ORIGINAL ARTICLE

Patient’s satisfaction and muscles activity after management of temporomandibular disorders patients using computer-aided design/computer-aided manufacturing versus conventional occlusal splints (randomized clinical trial)

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Abstract

Background: With continuous debate, regarding which are more effective in managements of the temporomandibular disorders (TMDs), CAD/CAM or conventionally made occlusal splint, this study aimed to answer the following question “does the CAD/CAM occlusal splints have different effect regard to patient satisfaction, muscle activity, and time of adjustments when compared with conventional splints?”

Materials and Methods: A sample of 30 TMD patients, with a mean age of 30.2 years were randomly allocated into Groups 1 (CAD/CAM splint 15 patients) and 2 (conventional splint 15 patients). The research diagnostic criteria for TMD were used for TMD Axis I (Groups II disc displacement with reduction). Numeric scales (TMD/NS, 10 cm) were used to measure headaches, face pain, jaw joint pain, jaw joint noises, mastication pain, neck pain, face tension, limitation of mouth opening, complaints during mastication, and teeth sensitivity at baseline and then monthly for 3 months. Electromyography was used to measure the muscle activity of masseter and temporalis muscles at baseline, 1 month, and 3 months. The time needed for adjustment of splint from the beginning of splint insertion until became well fitted and occclusally adjusted was calculated using stopwatch (minutes).

Results: TMD/NS showed statistically significant improvement in CAD/CAM splint group when compared to conventional splint after 1 and 3 months $P = 0.001$ and $< 0.0001$, respectively. There was highly statistical significant less time required for adjustment for the CAD/CAM occlusal splints when compared to the conventional occlusal splints ($P < 0.0001$).

Conclusion: The CAD/CAM occlusal splints significantly require less time of adjustment and improve the patient’s satisfaction of TMD patients greater than that of conventional occlusal splint. However, both splints are similar in regard to improvements of the muscle activities.

Keywords
Computer-aided design/computer-aided manufacturing occlusal splint, conventional occlusal splint, muscle activity, patient’s satisfaction

Introduction

Temporomandibular disorders (TMDs) are defined by the American Academy of Orofacial Pain as a collective term for a number of clinical problems, which involve the masticatory musculature, the temporomandibular joints (TMJs), and associated structures.\(^1\)

TMDs are considered to be the most common orofacial pain conditions of non-dental origin. The assessment TMD prevalence may be a complex matter due to the appearance of orofacial pain in addition to the frequent synchronous of different symptoms, such as ear pain, headache, and neuralgia, which may be associated to the TMD or be present as auxiliary findings to be considered in the differential diagnosis procedure.\(^2\)
According to published literatures, the prevalence of TMD is approximately 10% in patients over 18 years of age, with a considerable proportion being women of reproductive age.

Management of TMD can be either conservative or surgical treatments. The conservative treatments include analgesia, medications, physical therapy, occlusal adjustment, splint therapy, localized steam application, and external muscle massage. Conventional occlusal appliances are commonly used in the treatment of patients with TMD and have been reported to improve signs and symptoms in these patients. Conventional methods of splint manufacture are highly technique sensitive and often lead to poor splint fit, over contour, and hence poor patient compliance. They also require extensive chair-side time for adjustments to achieve passive fit and an appropriate occlusal scheme. Moreover, these appliances are more prone to fracture and failure during use.

With advent of the computer-aided design/computer-aided manufacturing (CAD/CAM) technologies, most of these problems resolved. The CAD/CAM splint eliminate of individual human errors inherent in technical processes, resulting in time savings and higher levels of predictability at both the technical and clinical level.

With continuous debate, regarding which are more effective in managements of the TMD, CAD/CAM or conventionally made occlusal splint, this study aimed to answer the following question “does the CAD/CAM occlusal splints have different effect regard to patient satisfaction, muscle activity, and time of adjustments when compared with conventional splints?”

Materials and Methods

Trial design and registry

This study was designed to be a parallel randomized controlled trial. The patients were randomly assigned to either one of the following groups: Test group (Group 1): Each patient received CAD/CAM stabilization occlusal splint using centric record. Control group (Group 2): Each patient received conventional stabilization occlusal splint using centric record.

The study protocol was approved by the Evidence-Based Dentistry Committee, Prosthodontic Department Board and Ethics Committee of Faculty of Oral and Dental Medicine, Cairo University. The study protocol registered on the Pan African Clinical Trial Registry (PACTR) with a registration number (PACTR: 201505001080998 in 22/03/2015).

Participants

Sample size calculation

A total sample size of 30 patients (15 patients in each group) will be sufficient to detect the effect size of 0.8, a power of 80%, and a significance level of 5% that the limits of a two-sided 95% confidence interval will exclude a difference in means.

Selection criteria

Thirty patients (24 female and 6 male) complaining of TMDs were selected from the outpatient clinic of oral and maxillofacial surgery department; Faculty of Oral and Dental Medicine, Cairo University to participate in this study. Patients were selected according to the following criteria:

1. Patient’s age ranged from 20 to 45 years.
2. TMDs according to the research diagnostic criteria (RDC) for TMD (RDC/TMD) and magnetic resonance imaging (MRI) for confirmation which include:
   i. Painful TMJ audible and palpable click.
   ii. No functional mouth limitation.
   iii. TMJ tenderness.
3. Absence of prior occlusal splint therapy.
4. Absence of substantial dental or periodontal disease with good oral hygiene.
5. The patient should be physically and psychologically able to tolerate procedures.
6. The patient should be cooperative to return for follow-up, examinations, and evaluation.
7. Patients with teeth loss that affects occlusal splint support were excluded.
8. Patients with systemic diseases which could affect TMJ, e.g., rheumatoid arthritis, osteoarthrosis, osteoporosis, and patients taking analgesic, muscle relaxant, or anti-inflammatory drugs were excluded because such drugs could influence the results.
9. Patients whom MRI examination did not reveal disc displacement with reduction (DDWR) were excluded from this study.

Examination methods

For TMD diagnoses, Axes I of the German version of the RDC for TMD were used. Axis I was used for TMD group diagnoses (i.e., Groups I-III). To confirm the presence or absence of an intra-articular disorder (i.e., DDWR [RDC/TMD Axis I Group II]), MRI examinations were requested due to the limitations in the clinical diagnosis of these disorders.

Randomization and blinding process

Random sequence generation

After clinical and MRI examinations for all eligible patients, the 30 patients were randomly assigned into two identical groups each of which 15 patients using special website concerned with randomization process called research randomizer (https://www.randomizer.org/). Group I (intervention group): 15 (2 male and 13 female) patients that were received a CAD/CAM stabilization occlusal splint. Group II (control Group): 15 (4 male and 11 female) patients that were received a conventional stabilization occlusal splint.

Allocation concealment

Only one investigator (Professor Kaddah A.), not involved in the selection and treatment of the patients, was aware of the randomization sequence and could have access to the randomization lists stored in his password-protected portable computer. The randomized codes were enclosed in sequentially numbered, identical, opaque, and sealed envelopes. Patients
were asked to select one of the envelope and the investigator that is aware of the randomization process was asked about the specific group and treated accordingly.

Blinding
Obviously, neither the participants nor care providers could be blinded as to the color of the splint delivered, but care providers were counseled to avoid commenting about treatment possibilities to participants and were not present when participants completed the TMD/numeric scale (NS) questionnaires. Furthermore, regarding the electromyographic activity of masseter and temporalis muscles and time needed for adjustment, blinding not necessary to done as it is an objective measurement. Consequently, in our study, the blinding concept is non-applicable.

Pre-treatment recordings
Patient’s satisfaction using NS Numeric scales (TMD/NS, 10 cm) were used to measure the patient satisfaction, this questionnaire include the following aspects; headaches, face pain, jaw joint pain, jaw joint noises, mastication pain, neck pain, face tension, limitation of mouth opening, complaints during mastication, and teeth sensitivity at baseline and then after 1 and 3 months.

The questioner was translated into Arabic language to be understood by the patients.

Muscular activity evaluation using surface electromyography (EMG) Muscular activity, represented by the root mean square value (RMS), was evaluated using a digital electromyogram (DantecTM KAYPOINT@ INC. U.S.A).

A transparent template (plastic mask) was modified for each patient to facilitate the accurate repositioning of the surface electrodes for subsequent visits. A triangular window was cut from the template following the outline of the patients’ nose to allow better adaptation of the template to the patient’s face.

Outer canthus of the eyes and angle of the mouth were marked on the adapted template and were used as reference landmarks to aid in the repositioning procedure.

The position of the surface electrodes on the anterior temporalis and the superficial masseter muscles was marked on the patient’s face by selecting the maximum bulging of the muscle fibers while the patient performed intermittent clenching. These points were then transferred to the transparent template that was perforated at the marked muscle positions.

During the EMG recording appointments, the patients were seated against the back of a chair, as relaxed as possible, positioning the head in such a way that the Frankfort plane is parallel to the floor (relaxed upright position). Before attaching the surface electrodes, the participant skin was cleaned with alcohol at the corresponding areas. Furthermore, the forehead was cleaned where the ground electrode was placed.

The inner sides of the electrodes were filled with Ten20 conductive EEG paste (Weaver and Co. Aurora, U.S.A) and were fixed on the patient’s skin using an adhesive tape on the anterior temporalis muscle and on the superficial masseter muscle.

Maximum voluntary teeth clenching (MCV)- data collection
Surface EMG activity of the right and left masseter and temporalis muscles was recorded during the performance of MCV clenching, with the patients clench in the intercuspal position. The patients were asked to clench as hard as possible the teeth on a cotton role.

EMG power spectrum- data analysis
From the surface EMG recordings of each muscle, a fast Fourier transform was carried out using the software of the EMG. The mean value of the EMG activity of each muscle was calculated from the RMS amplitude in microvolts (µV).

CAD/CAM and conventional stabilization splints
The conventional and the CAD/CAM splints used in this study had the same design (occlusal stabilization splint) so that any differences found between the two groups for TMD treatment outcome measures would not be attributed to splint design and occlusal scheme. They were designed and manufactured by prosthetic laboratory technicians (conventional) and at Technoplant Dental Lab (CAD/CAM).

For both splint types, maxillary and mandibular impressions were made (Cavex Holland B.V, Holland), models were poured with gypsum (Kimberlit, Type IV Dental Stone, Protechno-Spain), and interocclusal registrations were performed (Vinyl Polysiloxane, Futar D Fast, KETTEBACH, USA). The models were then mounted in a semi-adjustable articulator (Bio-art, A7Plus, Brazil). Both splints had a flat plane with posterior occlusal contacts in the supporting cusps and in the canine and incisal borders in centric relation, with anterior guidance for excursive movements. The conventional stabilization splint required a wax-up of the proposed occlusal scheme on a surveyed and mounted cast, which was then invested, and a clear heat-cured acrylic resin splint was fabricated. The resin splint was then trimmed, polished, and fitted back onto a duplicate of the investment cast. The CAD/CAM splint was designed using Dental Wings’ DWOS software and printed using ZENITH 3D printer, DENTIS, South Korea. They were made from a monomer based on acrylic esters, NextDent Ortho Rigid, the Netherlands [Figures 1 and 2].

The time needed for adjustment of both splints, from the beginning of splint insertion until became well-fitted and occlusally adjusted, was measured using a stopwatch.

Outcomes and follow-up visits
At baseline, patients were reviewed after 1 and 3 months. At each review, the NS, detailed examination, and EMG were repeated so that the outcome variables were outlined. The patient completed the NS in the waiting room to reduce bias.

Statistical analysis
Data from the two groups were collected, tabulated, and statistically analyzed and illustrated in tables and figures. The data were summarized as means and standard deviations. Collected
data were analyzed using a SPSS statistical package (Version 19, Chicago, IL, U.S.A).

Mean values were compared by independent t-test to compare between the two groups in regard to patient's satisfaction, muscles activity, and time of adjustments.

Paired t-test used to compare the effect of time in each group in regard to patient’s satisfaction and muscles activity. The level of significance was set at 5% for all statistical analyses.

Results
The sample of 30 patients (6 Male, 24 Female), with a mean age of 30.2 years were included in this study. A total of 30 occlusal splints were placed (15 each group). All patients attended the 3-months follow-up [Table 1 and Figure 3].

Patient’s satisfaction (TMD/NS)
The Arabic version of TMD/NS was used to evaluate the patient’s satisfaction.

In comparing two groups, there is no significant difference between CAD/CAM and conventional splints at baseline measurements; however, there is statistically significant improvement in TMD/NS of CAD/CAM splint group when compared to conventional splint after 1 and 3 months, \( P = 0.001 \) and <0.0001, respectively, as shown in Table 2 and Graph 1.

Muscles activity
The values RMS were recorded by digital electromyogram for masseter and temporalis muscles.

Effect of time on the muscles activity of both occlusal splint groups
The effect of time on EMG activity of masseter and temporalis muscles for both occlusal splints is shown in Graph 2. There was a gradual decrease of muscles activity throughout the whole follow-up periods with statistically significant difference from the baseline record to the 3-month period \( (P < 0.05) \).

Comparison between conventional and CAD\CAM groups regarding muscles activity
Massetor muscles activity
The comparison of the effect of conventional and CAD\CAM occlusal splints on EMG activity of masseter muscles is shown in Graph 3. There was a gradual decrease of muscles activity throughout the whole follow-up period in two groups, with no statistically significant differences at all follow-up periods \( (P > 0.05) \).

Temporalis muscles activity
The comparison of the effect of conventional and CAD\CAM occlusal splints on EMG activity of temporalis muscles is shown in Graph 4. There was a gradual decrease of muscles activity throughout the whole follow-up period in two groups, with no statistically significant differences at all follow-up periods \( (P > 0.05) \).

Time of adjustments
Time of adjustment was measured in minutes at the time of occlusal splint delivery.

The comparison between conventional and CAD\CAM occlusal splints regarding time of adjustment is shown in Graph 5.
**Figure 3:** CONSORT flowchart

**Table 2:** TMD/NS (10 cm, mean±SD) for Groups 1 and 2

<table>
<thead>
<tr>
<th>Group</th>
<th>Group I (CAD/CAM stabilization splint) (n=15)</th>
<th>Group II (conventional stabilization splint) (n=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>After 1 month</td>
</tr>
<tr>
<td>1. How strong was headache in the last month?</td>
<td>5.4±2.0</td>
<td>4.5±2.5</td>
</tr>
<tr>
<td>2. How strong was the face pain in the last month?</td>
<td>5.7±2.2</td>
<td>4.8±2.1</td>
</tr>
<tr>
<td>3. How strong was the pain in the jaw joint in the last month?</td>
<td>7.4±1.8</td>
<td>6.4±1.6</td>
</tr>
<tr>
<td>4. How strong was the noise in the jaw joint in the last month?</td>
<td>8.6±3.3</td>
<td>7.5±1.6</td>
</tr>
<tr>
<td>5. How strong was the pain during mastication in the last month?</td>
<td>5.6±2.0</td>
<td>4.3±2.0</td>
</tr>
<tr>
<td>6. How strong was the neck pain in the last month?</td>
<td>4.4±2.1</td>
<td>3.4±2.1</td>
</tr>
<tr>
<td>7. How strong was the face tension in the last month?</td>
<td>5.4±2.3</td>
<td>4.2±2.4</td>
</tr>
<tr>
<td>8. How strong was the neck tension in the last month?</td>
<td>4.2±2.1</td>
<td>3.1±2.1</td>
</tr>
<tr>
<td>9. How strong was the limitation on mouth opening in the last month?</td>
<td>4.2±2.1</td>
<td>3.4±2.1</td>
</tr>
<tr>
<td>10. How strong were the complaints during mastication in the last month?</td>
<td>5.7±2.0</td>
<td>4.8±2.1</td>
</tr>
<tr>
<td>11. How strong was the face tension on awakening in the last month?</td>
<td>4.5±2.8</td>
<td>4.0±2.1</td>
</tr>
<tr>
<td>12. How strong was the face tension at the end of the day (6 pm) in the last month?</td>
<td>4.1±2.2</td>
<td>3.2±2.3</td>
</tr>
<tr>
<td>13. How strong was the teeth sensitivity in the last month?</td>
<td>4.3±2.9</td>
<td>3.4±2.1</td>
</tr>
<tr>
<td>Total</td>
<td>7.34±0.91</td>
<td>5.38±1*</td>
</tr>
</tbody>
</table>

*P<0.001, **P<0.0001, NS: Numeric scales, TMD: Temporomandibular disorders, CAD: Computer aided design, CAM: Computer aided manufacturing
There was highly statistical significant less time required for adjustment for the CAD/CAM occlusal splints when compared to the conventional occlusal splints ($P < 0.0001$).

**Discussion**

The purpose of this study was to evaluate the effect of CAD/CAM versus conventionally fabricated occlusal splints on patient’s satisfaction and muscles activity after management of TMD patients in addition to measure the time needed for adjustment of the splint.

According to a recently published literature, to date, there has only been one clinical trial\(^{[12]}\) that compare CAD/CAM versus conventional occlusal splints compared the NS and optical axiography. No controlled studies have been found evaluating the influence on EMG muscles activity or time of adjustment in patients treated with CAD/CAM versus conventional occlusal splints.

The present study aimed to add to the available evidence for evaluating and comparing the patient’s satisfaction using NS, EMG muscles activity, and time of adjustment of patients treated with CAD/CAM versus conventional occlusal splints.

Regarding the NS of CAD/CAM and conventional occlusal splint groups, we can reject null hypothesis as the results of our study revealed statistically significant differences. Particularly, when comparing our NS result with Duc et al.\(^{[12]}\) who measured NS for a follow-up of 9 months, we found that the mean NS values of them were not comparable with our result. Therefore, the results cannot be compared to similar studies.

Conventional methods of splint fabrication are highly technique sensitive and often lead to poor splint fit, over contour, and hence poor patient compliance. Furthermore, patients often complain that they feel uncomfortable, too tight, or are too bulky to wear. They may also be self-conscious with wearing a cumbersome and obvious occlusal splint as reported by Dunn et al.\(^{[10]}\)

Traditionally, splint products are made from polymethylmethacrylate (PMMA) and as a result are prone to fracture and failure during use. One of the main advantages of the CAD/CAM product is the choice of base material used which possesses superior impact strength, yield strength, and wear resistance over traditional materials. This delivers an end product which is more durable, less bulky, and longer lasting as reported by Dunn et al.\(^{[10]}\)
Regarding the muscle activity of conventional and CAD/CAM splint groups, we cannot reject null hypothesis as the results of our study revealed no statistically significant differences. There are no controlled studies have been found evaluating the influence on EMG muscles activity in patients treated with CAD/CAM versus conventional occlusal splints. Considering that the results of this study cannot be compared with those of another similar study.

In our study, by time, the neuromuscular system adapts to the occlusal splint; consequently, the effort exerted by the masticatory muscles had been reduced gradually recording lesser values of EMG at 1 and 3 months of splint insertion.

These findings may be supported by most of the literatures that concluded that the exact therapeutic mechanism of the occlusal splint remains unclear, and although many theories have been proposed, there is little experimental evidence to support one theory over another because several factors may operate simultaneously.\(^{13-15}\)

Overall, the results of the present study revealed that the masseter muscle always exerts higher muscle activity when compared to the temporalis muscle. These findings may be explained at the basis of functional and anatomical differences between both muscles. Moreover, this may be attributed to the greater influence and the greater efforts exerted by the masseter muscle during chewing and clenching than the temporalis muscle.\(^{16}\)

When considering the analysis within groups, an earlier significant improvement in patient’s satisfaction and muscles activity was found for both groups. Splints are thought to unload the joint by disarticulating the dentition and increasing the vertical dimension of occlusion. By unloading the joint, there will be a reduction in both synovitis and masticatory muscle activity.\(^{17}\) Therefore, the result is a reduction in symptoms. These appliances may also change condylar position and the existing occlusal relationship, thereby reducing abnormal muscle activity and spasm as reported by Okeson.\(^{18}\)

Regarding the time needed for adjustment of conventionally fabricated and CAD/CAM splints groups, we can reject null hypothesis as there was statistically significant less time required for adjustment for the CAD/CAM occlusal splints when compared to the conventional occlusal splints. However, the results of this outcome cannot be compared to similar studies due to the lack of studies to measure this outcome.

The main benefits of CAD/CAM technologies are the elimination of human errors inherent in the casting and other technical processes, time savings and higher levels of predictability at the technical and clinical levels.\(^{19}\) However, the cost of CAD/CAM occlusal splint is significantly higher in the present clinical situation, but this might differ in other clinical settings and countries.

In addition to the over contour and the polymerization shrinkage associated with PMMA that results in poor fit and irregular occlusal scheme in conventionally fabricated occlusal splint, consequently, the conventional splints require extensive chair-side time for adjustments to achieve a passive fit and an appropriate occlusal scheme.

**Conclusion**

From the result of this study, it can be concluded that the CAD/CAM occlusal splint improves the patient’s satisfaction of TMD patients greater than that of conventional occlusal splint. Moreover, both CAD/CAM and conventional occlusal splint improves the masseter and temporalis muscle activities. In addition that CAD/CAM occlusal splint decreases to a large extent, the time needed for splint adjustment compared to conventional occlusal splint.

Within the limitations of this study, it could be recommended that:

CAD/CAM occlusal splint may be suggested as an alternative manufacturing modality for TMD patients who can offer the cost of this treatment modality.

**References**
