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Effect Of Using Occlusal Splints In Pain Management Related To TMJ Disorders By Using Digital Workflow

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Abstract

Background: Temporomandibular disorders (TMDs) are conditions that affect the jaw and muscles; they may cause pain and dysfunction in the jaw joint and muscles that control jaw movement. Occlusal stabilization splints are commonly employed as interocclusal devices to manage symptoms associated with temporomandibular disorders (TMDs). The fabrication of stabilization splints can be achieved via conventional & digital workflows. The goal of this study was to evaluate the efficacy of digitally fabricated occlusal splints in comparison to conventional splints in management of TMDs of muscular origin.

Methods: Forty eligible patients were selected from the outpatient clinic in the faculty of dentistry, October University of Modern Sciences & Arts MSA, Cairo, Egypt. Selected patients were randomly allocated into two groups using sealed envelopes. Group A received stabilization repositioning occlusal splint with conventional technique. Group B received occlusal splints made by intraoral scan and digitally designed to desire occlusal contacts and 3D printed.

Results: Comparing the two groups to each other's VAS scores & MMO at the baseline and through the follow-up intervals, there was a non-significant difference between them ($p > 0.05$). Comparing the chairside time of the two groups at acquisition, there was a non-significant difference ($p > 0.05$) between them at delivery; Group B had a significant decrease ($p \leq 0.05$) of chairside time.

Conclusion: It can be concluded that both conventional splints & digitally fabricated occlusal splints showed successful results in managing muscular TMDs. Chairside time was greatly decreased by the digital workflow, providing a suitable alternative to the conventional methods.

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1 Introduction

Temporomandibular disorders (TMDs) are conditions that affects jaw and muscles, they may cause pain and dysfunction in the jaw joint and muscles that control jaw movement.[1]The most common symptoms and signs of TMDs are severe pain, clicking, popping, or locking of the jaw.[2]

The TMJ disorders may have many different causes, a few among them are habits such as clenching or grating and grinding teeth (bruxism), malocclusion that puts muscles under pressure and stress, accidents that damage the bones of the face or jaw are infrequently, also some diseases such as arthritis or stiffness of joints.[3]

The majority of TMD patients can be treated primarily with occlusal therapy, which includes mouth appliances and rehabilitation in appropriate cases,[4-6] as well as with drugs, manual therapy,[7-9] procedures. In actuality, an

occlusal splint is a removable device that covers the entire occlusal and Incisal surface of all teeth in the upper or lower jaw. It is typically made of resin. Occlusal splint therapy is the most often utilized clinical strategy due to its versatility, affordability, and ease of application. [10]

Occlusal splints, particularly stabilization splints, are widely recommended for treating TMD. [11] They help achieving an optimal centric relation occlusion, which may decrease abnormal muscle activity and promote what is known as 'neuromuscular balance' in the masticatory system.[12]

The conventional method of creating splints involves taking mandibular and maxillary impressions. A clear, firm vacuum-formed template is built over the models that are manufactured. Using cold-cured transparent resin, the template occlusal surface is modified intra-orally to achieve balanced occlusion with a centric condylar location. Patient cooperation and tolerance for resin irritation are required for this time-consuming procedure. Moreover, adjusting resin intra-orally is a challenging process that demands a high level of operator experience.[13]

New technologies have increasingly developed and implemented in the dental field. The introduction of accurate intraoral scanners, CAD/CAM technology, and the increasing diffusion of precise 3D printing machines allow for the digital workflow to manufacture dental prostheses or other intraoral devices.[14–18]

Digitalization has revolutionized the production of oral appliances and prostheses through computer-aided design/computer-assisted manufacture (CAD/CAM) techniques, which utilize both subtractive and additive methods. Subtractive manufacturing involves grinding and milling, while additive manufacturing employs methods such as selective laser sintering, stereo lithography, photo-curing print, and fused deposition modeling (3D printing).

When it comes to occlusal splints, they can be fabricated using either conventional methods or a complete digital workflow that incorporates both additive and subtractive CAD/CAM techniques. [19]

Complete arch scans have evolved into a dependable and accurate routine for various appliance therapies, such as digital wax up [20] and orthodontic aligners [21] . The literature currently lacks clarity on the facts on the use of a full digital process for the fabrication of TMJ bite splints.

Therefore, the aim of this study was to evaluate the efficacy of digitally fabricated occlusal splints in comparison to conventional splints in management of TMDs.

2 Materials and Methods

2.1 Sample size:

The sample size calculation was based on the primary outcome measure. G*power version 3.1.9.4 software was used to calculate the effect size and sample size. Based on the previous study by Amr H. Elkhadem & Reem H. Hossameldin 2021 [22] , If there is truly no difference between conventional and digital fabricated occlusal splints with effect size 4.33, and with 10% drop outs then 20 specimens in each group are required to be 80% sure that the limits of a two-sided 95% confidence interval will exclude a difference in means of more than 1.5.

2.2 Study Design & Patient Selection

Forty patients were selected from the outpatient clinic in the faculty of dentistry, October University of Modern Since & Arts MSA, Cairo, Egypt. They were diagnosed with TMD pain of muscular origin. The study included participants who met the following criteria: (i) a clinical diagnosis of TMD according to the RDC/TMD [23], indicating the presence of muscle spasm & TMD of muscular origin (ii) at least 20 years old, and (iii) no general conditions (such as rheumatoid arthritis) that could impact the masticatory muscles or TMJ.

Moreover, subjects were excluded if had any of the following; (i) History of recent trauma or previous TMJ surgery, (ii) Patients suffering from manifestations of disc displacement (iii) psychiatric disorders, (iv) Pregnancy or (v) History of tumors.

All patients were informed about the study's nature, including the associated risks and benefits, and they were provided by a written informed consent for the treatment plan. In accordance with the Declaration of Helsinki on medical ethics and protocol, this study received approval from the Ethical Review Board of Ain Shams University (No. 052475).

2.3 Patients Grouping

Selected patients were randomly allocated into two groups using sealed envelopes.

Group A received stabilization repositioning occlusal splint with conventional impression and vacuum formed splints modified intra orally with cold cured resin.

Group B received stabilization repositioning occlusal splints made by intra oral scan and digitally designed to desire occlusal contacts and 3D printed.

2.4 Study Outcomes

- ***Primary outcome variable:*** Pain assessed using visual analog scale (VAS). Rated from 0 = no pain to 10 = worst pain.
- ***Secondary outcomes variable:*** change of maximum mouth opening (MMO)measured as the distance between the incisal edge of the upper and lower central incisors & chairside time measured by minutes.

The two groups were compared to each other based on improvements in pain levels, maximum mouth opening, and chairside time.

2.5 Pre- Operative Phase:

All personal information, including detailed medical and dental histories, was recorded for each patient. a comprehensive clinical & radiographic examination was carried out. The Visual Analog Scale (VAS) was used to assess pain, with a score of zero indicating no pain and a score of ten representing the worst pain conceivable. [24] The maximum unassisted mouth opening (MMO) was recorded in millimeters (mm) using a Vernier caliper. **(Fig. 1)**

Figure 1. Measurement of maximum mouth opening using Caliper.

Measurements were initially taken preoperatively (baseline) and then repeated at one month and three months postoperatively.

2.6 Operative Phase:

Group A: Fabrication Of Conventional Splints

At the first appointment, normal set alginate impression material (Cavex CA37, CAVEX HOLLAND BV, Netherlands) was used to create impressions of both the maxillary and mandibular arches. The impressions were made with at least a 5 mm extension below the gingival margins and extending distally beyond the last molar. Subsequently, the impressions were cast in type III dental stone.

A one mm thick hard vacuum formed sheet was thermally adapted over the maxillary models using a vacuum pressing machine from (Bioart , Brazil). The sheet was then trimmed at the gingival margin level with a scissor. Finally, the vacuum sheet was tested for proper seating and retention.

Cold cured resin from (Acrostone , Egypt) was mixed until it reached a dough-like consistency. It was then placed over the palatal area of the vacuum template, specifically at the upper incisors. To ensure proper alignment, the patient was guided to close their mouth in centric relation using a bimanual manipulation technique. This technique helped seat the condylar disc complex in the antero-superior position. The patient was instructed to close their mouth just before the first posterior contact between the vacuum template and the lower posterior teeth. Once the cold cured resin had set, any excess material was carefully trimmed using an acrylic bur. The centric position was verified inside the patient's mouth to ensure consistent closure on the set anterior jig.

A second mix of cold cured resin was then prepared to a dough-like consistency and applied bilaterally over the posterior region of the vacuum template. The patient was asked to close their mouth until the lower teeth made contact with the set anterior jig. After the resin had completely set, any excess material was trimmed away. Indentations on the buccal and lingual slopes of the lower teeth were also trimmed, leaving only the cuspal tip contact. The acrylic slope in the canine area was retained. To ensure proper occlusion, an articulating paper was used inside the patient's mouth to eliminate any interferences and prematurity.

The patient was then asked to slide their lower teeth laterally, and any excessive contacts were removed. This allowed for smooth gliding of the lower canines over the acrylic in the upper canine region. **(Fig 2. A, B)**

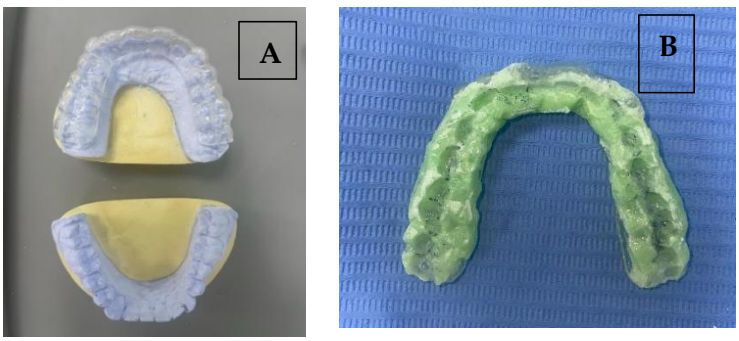

Figure 2. *Conventional splints fabrication*

Group B: Fabrication Of Digital Splints

Splints were commenced with the direct intraoral scanning of the patient's dental arches using the TRIOS 4, 3 Shape scanner, which exported STLs representing precise 3D models. **(Fig. 3)**

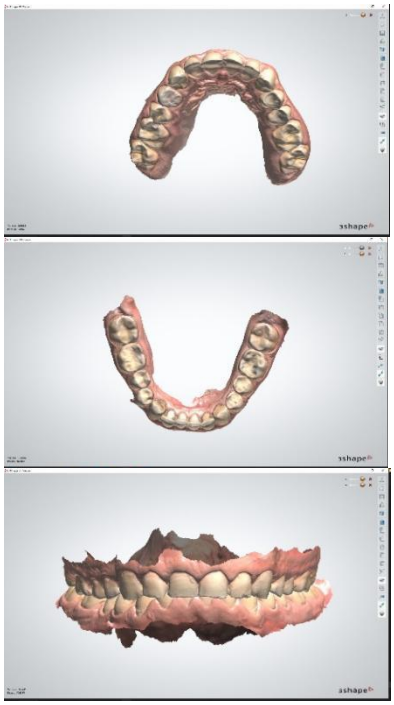

Figure 3. *STLs representing precise 3D digital models*

These digital models were subsequently imported into the Exocad Galaxy software. Within the Dental Desktop order form, a tooth from the upper jaw was selected, and the 'Splint' option was chosen to initiate the design process. The appropriate machine and material for splint production were selected to ensure compatibility with the chosen fabrication method.

The subsequent step involved verifying the bite configuration by confirming the correct positioning of the jaws within the virtual articulator. This was achieved using control points, with tools such as tooth outlines on the default plane assisting in model alignment, and control spheres allowing for precise adjustments to the jaw's tilt and height. With a bite increase of approximately 2.5 mm to ensure sufficient material thickness. The software then automatically generated the insertion direction for the occlusion splint.

The external geometry has designed to be permitting unrestricted mandibular movement. The final design underwent a thorough evaluation through articulation simulation within the virtual articulator, ensuring that no tooth contact occurred beyond the canines during lateral or mediotrusive movements, thereby achieving disocclusion in these excursions. **(Fig. 4)**

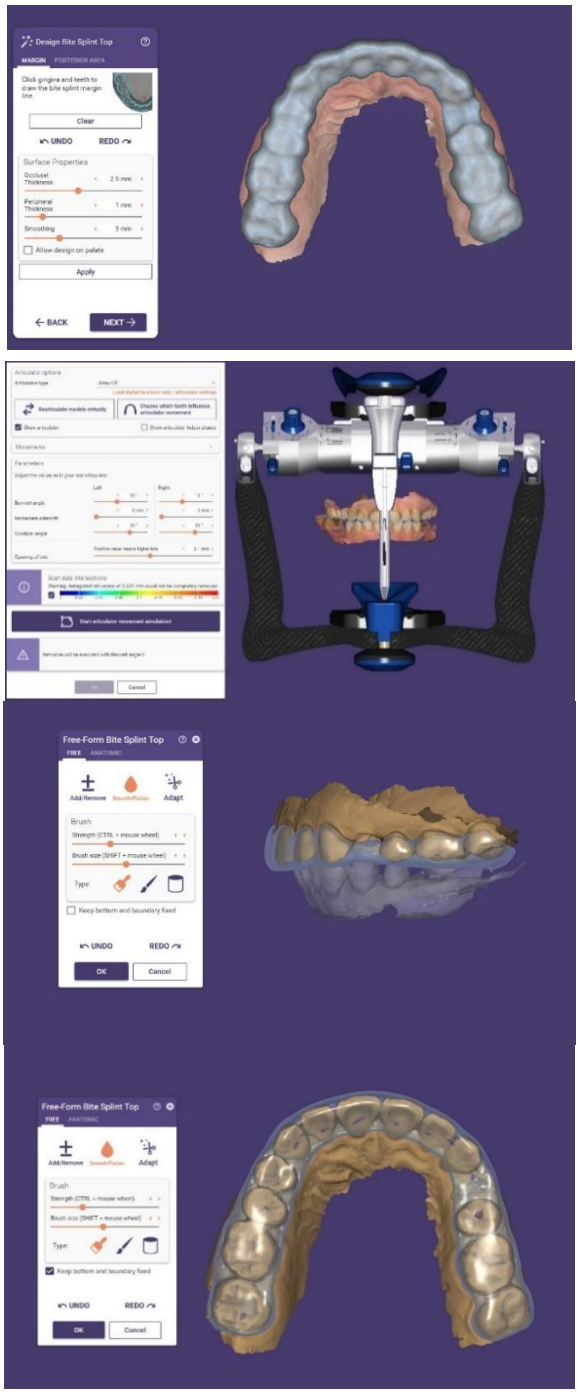

Figure 4: *The final digital design using virtual articulation*

Finally, the splint was smoothed and refined to ensure that it provided stable contact when the jaws were closed and to improve patient comfort. The completed design was then printed using the Anycubic Mono 6K printer, which is known for its high-resolution capabilities.

A specialized resin CreaPRINT Splint Dental Resin Merz Dental GmBH was used and cured at around 405 nm, ensuring the splint's durability and precision. After printing, the splint was polished. **(Fig. 5)**

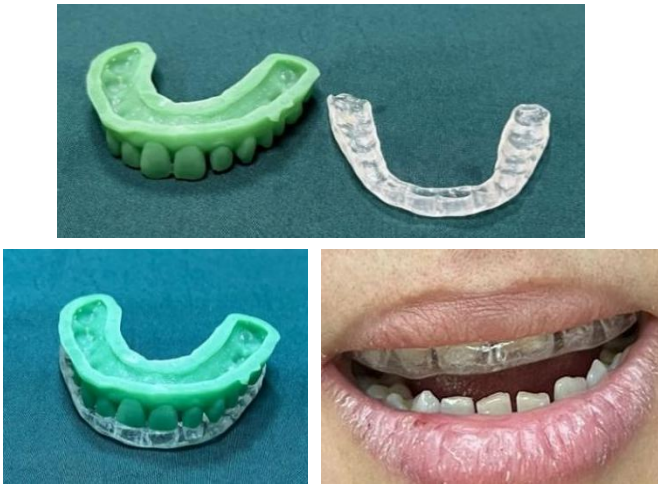

Figure 5: *digitally constructed splint on 3D printed models*

Chair side time calculation

For both groups, the duration of the impression visit and the fitting visit was recorded with a stopwatch.

2.7 Statistical analysis:

Numerical data were presented as mean, standard deviation (SD), median, and interquartile range (IQR) values. They were tested for normality by viewing the distribution and using Shapiro-Wilk's test. Chairside time data were normally distributed and analyzed using independent and paired t-tests for inter- and intragroup comparisons. Other data were non-parametric and analyzed using the Mann-Whitney test for intergroup comparisons and Friedman's test, followed by Nemenyi's post hoc test for intragroup comparisons. P-values were adjusted for multiple comparisons using the False Discovery Rate (FDR) method. The significance level was set at p<0.05 within all tests. Statistical analysis was performed with R statistical analysis software version 4.4.1 for Windows.[1].

3 Results

Forty eligible patients (11 males & 29 females) with TMD complaints of muscular origin were included in the current study. Patients mean age was 33 years. The present study was conducted to evaluate the efficacy of digitally fabricated occlusal splints in comparison to conventional splints in management of TMDs of muscular origin.

3.1 VAS score

The Mean VAS score for Group A was (8.17±0.75.) at the baseline, decreased significantly (p≤ 0.05) at 1 month (5.17±0.75) and 3 month (3.00±0.89) postoperatively.

As for Group B, the Mean VAS score was (8.00±0.89) at the baseline, decreased significantly (p≤ 0.05) at 1 month (4.67 ± 0.82^{B}) and 3 month (2.33±0.52) postoperatively.

Comparing the two groups together at the baseline and through the follow up intervals, there was no significant difference between them at the three intervals (p > 0.05). **Table 1 (Fig. 6)**

Table 1. Inter and intragroup comparisons of pain score.

Interval	Measurement	Pain score		Test statistic	p-value
		Group (A)	Group (B)		
Baseline	Mean±SD	8.17 ± 0.75^{A}	8.00 ± 0.89^{A}	20.00	0.798
	Median (IQR)	$8.00\ (0.75)^{A}$	$8.00\ (1.50)^{A}$		
One month	Mean±SD	5.17 ± 0.75^{B}	4.67 ± 0.82^{B}	24.50	0.306
	Median (IQR)	$5.00\ (0.75)^{B}$	$4.50\ (1.00)^{B}$		
3 months	Mean±SD	3.00 ± 0.89^{C}	2.33 ± 0.52^{C}	26.00	0.190
	Median (IQR)	$3.00\ (1.50)^{C}$	$2.00\ (0.75)^{C}$		
Test statistic		12.00	12.00		
p-value		0.002*	0.002*		

Values with **different superscripts** within the **same vertical column** are significantly different, * significant (p<0.05).

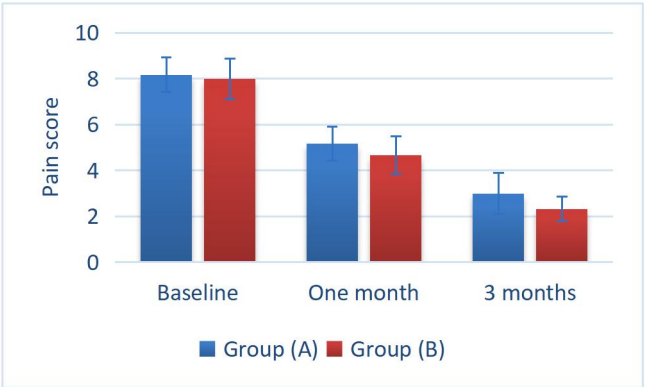

Figure 6. Bar chart showing mean and standard deviation (error bars) values for pain score.

[1]R Core Team (2024). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/.

3.2 MMO

The Mean MMO score for Group A was (27.25±0.96) at the baseline, increased significantly (p≤ 0.05) at one month (35.00±0.82) and three month (36.75±0.50) postoperatively.

As for Group B, the Mean MMO score was (25.00±0.82) at the baseline, increased significantly (p≤ 0.05) at one month (33.50±0.58) and three month (36.00±1.15) postoperatively.

Comparing the MMO of the two groups at the baseline and through the follow up intervals, there was no significant difference between them at the three intervals (p > 0.05). **Table 2 (Fig. 7)**

Table 2. Inter and intragroup comparisons of maximum mouth opening (MMO).

Interval	Measurement	MMO (mm)		Test statistic	p-value
		Group (A)	Group (B)		
Baseline	Mean±SD	27.25± 0.96^{C}	25.00± 0.82^{C}	15.50	0.078
	Median (IQR)	27.50 (1.25)^{C}	25.00 (0.50)^{C}		
One month	Mean±SD	35.00± 0.82^{B}	33.50± 0.58^{B}	15.00	0.078
	Median (IQR)	35.00 (0.50)^{B}	33.50 (1.00)^{B}		
3 months	Mean±SD	36.75± 0.50^{A}	36.00± 1.15^{A}	11.00	0.405
	Median (IQR)	37.00 (0.25)^{A}	36.00 (2.00)^{A}		
Test statistic		8.00	8.00		
p-value		0.018*	0.018*		

Values with **different superscripts** within the **same vertical column** are significantly different, * significant (p<0.05).

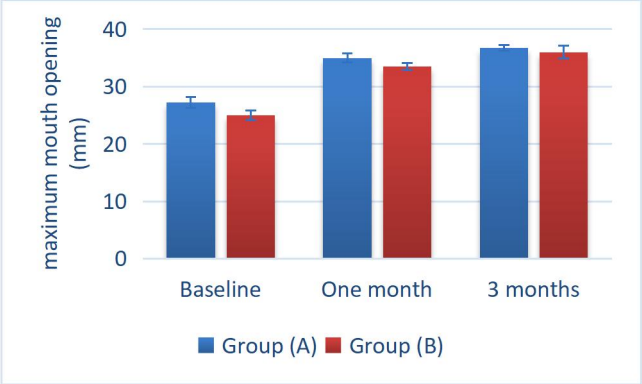

Figure 7. Bar chart showing mean and standard deviation (error bars) values for maximum mouth opening.

3.3 Chair side time

The Mean chair side score for Group A was (14.50±0.58) at acquisition, increased significantly (p≤ 0.05) at delivery (37.50±2.08).

While for Group B, the Mean chair side score was (13.75±0.50) at acquisition, decreased significantly (p≤ 0.05) at delivery (9.00±0.58).

Comparing the chair side time of the two groups at acquisition, there was a non-significant difference (p > 0.05) at the chair side timing between the two groups, while at delivery, a significant difference (p ≤ 0.05) was found between the two groups, in favor for Group B with less chair side time. **Table 3 (Fig. 8)**

Table 3. Inter and intragroup comparisons of chairside time.

Interval	Measurement	Chairside time (minutes)		Test statistic	p-value
		Group (A)	Grou p (B)		
At acquisition	Mean±SD	14.50±0 .58	13.75± 0.50	1.96	0.097ns
	Median (IQR)	14.50 (1.00)	13.50 (0.25)		
At delivery	Mean±SD	37.50±2 .08	9.00±0 .58	26.39	<0.001*
	Median (IQR)	37.50 (2.00)	9.00 (1.00)		
Test statistic		21.29	19.00		
p-value		<0.001*	<0.001 *		

* Significant, ns not significant.

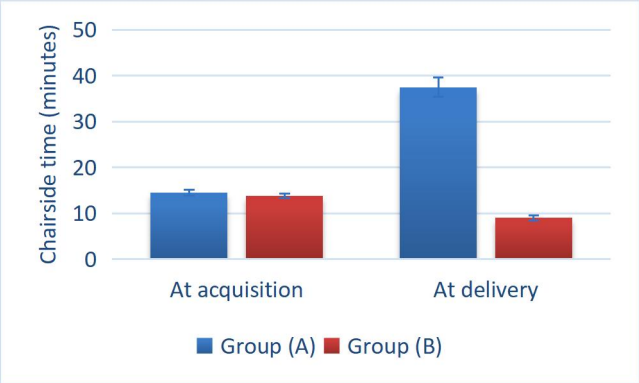

Figure 8. Bar chart showing mean and standard deviation (error bars) values for chair side time.

4 Discussion

Occlusal stabilization splints are commonly employed as interocclusal devices to manage symptoms associated with temporomandibular disorders (TMD) of muscular origin. [25] The primary therapeutic goal of occlusal stabilization splints (SS) is to provide pain relief, and evidence suggests that altering the vertical dimension can be one way to achieve this. This mechanism is linked to changes in the functional patterns of the masticatory muscles and the position of the condyles.[26] They establish an optimal centric relation occlusion, which may help reduce abnormal muscle activity and promote what is referred to as 'neuromuscular balance' within the masticatory system.[27]

The fabrication of stabilization splints traditionally begins with creating plaster casts from impressions of the patient's dental arches. These splints are then tested and adjusted in the patient's mouth to ensure proper fit and comfort. This process can be both time-consuming and costly for the dental technician, dentist, and patient.[19]

Intraoral scanning is now a viable alternative to conventional impression methods. Scanning has been demonstrated to save time and enhance treatment comfort, with its precision surpassing that of traditional impression methods.[28,29] The digital workflow improves clinical practice and patient experience by offering a minimally invasive impression technique, faster bite plane recording, and greater appliance precision. [30] The goal of this study was to evaluate the efficacy of digitally fabricated occlusal splints in comparison to conventional splints in management of TMDs.

The current study was conducted on 40 patients complaining of TMD problems of muscular origin with characteristic muscle spasm., including 11 males & 29 females and their age range 21 to 45 with mean value 33 years. Women made up the majority of our study group (72.5 %), which supports other researches showing that women have higher TMD pain than males.[31–33] Furthermore, the average age of the study groups (33 years old) was comparable to what has been documented in the literature.[34–36]

Results of the present study showed that both conventional & digitally constructed splints were comparable in terms of pain relief and an increase in the maximum moth opening. Comparing the two groups there was no significant difference between them at the follow up intervals. This can be attributed to the fact that the occlusal contact principles and fit quality of both final splints are similar. These findings are in accordance with other clinical trials and systematic reviews that demonstrate the effectiveness of occlusal splint therapy in improving masticatory function and lowering pain levels in patients with painful TMDs.[10,37,38]

Moreover, comparing the chair side time between the two groups during the impression taking visit there was a non-significant difference. This explained by the fact that a number of variables, including patient compliance, operator expertise, and learning curve, affect how long it takes to make imprints and scans. Similar findings were found in research by ***Gjelvold et al***. [39] that contrasted the intraoral digital imprint technique with the traditional impression technique. With an average duration of 11–12 minutes, they discovered that there was no statistically significant difference between the two groups.

However, comparing the chair side time between the two groups during the delivery & fitting visit reveled signific decrease, in favor for digital group. The primary reason for this decline is because the intra oral scan group's occlusal equilibration was carried out using software that was based on a digital jaw record registration. Therefore, less occlusal adjustments were necessary for occlusal devices made using a fully digital workflow. This is accordance with ***Blasi et al,*** [40] they anticipated that occlusal devices manufactured with a fully digital approach would require fewer occlusal adjustments.

An investigation by ***Patzelt et al,*** [41] comparing conventional and digital workflows for the production of occlusal splints with regard to time efficiency, overall fit, and wear, relative to time, the digitally fabricated splints were suggested because there is a decrease in the number of steps during the construction. These results support what was observed in our study. These facts support fabrication of occlusal devices using a fully digital workflow, suggesting that they would be a good substitute for devices made using an analog approach as consuming less timing.

5 Conclusion

Within the limitations of this study, it can be concluded that both conventional splints & digitally fabricated occlusal splints showed successful results in management of pain & improvement in mouth opening without significant difference between them. In terms of chairside time it was greatly decreased by the digital workflow used to fabricate stabilizing splints, particularly the time spent during the fitting procedure. The digital work follow can provide a suitable alternative to the conventional methods with reduced chair side time.

Authors' Contributions

Samar Saeed. Managed study design along with manuscript preparation. Omnia Sultan managed Diagnosis & fabrication of conventional splint along with manuscript witting. Ahmed Wagdy & Hesham Amr managed designing of digital occlusal splint along with manuscript editing & reviewing.

Conflict of interest

The authors declare that they hold no competing interests.

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