Official Title:
A Randomized Controlled Trial Comparing Digitally Fabricated and Conventional Stabilizing Splints in the Management of Temporomandibular Disorders
Brief Running Title:
Digitally Fabricated Versus Conventional Stabilizing Splints in Temporomandibular Disorders
NCT ID: not yet assigned

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Background

Temporomandibular Disorders (TMD) are common conditions characterized by pain, joint dysfunction, and reduced mandibular function, significantly affecting patient's quality of life. Stabilization splints are widely used as a first-line conservative treatment to reduce muscle activity, redistribute occlusal forces, and alleviate joint loading.

Conventional stabilization splints are typically fabricated using heat-cured acrylic resin through a laboratory-based process that is technique-sensitive and time-consuming.

Advances in digital dentistry have introduced computer-aided design and manufacturing (CAD/CAM) and three-dimensional printing technologies, enabling the fabrication of digitally produced splints with improved standardization and reproducibility.

Despite these potential advantages, there is limited high-quality clinical evidence comparing digitally fabricated stabilization splints with conventional splints in the management of TMD.

This randomized controlled trial aims to evaluate and compare the effectiveness of digitally fabricated and conventional stabilization splints in reducing pain and improving functional outcomes in patients with TMD over a 3-month follow-up period.

Primary Objective

To evaluate change in pain intensity

Secondary Objectives:

- To evaluate change in pain related disability
- To evaluate change in Maximum mouth opening in millimeters (mm)
- To evaluate change in jaw in function by using Jaw Functional Limitation Scale (JFLS)
- To evaluate resolution of Temporomandibular Joint clicking (present/absent)
- To evaluate Oral health related quality of life using OHIP-14 score
- To Evaluate Patient Compliance (hours/night)

Study Design

This study is designed as a prospective, parallel-group, randomized controlled clinical trial with a 1:1 allocation ratio. It will be conducted to compare the clinical effectiveness of digitally fabricated and conventional stabilization splints in the management of temporomandibular disorders.

Participants meeting the eligibility criteria will be randomly assigned to either the intervention group (digitally fabricated stabilization splints) or the control group (conventional heat-cured acrylic resin stabilization splints).

Randomization and Allocation Concealment

A computer-generated randomization sequence will be used to allocate participants into the two study groups. Allocation concealment will be ensured using sequentially

numbered, sealed opaque envelopes, prepared by an independent researcher who is not involved in participant recruitment, intervention delivery, or outcome assessment. The allocation sequence will remain concealed until the point of assignment.

Blinding

This study will employ an assessor-blinded design. Outcome assessor responsible for data collection and analysis will remain blinded to group allocation throughout the study. Due to the nature of the intervention, patients and the operator fabricating and delivering the splints cannot be blinded.

Study Duration and Follow-up

Each participant will be followed for a total duration of 3 months. Clinical assessments will be conducted at:

- Baseline (prior to intervention)
- 3 months post-intervention (primary endpoint)

At each follow-up visit, outcome measures will be recorded, and necessary occlusal adjustments will be performed according to a standardized protocol.

Study Framework

- Study Type: Interventional
- Design Model: Parallel Assignment
- Allocation Ratio: 1:1
- Blinding: Assessor (Single-blinded)
- Primary Purpose: Treatment

Participants Inclusion Criteria

- Adults aged 18–40 years
- Diagnosis of temporomandibular disorder (TMD) according to standardized Diagnostic Criteria for Temporomandibular disorders Axis I
- Maximum unassisted mouth opening between 20–30 mm
- Symptoms present for ≥3 months (to exclude transient/self-limiting cases)
- Willingness to comply with study protocol and provide informed consent

Exclusion Criteria

- Diagnosis of Temporomandibular joint myalgia or myofascial pain as the primary condition
- History of trauma to the Temporomandibular joint or mandible
- Presence of degenerative joint diseases (e.g., osteoarthritis, rheumatoid arthritis)
- Congenital or developmental craniofacial anomalies affecting Temporomandibular joint
- Prior Temporomandibular joint surgery or ongoing orthodontic treatment
- Current use of: Analgesics, muscle relaxants, or anti-inflammatory drugs affecting TMJ symptoms
- Prior Occlusal splint therapy within the last 3 months
- Systemic conditions affecting joint function (e.g., connective tissue disorders)
- Pregnancy or lactation (if intervention may influence compliance or physiology

Interventions

Digital splint:

- Three dimensionally printed using Digital light processing printer
- 2 mm thickness
- Flat plane, canine guidance
- Usage: ≥8 hours/night

Conventional splint:

- Conventional stabilizing splint fabricated using Conventional heat-cured acrylic Resin
- Same design as Digital splint
- Usage: ≥8 hours/night

Outcome Measures

Primary:

Change in Pain intensity: **Change in Pain Intensity**

Description: Change in Pain intensity will be assessed using the Characteristic Pain Intensity (CPI) component of the Graded Chronic Pain Scale (GCPS). The CPI is calculated based on patient-reported current, worst, and average pain scores and is expressed on a 0–100 scale, where higher scores indicate greater pain intensity. The outcome measure is the mean change in CPI score from baseline to 3 months post-intervention.

Time Frame: Baseline to 3 months post-intervention

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Secondary:

Change in Pain-Related Disability: Change in Pain-related disability will be assessed using the disability component of the Graded Chronic Pain Scale (GCPS), which includes three items evaluating interference with daily activities, social activities, and work, each scored on a 0–10 scale. The mean of these items is multiplied by 10 to generate a disability score ranging from 0 to 100, where higher scores indicate greater disability. The outcome measure is the mean change in disability score from baseline to 3 months post-intervention.

Time Frame: Baseline to 3 months post-intervention

Change in maximum mouth opening (MMO): Maximum mouth opening will be measured in millimeters (mm) as the maximum unassisted inter-incisal distance using a calibrated ruler or digital caliper. The mean change from baseline will be compared between groups to assess improvement in mandibular function.

Time Frame: Baseline and 3 months post-intervention.

Change in Jaw Functional Limitation: Jaw Functional limitation will be assessed using the Jaw Functional Limitation Scale (JFLS-20), a validated patient-reported outcome measure consisting of 20 items evaluating mastication, vertical jaw mobility, and emotional and verbal expression. Each item is scored on a 0–10 scale, and the total score is calculated as the mean of all items, resulting in a score ranging from 0 to 10, where higher scores indicate greater functional limitation. The outcome measure is the mean change in JFLS-20 score from baseline to 3 months post-intervention.

Time Frame: Baseline to 3 months post-intervention.

Resolution of Temporomandibular joint (TMJ) clicking: Resolution of TMJ clicking will be assessed clinically during mandibular opening and closing movements by a trained examiner under standardized conditions. Clicking will be recorded as a dichotomous variable (present/absent) based on the presence of an audible or palpable click during at least one of three consecutive mandibular opening–closing cycles. The outcome measure is the proportion of participants demonstrating resolution of TMJ clicking (present at baseline and absent at 3 months post-intervention).
Time Frame: Baseline and 3 months post intervention.

Change in oral health-related quality of life: Oral health-related quality of life will be assessed using the Oral Health Impact Profile (OHIP-14) questionnaire. The OHIP-14 consists of 14 items scored on a 5-point Likert scale (0 = never to 4 = very often), with total scores ranging from 0 to 56. Higher scores indicate worse quality of life. The outcome measure is the mean change in OHIP-14 score from baseline to 3 months, compared between the conventional stabilizing splint group and the digital stabilizing splint group.
Time Frame: Baseline and 3 months post-intervention.

Compliance with splint use: Compliance will be assessed based on self-reported average nightly use (hours per night). Mean compliance will be compared between groups and explored as a modifier of treatment outcomes.
Time Frame: From intervention (day of splint delivery) to 3 months post-intervention, with compliance recorded continuously and summarized as average nightly wear time at 3 months.

Sample size: The sample size for this randomized controlled trial was calculated based on the primary outcome, change in pain intensity measured using the Graded Chronic Pain Scale (GCPS). As previous clinical trials evaluating splint therapy in temporomandibular disorders have primarily reported pain outcomes using visual analogue scales (VAS), a standardized effect size approach was adopted. Based on evidence from randomized trials and systematic reviews of stabilization splint therapy, a moderate effect size (Cohen's $d = 0.5$) was assumed for between-group differences in pain reduction. Using a two-sided significance level ($\alpha = 0.05$) and a statistical power of 80% ($\beta = 0.20$), the required sample size was calculated using G*Power software (version 3.1, Heinrich-Heine-University Düsseldorf, Germany). The calculated sample size was 102 participants (51 per group). To account for an anticipated 10–15% attrition rate, the final sample size was increased to 120 participants, with 60 participants allocated to each group.

Randomization: Participants will be randomly allocated to either the intervention group (digitally fabricated stabilization splints) or the control group (conventional stabilization splints) in a 1:1 allocation ratio.

Sequence Generation: A computer-generated randomization sequence will be created using a random number generator by an independent researcher who is not involved in participant recruitment, intervention delivery, or outcome assessment.

Allocation Concealment Mechanism: Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes (SNOSE). Each envelope will contain the group assignment and will be prepared in advance according to the randomization sequence.

Implementation: The envelopes will be opened sequentially only after participant enrollment and baseline assessment, ensuring that allocation remains concealed until assignment.

Statistical Analysis Plan: All statistical analyses will be performed using IBM SPSS Statistics (version 26.0; IBM Corp., Armonk, NY, USA). A two-sided p-value < 0.05 will be considered statistically significant.

Continuous variables will be assessed for normality using the Shapiro–Wilk test. Normally distributed data will be presented as mean ± standard deviation, while non-normally distributed data will be presented as median and interquartile range.

The primary outcome (change in pain intensity measured using the Characteristic Pain Intensity component of the Graded Chronic Pain Scale) will be analyzed by calculating the change from baseline to 3 months. Within-group comparisons will be performed using paired t-test (or Wilcoxon signed-rank test if non-parametric), and between-group differences will be assessed using independent samples t-test (or Mann–Whitney U test).

Secondary continuous outcomes, including pain-related disability (GCPS disability score), maximum mouth opening (mm), jaw functional limitation (JFLS score), and oral health-related quality of life (OHIP-14), will be analyzed similarly using change scores from baseline to 3 months. Within-group changes will be assessed using paired t-tests, and between-group comparisons will be performed using independent samples t-tests (or corresponding non-parametric tests where appropriate).

The categorical outcome (resolution of TMJ clicking) will be analyzed using Chi-square test or Fisher's exact test for between-group comparisons, and McNamara's test for within-group changes over time.

Compliance with splint use will be summarized using descriptive statistics (mean hours/night). Exploratory analyses may include incorporation of compliance as a covariate using analysis of covariance (ANCOVA) to assess its influence on treatment outcomes.

All analyses will follow the intention-to-treat principle. Missing data will be handled using appropriate methods such as last observation carried forward or sensitivity analyses where applicable.

Data Management: All participant data will be collected using standardized case report forms and entered into a secure electronic database.

Data Coding and Confidentiality: Each participant will be assigned a unique study identification number, and all data will be de-identified prior to analysis. Personal identifiers (e.g., name, contact details) will be stored separately from study data to ensure confidentiality.

Data Storage and Security: All electronic data will be stored on password-protected computers and encrypted storage systems with access restricted to authorized study personnel only. Physical documents (if any) will be stored in locked cabinets within secure institutional premises.

Data Access and Control: Access to the dataset will be limited to the principal investigator and designated research team members. Data handling procedures will comply with institutional policies and applicable ethical guidelines.

Data Quality Assurance: Data entry will be monitored for accuracy and completeness. Periodic checks will be performed to identify inconsistencies, missing values, or outliers. Any discrepancies will be resolved by cross-verification with source documents.

Data Retention: All study data will be retained securely for a minimum of 3–5 years after study completion, in accordance with institutional and regulatory requirements.

Ethical Considerations: Ethical approval for this study has been obtained from the Institutional Review Board (IRB) of Shifa Tameer-e-Millat University (Approval No: 243-25). The study will be conducted in accordance with the principles of the Declaration of Helsinki and applicable institutional and national guidelines.

Informed Consent: Written informed consent will be obtained from all participants prior to enrollment. Participants will be provided with detailed information regarding the study objectives, procedures, potential risks, and benefits. They will be informed of their right to withdraw from the study at any time without any consequences to their treatment.

Confidentiality and Data Protection: All participant data will be de-identified using unique study identification numbers. Personal identifiers will be stored separately from study data to ensure confidentiality. Electronic data will be stored in encrypted, password-protected systems, with access restricted to authorized research personnel only. Data handling procedures will comply with institutional data protection policies.

Risk–Benefit Assessment: The study involves minimal risk, as both interventions represent standard or widely accepted treatment modalities. Any adverse events will be documented and managed according to institutional clinical protocols.

Protocol Amendments: Any modifications to the study protocol (including changes to objectives, eligibility criteria, outcomes, or statistical methods) will be documented with a revised protocol version number and date. It will be Submitted for approval to the Institutional Review Board prior to implementation It will be Updated in the trial registry (e.g., ClinicalTrials.gov) and it will be reported transparently in any resulting publications.