

Efficacy of Digitally fabricated occlusal splints for treatment Temporomandibular disorders: A randomized controlled trial

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Aim: The main objective of this prospective study was to assess the digitally fabricated splints on Treatment of temporomandibular disorders, in terms of pain, mouth opening, and muscle biting force.

Materials and methods: A twenty patients with myofascial pain diagnosed in accordance with research diagnostic criteria for temporomandibular disorders RDC/TMD. The patients were randomly divided into two groups the first group was treated by traditional occlusal splints and the second group was treated by Digitally fabricated occlusal splints. All patients will be followed up on specific dates; the first day, two weeks, one, and three months later.

Results: Across all variables and time points, no statistically significant differences were observed between the Acrylic and Digital splints. The mean force values for the Acrylic and Digital (3D printed) occlusal splints were assessed across five time points. No statistically significant differences were observed at any stage. Both types of splints showed consistent improvements over suggested period of this study, indicating that they are both effective in treating TMD symptoms.

Conclusion: Digitally fabricated occlusal splints are a viable alternative to traditional acrylic splints for TMD treatment, offering equivalent efficacy in pain reduction, enhanced maximum mouth opening (MMO), and improved biting force. Their use could modernize and streamline therapeutic approaches in TMD management.

Keywords: Conventional Splint, Digital Splint , Biting Force , Maximum mouth opening, Pain, TMD

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Introduction

Studies revealed a high prevalence of temporomandibular joint (TMJ) dysfunction across countries ranges from 10.5% to 54%.^{1,2,3} Effective management of TMJ dysfunction is essential prior to initiating restorative dental procedures, as recording mandibular movements and occlusal registrations without resolving symptomatic musculature can compromise treatment outcomes. The etiology and treatment strategies for TMJ dysfunction remain complex and not entirely understood.⁴

The masticatory system plays a vital role in chewing, speaking, and swallowing, while contributing to breathing and taste perception.⁵

Temporomandibular disorders (TMD) are complex, multifactorial conditions affecting the temporomandibular joint (TMJ), masticatory musculature, and associated musculoskeletal structures of the head and neck. Clinically, TMD presents with diverse symptoms, including pain, restricted mandibular motion, abnormal joint sounds, and functional impairments such as difficulty chewing and speaking, often accompanied by psychological disturbances.^{6,7}

These disorders affect 5–12% of the population, with a greater prevalence in females aged 18–45 years.⁸

The etiology of TMD is multifactorial, incorporating biomedical and biopsychosocial perspectives, with risk factors such as stress, bruxism, and hyperlaxity.⁹ Among TMD subtypes, myogenic TMD is the most prevalent, involving muscle-origin pain that exacerbates with jaw function or parafunction.¹⁰ This condition is often linked to overuse, muscle guarding, and hyperactivity of the lateral pterygoid muscle, which may contribute to disc displacement and secondary disorders.¹¹

Despite its prevalence, gaps in research remain regarding the functional and

musculoskeletal impairments associated with TMD. Specifically, pain levels, maximum mouth opening, and biting force lack sufficient investigation, particularly in myogenic TMD.⁷

Treatment options for temporomandibular disorders (TMD) are generally categorized into three groups: non-invasive, minimally invasive, and invasive methods. Non-invasive treatments traditionally include occlusal splints, pharmacotherapy, and physical therapy. Minimally invasive techniques encompass interarticular injections and arthrocentesis, while invasive approaches involve arthroplasty and total TMJ replacement. Among these, non-invasive methods are most frequently employed due to their safety and ease of implementation.^{12,13}

Temporomandibular disorders (TMD) encompass a diverse range of clinical conditions that involve the temporomandibular joint (TMJ), the associated myofascial musculature, and related anatomical structures. Although a universally accepted classification system for TMD is lacking, the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) remain the most widely utilized framework for diagnostic purposes.^{10,14}

Emerging digital technologies, such as digitally fabricated occlusal splints, have shown potential as treatment modalities. This study evaluates the efficacy of such splints. Does digitally fabricated one have the same effect as traditional occlusal splints in TMD treatment in reducing pain, improving mouth opening, and enhancing biting force in patients with TMD or not? This study was made through a randomized controlled trial.

Material and methods

The present study was conducted in Minia university dental hospital after the approval of the ethical committee (Ethical committee approval number: 106, Decision

number: 917, Date: 30/4/2024). Patient selection was made according to the following criteria;

Inclusion criteria

- subjects with Myogenic TMD according to RDC/TMD algorithm for diagnosing myogenic TMD (Muscle Disorders).¹⁰
- Both genders.
- Age ranges between (18 to 45).¹⁵
- Same number of original molars to avoid affection of Periodontal Proprioception and bite force.¹⁶

Exclusion criteria

- Arthrogenic or disc displacement TMD diagnosed by RDC/TMD algorithms for diagnosing disc displacement or articular disorder.
- Acute traumatic injury of TMJ.
- Patients with dental prosthesis or dental implants.¹⁶
- Presenting with two or more lost molars.
- Presence of acute toothache or unsatisfactory periodontal health.¹⁷
- Cognitive deficits.
- Medication intake (analgesics, anti-inflammatory or muscle relaxant drugs)

Sample size

The current prospective study was carried out on twenty patients with myofascial pain diagnosed in accordance of research diagnostic criteria for temporomandibular disorders RDC/TMD.¹⁰ The patients were randomly divided into two groups the first group was treated by traditional occlusal splints and the second group was treated by Digitally fabricated occlusal splints.

The randomization was made by Simple Randomization Using a Computer-Generated Random Sequence. This method involves creating a random sequence using computer statistical programs (Excel). Each patient is assigned to one of the two groups

(conventional splints or digitally fabricated splints) based on this sequence.¹⁸

Fabrication of Conventional TMD Splints

The conventional occlusal splint was fabricated following the guidelines outlined by Okeson (2019).⁵ Impressions of the maxillary and mandibular arches were obtained using a high-accuracy vinyl polysiloxane (VPS) impression material. These impressions were poured with dental stone to create precise casts. A facebow transfer was performed to record the spatial relationship of the maxillary arch to the hinge axis and to mount the maxillary cast onto a semi-adjustable articulator.

A centric relation record was obtained using a bimanual manipulation technique to accurately position the mandibular cast in centric relation. This was used to mount the mandibular cast against the maxillary cast on the articulator. Using a vacuum-formed thermoplastic material or processed acrylic resin, a flat-plane stabilization splint was fabricated on the maxillary arch cast.

The occlusal surface of the splint was adjusted to ensure uniform contact with all opposing teeth in centric relation and smooth, non-restrictive gliding movements in lateral and protrusive excursions. Final adjustments were made intraorally to confirm fit, comfort, and proper occlusal relationships before delivery to the patient.

Fabrication of Digitally Designed TMD Splints

For the digital method, the intraoral scanning was made using Omnicam intraoral scanner (Cerec AC Omnicam, software version 4.6.1, DENTSPLY Sirona, 13320-B, Ballantyne Corporate Pl Charlotte, NC 28277 USA) according to the scan path proposed by the manufacturer to create high-resolution digital impressions.

Two Tongue depressors was used bilaterally to make jaw separation (about 2 mm) and the patient were guided to bite on

tongue depressors in centric relation position. (Figure 1: A)

The digital impressions and bite registration were exported into in Lab Splint design software (in Lab Splint design software, version 20.0.4., Dentsply Sirona , Cerrec software , DENTSPLY Sirona , 13320-B, Ballantyne Corporate Pl Charlotte, NC 28277 USA), where the occlusal splint was virtually designed as a flat-plane stabilization splint. (Figure 1: B)

The design included even occlusal contacts across the arch and smooth guidance in lateral and protrusive movements. Adjustments to the design were made digitally to optimize fit and functionality. (Figure 1: C)

The finalized design was then exported as an STL file and fabricated using an additive manufacturing process, specifically a dental-grade resin (Detax Freeprint SPLINT 2.0 (HARD) 385 DLP 3D Printing Resin 02080 - 500g, Unit 6 / 51 Jersey Road, Bayswater, Victoria AUSTRALIA 3153) through a stereolithography (SLA) printer (Phrozen Sonic Mighty 8K Resin 3D Printer, Germany)

After fabrication, the splint was post-processed following the manufacturer's instructions, including washing, curing, and polishing. The completed splint was assessed intraorally to ensure a precise fit, comfort, and check for occlusal adjustments.

Patients were instructed on usage and maintenance for both types of splints. This dual approach allowed for a comparison of the clinical efficacy of conventionally fabricated and digitally fabricated occlusal splints in the management of TMD symptoms.

Clinical assessment

Clinical assessment was conducted using the RDC/TMD system which involved the use of history questionnaire and clinical

examination form (which includes; palpation of TMJ for detection of pain and joint noises, measurement of mandibular range of motion and palpation of muscles of mastication), to achieve clinical TMD diagnosis and a psychological.

All patients were treated by following conservative therapy program for a period of 3 months as first line treatment, consisting of soft diet, physiotherapy, occlusal stabilizing splint, non-steroidal anti-inflammatory drugs and habit modification.

Pain rating scale:

The Wong-Baker Faces Pain Rating Scale is a widely used tool to assess pain intensity, especially in children and patients with communication difficulties. It uses a series of faces to represent different levels of pain, ranging from no pain to the worst pain imaginable.^{19,20} (Figure 2) The scale typically includes 6 faces numbered 0, 2, 4, 6, 8, and 10. Faces: The expressions range from a happy, smiling face (no pain) to a crying, distressed face (worst pain Interpretation: 0 :No pain, 2 :Hurts a little bit, 4 :Hurts a little more, 6 :Hurts even more, 8 :Hurts a whole lot, 10 :Hurts the worst

Showing the scale to the patient and ask them to choose the face that best describes their pain level. Record the corresponding number for clinical evaluation.

Maximum Biting force

To measure the maximum bite force, Patients were seated in an upright position in the dental chair and instructed to bite on the force transducer bite sensor device ((occlusal force – meter, GM10, Nagano Kieki., LTD)) was placed on the occlusal surface of the mandibular premolar- molar region. Then, each patient was instructed to bite as much as they could on the bite gauge with 45 seconds intervals between biting on each side.



Figure 1: A) Showing two Tongue depressors were used bilaterally to make jaw separation. B) Scan of the both arches showing the amount of teeth separation. C) showing Adjustments of the design were made digitally using InLab splint software to optimize

Wong-Baker FACES Pain Rating Scale



Figure 2: The Wong-Baker's Faces Pain Rating Scale

The procedure was repeated three times for each side in each patient, and the maximum value of the bite force (MBF) was recorded for each side in newtons (N). The readings were recorded immediately at first day, two weeks, one and three months later.

Mouth opening

Digital Vernier Calipers ((Manufacture TOTAL brand, TMT321501, stainless handed caliper, China) was used for assessing mandibular range maximum mouth opening.

The participant opened his mouth maximally as possible as he/she can, and the vertical distance from the incisal edge of the maxillary central incisor to the incisal edge of the opposing mandibular incisor was measured by the inner jaws of the caliper Statistics.

The data were collected at time of delivery, two weeks, one month, three months then tabulated and statistically analyzed by the Unpaired Student's t-test to analyze normally distributed variables, while the Mann-Whitney test was used for non-parametric data. Significant level was set at P value < 0.05.

Results

The study evaluated the efficacy of digitally fabricated occlusal splints compared to traditionally fabricated acrylic splints for management of temporomandibular disorders (TMD). The parameters assessed were pain levels, maximum mouth opening (MMO), and biting force.

All analyses, graphics and descriptive statistics were performed using GraphPad Prism version 8.01 (GraphPad Software, San

Diego). Data was reported as mean \pm standard deviation

All data were subjected to normality test (D'Agostino test); data that passed the normality test (follow a Gaussian distribution) was treated with the parametric tests while that did not pass (not follow a Gaussian distribution) was treated with non-parametric tests. Mann-Whitney U test was used for comparison between the medians of two groups for the pain score, while Unpaired student-t-test was used for comparison between the means of two groups.

Differences between means or medians were considered statistically significant at $P < 0.05$.

Across all variables and time points, no statistically significant differences were observed between the Acrylic and Digital splints. The mean force values for the Acrylic and Digital (3D printed) occlusal splints were assessed across five time points. No statistically significant differences were observed at any stage: (Table 1)

Biting Force

Both groups showed an improvement in biting force over time. At baseline, the mean biting force was 20.7 ± 2.71 N (for acrylic group) and 21.7 ± 5.76 N (for digital group). There is no statistically significant difference between both groups in improving biting force ($p = 0.6251$). By three months, both groups recorded a mean force of 26.0 N ($p = 0.9999$). (Figure 3)

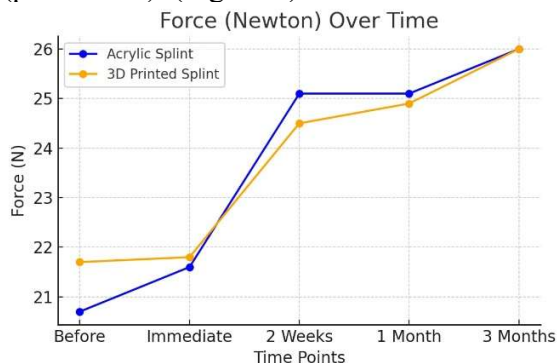


Figure 3: Showing both groups showed an improvement in biting force over time

Maximum Mouth Opening (MMO)

Similar improvements in MMO were observed in both groups. Initial values were 39.6 ± 2.55 mm (acrylic) and 39.1 ± 5.59 mm (digital), with no statistically significant difference ($p = 0.7997$). After three months, MMO values increased to 44.2 ± 1.14 mm (acrylic) and 44.4 ± 0.97 mm (digital), showing no statistically significant differences ($p = 0.6764$). (Figure 4)

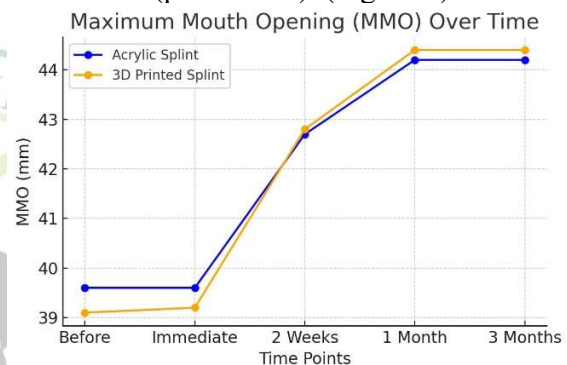


Figure 4: Showing improvements in Maximum Mouth Opening were observed in both groups.

Pain Levels

Both groups exhibited significant pain reduction. Initial pain levels were 7.60 ± 1.43 (acrylic) and 7.70 ± 1.06 (digital), with no statistical significance difference ($p = 0.9922$). At three months, pain reduced to 1.00 ± 0.94 (acrylic) and 0.80 ± 0.63 (digital), maintaining non-significance ($p = 0.8732$). (Figure 5)

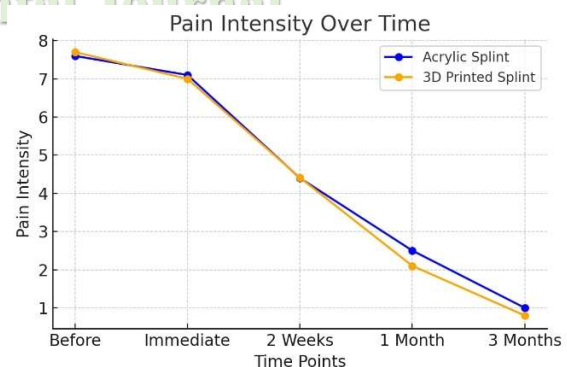


Figure 5: Showing Both groups exhibited significant pain reduction

Table 1: Showing the parameters assessed were pain levels, maximum mouth opening (MMO), and biting force

	Force (Newton)			MMO (mm)			Pain		
	Acrylic	Digital	P-Value	Acrylic	Digital	P-Value	Acrylic	Digital	P-Value
<i>Before</i>	20.7 ± 2.71	21.7 ± 5.76	0.6251	39.6 ± 2.55	39.1 ± 5.59	0.7997	7.60 ± 1.43	7.70 ± 1.06	0.9922
<i>Immediate</i>	21.6 ± 2.68	21.8 ± 5.43	0.9180	39.6 ± 2.50	39.2 ± 5.55	0.8378	7.10 ± 1.79	7.00 ± 1.25	0.6226
<i>2 weeks</i>	25.1 ± 2.89	24.5 ± 5.42	0.7609	42.7 ± 1.77	42.8 ± 1.99	0.9067	4.40 ± 0.97	4.41 ± 0.99	0.6476
<i>One month</i>	25.1 ± 2.89	24.9 ± 5.02	0.9142	44.2 ± 1.03	44.4 ± 0.97	0.6601	2.50 ± 1.27	2.10 ± 0.88	0.5576
<i>Three months</i>	26.0 ± 2.87	26.0 ± 5.10	0.9999	44.2 ± 1.14	44.4 ± 0.97	0.6764	1.00 ± 0.94	0.80 ± 0.63	0.8732
	Unpaired student-t-test			Unpaired student-t-test			Mann Whitney test		

*, significant ($p < 0.05$) ns; non-significant ($p > 0.05$)

Discussion

This study used well-designed methods to ensure accurate and reliable results when comparing traditional and digitally fabricated occlusal splints for treating myogenic TMD. The approach followed clinical standards and utilized advanced technology to overcome the limitations of traditional fabrication methods.²¹

By using simple randomization, this study can ensure an unbiased allocation of participants to both treatment groups, reducing selection bias and enhancing the validity of the results.¹⁸

Conventional occlusal splints are fabricated following Okeson's (2019)⁵ principles for TMD management. Vinyl polysiloxane (VPS) impressions ensure accurate reproduction of the intraoral anatomy, while a semi-adjustable articulator and facebow transfer simulate jaw

movements and occlusal relationships. Flat-plane stabilization splints effectively distribute occlusal forces, reduce muscle hyperactivity, and relieve pain in myogenic TMD.¹⁰ However, this method is time-consuming, requires several clinical visits, and involves a risk of human error during manual fabrication.

Digital methods, on the other hand, employ cutting-edge technology to address these challenges. Intraoral scanning produces highly accurate digital impressions and eliminates errors associated with conventional impression materials. In Lab Splint design software allows for precise customization of the splint design, including adjustments for even occlusal contacts and smooth guidance in excursive movements. Additive manufacturing through stereolithography (SLA) ensures high precision and reproducibility while reducing

fabrication time. Studies have shown that digitally fabricated splints provide comparable or superior outcomes in terms of fit, comfort, and patient satisfaction.^{22,23}

The selection of outcome measures; pain intensity, maximum mouth opening (MMO), and maximum bite force (MBF) was based on their clinical relevance in assessing the functional and symptomatic improvement in patients with myogenic TMD.

Pain Intensity is the most prominent symptom in myogenic TMD and has a direct impact on patients' quality of life.²⁴ The Wong-Baker Faces Pain Rating Scale (WBS) was used because it is simple, effective, and widely accepted for quantifying subjective pain levels which has a minimal and set number of categorical responses which are presented in each pattern. Garra G. et al 2010 validated the WBS in children with pain by identifying a corresponding mean value of the visual analog scale (VAS) for each face of the WBS and determined the relationship between the WBS and VAS. Their hypothesis was that the pain severity ratings on the WBS would be highly correlated (Spearman's rho > 0.80) with those on a VAS.¹⁹

Maximum Mouth Opening (MMO) Restricted mandibular range of motion is a key diagnostic and functional parameter in TMD.¹⁰ Measuring MMO with a digital Vernier caliper provides high accuracy and objectivity, enabling the detection of subtle improvements during treatment.

Maximum Bite Force (MBF) is a critical indicator of muscle function and masticatory efficiency. Patients with myogenic TMD often exhibit reduced bite force due to muscle pain or dysfunction.²⁵ Using a force transducer device provides reliable and repeatable bite force measurements in Newtons (N), which can be used to assess functional recovery.

By employing both conventional and digital methods of splint fabrication, this study provides a comprehensive evaluation of

their efficacy. The random allocation of patients into two groups minimizes selection bias, while the follow-up ensures that both short and long-term outcomes are assessed. The inclusion and exclusion criteria ensure homogeneity of the study sample by eliminating confounding factors such as arthrogenic or disc-displacement TMD, loss of molars, or cognitive impairments that could influence outcomes.^{10,16}

The results indicate that digitally fabricated occlusal splints are equally effective as traditional acrylic splints in managing TMD symptoms. The study demonstrates that improvements in biting force, MMO, and pain reduction are comparable between the two fabrication methods.^{26,27}

Conclusion

The combination of evidence-based conventional methods and innovative digital technologies ensures a thorough evaluation of occlusal splint efficacy in managing myogenic TMD. Digitally fabricated occlusal splints are a viable alternative to traditional acrylic splints for TMD treatment, offering equivalent efficacy in pain reduction, enhanced MMO, and improved biting force. Their use could modernize and streamline therapeutic approaches in TMD management. Taking in consideration other factors like how comfortable the splints are for patients, how much they cost and how much time the chairside visit takes for adjustment could help to support the benefits of using digital splints.

Clinical Implications

Digital fabrication offers advantages such as precision, customization, and efficiency in production, which may enhance patient satisfaction and clinical workflow and decreasing the chairside adjustment.

Both types of splints showed consistent improvements over suggested

period of this study, indicating that they are both effective in treating TMD symptoms.

This study incorporates advanced technology, including intraoral scanning and SLA, to enhance the precision and efficiency of splint fabrication. Furthermore, the focus on functional outcomes such as MBF and MMO, along with subjective pain assessments, provides a comprehensive evaluation of treatment efficacy. The integration of evidence-based protocols ensures that findings are grounded in established clinical practice.

Limitations and Future Directions

One limitation of this study is the relatively small sample size, which may limit the generalizability of results. Future studies with larger cohorts are recommended to validate the findings. Additionally, investigating the cost-effectiveness of digital methods compared to conventional techniques would provide valuable insights for clinical decision-making.

Disclosure

This study was approved by the Faculty of Dentistry – Minia University Ethical Committee under approval number 106, decision number 917, dated April 30, 2024. The authors confirm that they have no competing interests related to this research. All data used and analyzed in this study are available upon reasonable request from the corresponding author. Additionally, this research did not receive funding from any public, commercial, or non-profit organizations. There are no conflicts of interest to declare.

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