analysis of three parameters among TENS and Soft Splint therapy at consecutive
- 385 weeks by ANOVA test



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402	Figure 3: Soft splint adaptation in the patient
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## GITAM DENTAL COLLEGE AND HOSPITAL RUSHIKONDA, VISAKHAPATNAM - 530045

## ETHICAL COMMITTEE CLEARANCE CERTIFICATE

This is to certify that Dr. P.VIJAY ANIL KUMAR is a bonafide Post Graduate student in the speciality of Oral & Maxillofacial Surgery in GITAM DENTAL COLLEGE & HOSPITAL, Visakhapatnam.

The Ethical Committee gives its consent for the study on "TRANSCUTANEOUS ELECTRIC NERVE STIMULATION AND SOFT SPLINT THERAPY IN THE TREATMENT OF PATIENTS WITH TEMPOROMANDIBULAR JOINT DISC DISPLACEMENT WITH REDUCTION- A COMPARATIVE STUDY".

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