



Comparative efficacy of different thicknesses of soft and hard splints in reducing clinical symptoms in patients with temporomandibular disorders

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ABSTRACT

Introduction: The effectiveness of two soft and hard splint thicknesses in reducing temporomandibular joint (TMJ) pain and dysfunction was compared.

Materials and Methods: Sixty patients with TMJ pain and dysfunction were randomly assigned to four groups (n=15); the patients treated with hard occlusal splints of 1 and 3mm thicknesses were assigned to Groups A and B, respectively, and those treated with soft occlusal splints of 1 and 3mm thicknesses were assigned to Groups C and D, respectively. Maximum mouth opening (MMO) and the severity of pain based on the visual analog scale (VAS) were assessed before treatment and after 7, 30 and 90 days.

Results: After both 7 and 30 days, no significant differences were found between the groups for any variable ($P>0.05$). However, Group C had a significantly lower MMO compared to Groups A and B after 90 days ($P=0.001$). Additionally, and in relation to masticatory muscle pain, Group C had a significantly higher VAS score than other groups ($P<0.05$). The VAS score for TMJ pain at rest was also significantly higher in Group C compared to Groups A and B ($P<0.05$).

Conclusion: A 3-mm hard occlusal splint seems to be the best treatment to reduce pain and dysfunction of the TMJ.

Keywords: Temporomandibular disorders; Soft and hard occlusal splints; Pain; Dysfunction.

Introduction

Temporomandibular disorders (TMD) refer to a variety of conditions affecting the temporomandibular joint (TMJ) and are characterized by symptoms such as pain in the masticatory muscles and the TMJ, headache, limited jaw movements, and articular sounds when opening or closing the mouth. TMD can develop due to a number of reasons such as trauma, systemic dis-

orders, iatrogenic causes, occlusal problems or mental and psychological conditions. Evidence shows that impaired mental health plays a fundamental role in the pathogenesis of TMD [1-8]. The neuromuscular system responsible for mastication has high potential to cope with variable conditions. However, dysfunction occurs when the compensatory potential of the masticatory system or the neuromuscu-

lar system is impaired. As a result, clinical symptoms such as pain, joint clicking, and limitations in the movement of mandible occur, forcing the patient to seek treatment. TMD pain can relate to other areas such as the dental arch, temporal region, forehead, occiput, neck, spine, and even shoulders. Despite the fact that patients are often reluctant to seek treatment unless in severe cases, the prevalence of TMD is high in developed countries [9-11]. TMD comprise a group of dysfunctions and disorders related to the poor function of the TMJ and masticatory muscles, which can lead to painful functioning of the stomatognathic system [12]. TMJs are used 1500-2000 times a day, which underlines the extent of the impact of pathogenic factors on jaw movements [13].

Increased tension often leads to functional disorders of the masticatory muscles, and parafunctions can further aggravate the symptoms [14]. Given the subjective nature of the symptoms, the diagnosis of TMD is difficult, especially because patients often consult specialists other than dentists, such as neurologists, otolaryngologists, or ophthalmologists [9,15]. Aside from pain, patients with TMD often suffer from tooth hypersensitivity due to severe abfraction and attrition, gingival recession, tooth mobility, bone loss, and non-carious tooth lesions (which are pathognomonic of TMD) [16,17].

Treatment of TMD can range from conservative approaches to more invasive procedures such as surgery [18]. The most common conservative approaches include psychological counseling, pharmacotherapy, physical therapy, and splint therapy [19]. Occlusal splints have been widely accepted for the treatment of TMD due to their optimal efficacy and easy availability [18,20, and 21]. Soft occlusal splints are most commonly prescribed to patients because their flexibility can help better distribute heavy occlusal loads associated with parafunctional habits. They are also quick and easy to make. However, they do not have high adjustment accuracy [20,22, and 23]. Hard splints are designed to be able to make equal and consistent occlusal contacts. They can change the occlusal balance, improve the vertical dimension of the face and correct the condylar position [20,21,24, and 25]. The use of occlusal splints is also generally recommended for patients with TMD. However, literature search by the authors did not reveal any study on the efficacy of hard and soft occlusal splints of different thicknesses in reducing TMD symptoms. Therefore, this study compared the effectiveness of different thicknesses of soft and hard occlusal splints in reducing clinical symptoms

in patients with TMD. The null hypothesis was that the effectiveness of different thicknesses of occlusal splints would not differ significantly.

Materials and Methods

This study was conducted at the Department of Prosthodontics, Mashhad Dental School, Iran and approved by the University Ethics Committee (IR.MUMS.DENTISTRY.REC.1397.002). The study protocol was registered in the Iranian Registry of Clinical Trials (IRCT20180513039631N1).

Trial design

This clinical trial evaluated the efficacy of different thicknesses of soft and hard occlusal splints in reducing clinical symptoms of patients with TMD. The criteria for reporting the results were derived from the guidelines of the Consolidated Standards of Reporting Trials.

Participants, eligibility criteria, and settings

Sixty patients presenting to the Prosthodontics Department of Mashhad Dental School between 2018 and 2019 with restricted mouth opening and pain in the TMJ and/or masticatory muscles were selected using convenience sampling. The inclusion criteria were (I) signed informed consent form, (II) complaint of restricted mouth opening with a soft end feel and TMJ or masticatory muscle pain, (III) age between 15 and 55 years, (IV) class I occlusion, (V) complete dentition, and (VI) no other facial, oral, or dental conditions causing symptoms similar to TMD. The exclusion criteria were (I) systemic diseases associated with the TMJ, such as rheumatoid arthritis, (II) neurological disorders or head and neck cancer, (III) edentulous patients, (IV) history of TMJ surgery, (V) idiopathic clinical symptoms, (VI) history of joint, facial, or neck trauma within the past three months, (VII) addiction, and (VIII) use of analgesics, muscle relaxants, tranquilizers, or antidepressants.

Interventions

All patients were clinically examined by a prosthodontist who was blinded to the type of intervention. The patients who were assigned to the following groups according to the RDC/RMD criteria [26] received intervention; I.B (key: painful muscles, limited movement, criteria: myofascial pain, pain-free unassisted opening < 40mm and passive stretch ≥5mm) and III.A (key: painful TMJ/no crepitus, criteria: pain on TMJ palpation, either laterally or intra-auricular, self-reported

joint pain with/without jaw movement, no crepitus, and the possibility of clicking).

Patients were then randomly divided into the following four groups (n=15).

Group A: hard occlusal splint with a thickness of 1mm.

Group B: hard occlusal splint with a thickness of 3mm.

Group C: soft occlusal splint with a thickness of 1mm.

Group D: soft occlusal splint with a thickness of 3mm.

For both splint types, a master cast of the maxilla was fabricated by making an alginate impression of the maxilla. For hard splints, heat-curing transparent acrylic resin with thicknesses of 1 and 3mm were used in Groups A and B, respectively, at the site of the mesiobuccal cusp of the upper first molar. The splint was adjusted intraorally in centric relation to create even occlusal contacts by applying self-curing acrylic resin to the occlusal surface. Prior to polishing, the thickness of the molar area was measured to ensure accurate thickness. Soft splints with a thickness of 1mm for Group C and with a thickness of 3mm for Group D were fabricated from transparent sheets (13×13mm) using a vacuum pressing device. The transparent sheets were fully conformed to the plaster casts in a vacuum former. Next, the sheets were removed from the cast and trimmed with sharp scissors. The palatal portion of the splint was removed down to the rugae area to obtain the final shape. The splints were fabricated and polished by an experienced technician, and a graduate student in prosthodontics made the final adjustments.

Patients were instructed to wear the splint for at least 8 hours daily (preferably at night). They were also instructed in the correct insertion and removal of the splint. The splint could be seated primarily with finger pressure followed by moderate bite force for final positioning. To remove, the splints had to be removed from near the area of the first molar using the index fingernail and pulling its distal end down. Patients were informed of the possibility of a slight increase in salivation after using the splint, which would resolve within a few hours. The occlusal splint had to be rinsed after removal. Teeth had to be brushed to remove plaque and debris and eliminate bad taste. Hard occlusal splints had to be stored in water when not in use. Regular follow-ups were scheduled and clinical examination was performed after 7, 30, and 90 days by a prosthodontist blinded to the primary examination. Maximum mouth opening (MMO), or the inter-incisor distance, was measured with a Boley gauge. The

subjective pain rating was based on a visual analog scale (VAS); “0” meant no pain and “10” meant the worst pain imaginable. TMJ pain was measured by palpation of TMJs at rest, during opening or closing the mouth, and during lateral movements. Maximum masticatory muscle pain scores (masseter and temporalis) was recorded on bilateral palpation at each duration. To examine the masseter, the fingers were first placed over the zygomatic arch of each side. Next, they were moved slightly downward into the area where the masseter was attached to the zygomatic arch just in front of the TMJ. Finally, the fingers were moved downward towards the inferior attachment of the muscle at the base of the ramus. When examining the temporalis muscle, all three areas of anterior, middle and posterior were palpated. The anterior area was palpated just above the zygomatic arch and anterior to the TMJ. The middle area was palpated just above the TMJ and above the zygoma, and the posterior area was palpated above and behind the ear.

Outcomes (primary and secondary)

TMJ pain at rest and in function, masticatory muscle pain, and MMO were the primary outcome measures in this study.

Interim analysis and stopping guidelines

No interim analysis was performed, and no stopping guideline was established.

Randomization

For randomization, each patient randomly picked an envelope and was then assigned to one of the four groups based on the number inside.

Blinding

First, the patients were clinically examined by a prosthodontist blinded to the type of intervention. During follow-ups, clinical examinations were performed by another prosthodontist who was also blinded to patient group allocation.

Statistical Analysis

The Shapiro-Wilk test was used to assess the normality of the data. Groups were compared using the Kruskal-Wallis test, one-way ANOVA, Friedman's test, Fisher's exact test, and chi-square test. Statistical analyses were performed using SPSS version 22 and the significance level was set at 0.05.

Results

Participant flow

This study involved 60 patients, including 46 females (76.7%) and 14 males (23.3%) with a mean age of 28.95 ± 8.38 years (15-53 years).

Subgroup analyses

Age: The four groups did not differ significantly in mean age (Kruskal-Wallis test, $P=0.902$).

Gender: The four groups did not differ significantly in gender (Fisher's exact test, $P=1.00$).

Comparison of functional TMJ pain: Table 1 compares the measurements of the central distribution of functional TMJ pain in the four groups at different durations. As shown, the four groups did not differ significantly in terms of functional TMJ pain at baseline ($P=0.931$), after 7 days ($P=0.951$), and after 30 days ($P=0.989$). However, after 90 days, the four groups differed significantly in terms of TMJ pain and minimum and maximum pain scores were recorded in Groups B and C, respectively ($P=0.003$). Pairwise comparisons of groups after 90 days for functional TMJ pain revealed that Group C had a significantly higher mean pain score compared to Groups A ($P=0.035$) and B ($P=0.002$). No other significant differences were found ($P>0.05$).

Within-group comparison of functional TMJ pain at different durations: Groups A and B had the maximum and minimum mean pain scores recorded at baseline and after 90 days, respectively ($P<0.001$). In Group C, the maximum and minimum mean pain scores were recorded at baseline and after 30 days, respectively ($P<0.001$), while in Group D, such values were recorded at baseline and after 90 days, respectively ($P<0.001$). Within-group pairwise comparisons of durations (Figure 2) showed that in Groups A, B and D and compared to baseline, the mean pain score decreased significantly after 30 days ($P=0.014$, $P=0.028$, and $P=0.007$, respectively) and after 90 days ($P<0.001$). This was also the case after 90 days compared to after 7 days ($P=0.005$, $P=0.001$, and $P=0.004$, respectively). No other significant difference was found ($P>0.05$). In Group C and compared to baseline, the mean pain score decreased significantly after 7 days ($P=0.004$). Such a significant decrease was also the case when comparing the mean score after 30 days to 7 days ($P<0.001$). However, the mean score showed an increase after 90 days compared to 7 days ($P=0.002$).

Comparison of resting TMJ pain: Table 2 compares the central dispersion of TMJ pain at rest in the four groups at different durations. As shown, the four groups did not differ significantly in terms of TMJ at rest pain scores at baseline ($P=0.922$), after 7 days ($P=0.942$), and after 30 days ($P=0.937$) of treatment. However, the four groups differed significantly after 90 days, and Groups B and C and had the minimum and maximum pain scores, respectively ($P=0.014$).

Pairwise comparisons of the groups after 90 days showed that Group C had significantly higher mean score in terms of TMJ pain at rest compared to Groups A ($P=0.047$) and B ($P=0.019$). No other significant difference was observed ($P>0.05$). Within-group comparison of resting TMJ pain at different durations: In Group A, the maximum and minimum mean pain scores were recorded at baseline and after 90 days, respectively ($P<0.001$). The same was true in Group B ($P<0.001$). In Group C, the maximum and minimum mean pain scores were recorded at baseline and after 30 days, respectively ($P=0.002$), while in Group D, such scores were recorded at baseline and after 90 days, respectively ($P<0.001$). Within-group pairwise comparisons of durations (Table 3) showed that compared to baseline, the mean pain score decreased significantly in Groups A and B after 30 days ($P=0.035$ and $P=0.018$, respectively) and after 90 days ($P=0.001$ and $P<0.001$, respectively). Such a significant decrease was also the case after 90 days compared to 7 days ($P=0.009$ and $P=0.011$, respectively). No other significant difference was found ($P>0.05$). In Group C and compared to baseline, the mean pain score decreased significantly after 7 days ($P=0.028$) and after 30 days ($P=0.002$). It also decreased significantly after 30 days compared to 7 days ($P=0.002$), and after 90 days compared to 30 days ($P=0.032$). In Group D, all differences were significant ($P<0.05$) except for the change in pain score after 7 days compared to baseline ($P>0.05$), and after 90 days compared to 30 days ($P>0.05$). Comparison of masticatory muscle pain: Table 3 compares the central dispersion of masticatory muscle pain in the four groups. The four groups did not differ significantly in terms of resting masticatory muscles pain at baseline ($P=0.619$), after 7 days ($P=0.319$), and after 30 days ($P=0.560$). However, the four groups differed significantly in terms of resting masticatory muscle pain after 90 days, and the maximum and minimum pain scores were observed in Groups C and B, respectively ($P<0.001$). Pairwise comparisons regarding masticatory muscle pain after 90 days showed that Group C had a significantly higher mean pain score compared to Groups A ($P=0.001$), B

($P < 0.001$) and D ($P = 0.025$). No other significant difference was found ($P > 0.05$). Within-group comparison of masticatory muscle pain at different durations: In Group A, the maximum and minimum mean pain scores were recorded at baseline and after 90 days, respectively ($P < 0.001$). The same was true for group B ($P < 0.001$). In Group C, the maximum and minimum mean pain scores were recorded at baseline and after 30 days, respectively ($P < 0.001$), whereas in Group D, such scores were recorded at baseline and after 90 days, respectively ($P < 0.001$). Within-group pairwise comparisons of durations (Table 4) showed that in groups A, B and D and compared to baseline, the mean pain score decreased significantly after 30 days ($P = 0.004$, $P = 0.007$, and $P = 0.001$, respectively) and after 90 days ($P < 0.001$ for all three groups). Such a significant decrease was also the case after 90 days compared to 7 days ($P < 0.001$ for all three groups). No other significant difference was observed ($P > 0.05$). The mean pain score in Group C decreased significantly after 30 days when compared to baseline and 7 days ($P = 0.001$ and $P = 0.028$, respectively).

Comparison of MMO: Table 4 compares the central dispersion of MMO in the four groups. The four groups did not differ significantly in terms of MMO at baseline ($P = 0.969$), after 7 days ($P = 0.931$), and after 30 days ($P = 0.767$). However, they differed significantly after 90 days, and the maximum and minimum

MMO were observed in Groups B and C, respectively ($P < 0.001$). Pairwise MMO comparisons after 90 days indicated that Group C had a significantly lower mean MMO than groups A ($P = 0.001$) and B ($P < 0.001$). No other significant difference was observed ($P > 0.05$). Within group comparison of MMO at different durations: In Group A, minimum and maximum MMO were recorded at baseline and after 90 days, respectively ($P < 0.001$). This was also true in Group B ($P < 0.001$). In Group C, minimum and maximum MMO were recorded at baseline and after 30 days, respectively ($P < 0.001$), while in Group D, they were recorded at baseline and after 90 days, respectively ($P < 0.001$). Within-group pairwise comparisons of durations (Table 5) indicated that in Group A, the mean MMO increased significantly at each duration compared to its previous one ($P < 0.001$ for all comparisons). In Groups B and D and compared to baseline, the mean MMO increased significantly after 30 ($P < 0.001$ in both groups) and 90 days ($P < 0.001$ in both groups). Such a significant increase was also the case after 90 days compared to 7 days ($P < 0.001$ in both groups). No other significant difference was found ($P > 0.05$). The change in the mean MMO in Group C was not significant after 90 days when compared to 30 days ($P > 0.05$), though other differences were significant ($P < 0.05$). Comparison of clicks: Table 5 shows the frequency of clicks in the four groups at different durations.

Table 1. Comparison of the central dispersion of functional TMJ pain in the four groups at different durations (n=15).

| Duration | Group | Mean | Std. deviation | Min. | Max. | P-value (Kruskal-Wallis) |
|----------|-------|------|----------------|------|------|------------------------------|
| Baseline | A | 5.20 | 2.93 | 0 | 9 | $X^2 = 0.44$ $P = 0.931$ |
| | B | 5.53 | 3.23 | 0 | 9 | |
| | C | 5.40 | 2.87 | 0 | 9 | |
| | D | 5.73 | 2.84 | 0 | 9 | |
| 7 days | A | 4.73 | 2.63 | 0 | 8 | $X^2 = 0.34$ $P = 0.951$ |
| | B | 5.00 | 2.78 | 0 | 8 | |
| | C | 4.93 | 2.71 | 0 | 9 | |
| | D | 5.13 | 2.39 | 0 | 8 | |
| 30 days | A | 2.80 | 1.74 | 0 | 5 | $X^2 = 0.12$ $P = 0.989$ |
| | B | 2.73 | 1.75 | 0 | 5 | |
| | C | 2.93 | 1.83 | 0 | 5 | |
| | D | 2.87 | 2.10 | 0 | 6 | |
| 90 days | A | 1.47 | 1.36 | 0 | 4 | $X^2 = 14.06$ $P = 0.003$ |
| | B | 0.93 | 0.88 | 0 | 3 | |
| | C | 3.47 | 1.88 | 0 | 6 | |
| | D | 1.80 | 1.70 | 0 | 4 | |

Table 2. Comparison of the central dispersion of TMJ pain at rest in the four groups at different durations (n=15).

| Duration | Group | Mean | Std. deviation | Min. | Max. | P-value (one-way ANOVA) |
|----------|-------|------|----------------|------|------|-------------------------|
| Baseline | A | 3.40 | 2.20 | 0 | 7 | F=0.16 |
| | B | 3.80 | 2.46 | 0 | 8 | P=0.922 |
| | C | 3.60 | 23.23 | 0 | 8 | |
| | D | 3.93 | 2.09 | 0 | 7 | |
| 7 days | A | 3.13 | 2.03 | 0 | 6 | F=0.13 |
| | B | 3.07 | 1.91 | 0 | 6 | P=0.942 |
| | C | 3.20 | 1.82 | 0 | 6 | |
| | D | 3.47 | 1.77 | 0 | 6 | |
| 30 days | A | 1.60 | 1.24 | 0 | 4 | F=0.14 |
| | B | 1.53 | 1.06 | 0 | 3 | P=0.937 |
| | C | 1.80 | 1.32 | 0 | 4 | |
| | D | 1.60 | 1.18 | 0 | 4 | |
| 90 days | A | 0.80 | 0.86 | 0 | 3 | X ² =10.59* |
| | B | 0.67 | 0.72 | 0 | 2 | P=0.014 |
| | C | 2.67 | 1.95 | 0 | 6 | |
| | D | 1.47 | 1.40 | 0 | 4 | |

Table 3. Comparison of the central dispersion of masticatory muscles pain in the four groups at different durations (n=15).

| Duration | Group | Mean | Std. deviation | Min. | Max. | P-value (Kruskal-Wallis) |
|----------|-------|------|----------------|------|------|--------------------------|
| Baseline | A | 6.37 | 3.03 | 0 | 9 | X ² =1.78 |
| | B | 6.13 | 3.00 | 0 | 10 | P=0.619 |
| | C | 6.20 | 3.14 | 0 | 10 | |
| | D | 6.07 | 2.55 | 0 | 9 | |
| 7 days | A | 6.13 | 2.80 | 0 | 9 | X ² =3.51 |
| | B | 5.60 | 2.87 | 0 | 10 | P=0.319 |
| | C | 5.40 | 2.56 | 0 | 8 | |
| | D | 5.20 | 2.04 | 0 | 8 | |
| 30 days | A | 3.33 | 1.63 | 0 | 5 | X ² =2.06 |
| | B | 2.87 | 1.64 | 0 | 5 | P=0.560 |
| | C | 2.87 | 1.41 | 0 | 5 | |
| | D | 2.80 | 1.21 | 0 | 4 | |
| 90 days | A | 0.87 | 0.92 | 0 | 2 | X ² =0.48 |
| | B | 0.73 | 0.80 | 0 | 2 | P 0.001 |
| | C | 4.13 | 2.29 | 0 | 7 | |
| | D | 1.33 | 1.18 | 0 | 3 | |

Table 4. Comparison of the central dispersion of MMO in the four groups at different durations (n=15).

| Duration | Group | Mean | Std. deviation | Min. | Max. | P-value (one-way ANOVA) |
|----------|-------|-------|----------------|------|------|-------------------------|
| Baseline | A | 23.40 | 4.66 | 16 | 30 | F=0.08 |
| | B | 23.93 | 3.92 | 18 | 32 | P=0.969 |
| | C | 23.93 | 4.25 | 18 | 32 | |
| | D | 24.07 | 2.87 | 20 | 28 | |
| 7 days | A | 24.93 | 4.20 | 18 | 32 | F=0.15 |
| | B | 24.93 | 3.45 | 20 | 32 | P=0.931 |
| | C | 25.07 | 3.81 | 20 | 32 | |
| | D | 25.67 | 2.41 | 22 | 29 | |
| 30 days | A | 27.60 | 3.09 | 23 | 33 | F=0.38 |
| | B | 27.13 | 2.77 | 24 | 33 | P=0.767 |
| | C | 26.80 | 3.14 | 22 | 32 | |
| | D | 27.80 | 2.24 | 25 | 32 | |
| 90 days | A | 31.20 | 2.43 | 27 | 36 | X ² =22.33* |
| | B | 32.13 | 2.90 | 29 | 37 | P<0.001 |
| | C | 26.40 | 3.29 | 20 | 30 | |
| | D | 29.80 | 2.24 | 27 | 34 | |

Discussion

To the best of our knowledge, this study was the first to compare the effectiveness of different thickness soft and hard occlusal splints in reducing symptoms in TMD patients. The patients had a mean age of 28.95±8.38 years. Such a relatively low mean age may be due to higher stress levels in students and young individuals under the pure effect of malocclusion or its combination with other environmental factors. Furthermore, 76.7% of the patients were females and 23.3% were males, indicating the higher prevalence of TMD in females. Many epidemiological studies have pointed to the higher frequency of TMD in women [27,28]. Difference in pain perception between men and women may be due to their hormonal and anatomical differences [29]. The four groups in this study did not differ significantly in terms of age and gender (P>0.05). Therefore, the confounding effect of such factors on the results was eliminated. In this study, there was a significant decrease in resting and functional TMJ and masticatory muscle pain scores during follow-ups in Groups A, B and D compared to baseline. These three variables also decreased significantly over time up to 30 days in Group C. However, after 90 days, a slight increase was observed in functional TMJ and masticatory muscle pain scores in Group C. Nevertheless, only the score of functional TMJ pain decreased significantly after 90 days compared to baseline

in this group. No significant difference was observed between the groups in any variable after either 7 or 30 days (P>0.05). After 90 days, however, Group C had a significantly higher masticatory muscle pain score than other groups (P<0.05). Moreover, Group C had a significantly higher resting and functional TMJ pain score than Groups A and B (P<0.05).

Daif [30] evaluated the electromyographic data of the masticatory muscles and reported that splint therapy reduced TMD symptoms. Amin et al. [31] reported that both hard and soft occlusal splints with 3mm thickness successfully reduced pain upon a 3-month follow-up; such an improvement was greater in the hard splint group. Sonie et al. [29] showed a decrease in pain score after six months of using the soft splints, though they did not mention the splint thickness. Lin et al. [32] reported that two types of smooth-surfaced hard splints, 3 and 5mm thick, positively reduced pain in patients with disc displacement. Pita et al. [33] used electromyography to test the masseter and temporalis muscles and reported that both 3 and 6 mm thick splints reduced muscle activity and did not differ significantly in terms of performance. Abekura et al. [34] studied nocturnal bruxism and showed that 3-mm splints decreased electromyographic readings of the masseter and temporal muscles, while 6-mm splints did not have such an effect.

Considering the above studies, and since patients' tolerance and adaptation to the splints is higher when the vertical distance and freeway space are the same, in this study we compared hard and soft splints with 1 and 3mm thickness. Hard occlusal splints are made from self-curing or heat-curing acrylic resins. Therefore, they provide a strong occlusal surface that is wear resistant and can be used over a long period of time [35]. On the other hand, soft bite splints are flexible and cannot be well adjusted to achieve optimal occlusal contact with opposing teeth. In addition, they can deform after prolonged use and if so, they cannot establish occlusal balance and can lead to premature posterior contacts [31] and aggravate bruxism [36]. Similarly, our study showed that hard occlusal splints with a thickness of one and 3mm and soft occlusal splints with a thickness of 3mm stably reduced pain during a period of 3 months, as they did not wear or deform under destructive occlusal forces in TMD patients. This confirms the results of previous studies regarding the insignificant influence of splint material on its effectiveness [18,37 and 38].

In Group C, the use of a soft occlusal splint with a thickness of 1 mm led to promising results after one month. However, the level of pain later increased with the deformation, wear and thickness of the splint. Thus, as suggested by Amin et al. [31], thin soft occlusal splints can be used as an interim solution until the hard acrylic splints are delivered. The patient can also be adjusted to the splint during this time. However, thin soft splints do not offer long-term success in reducing TMD symptoms.

In this study, a progressive increase in MMO over time was observed in Groups A, B, and D. In Group C, such an increase persisted up to 30 days, although the MMO decreased slightly after 90 days. Nevertheless, the improvement in MMO after 30 and 90 days was significant in all groups compared to baseline ($P < 0.001$). The four groups did not differ significantly with regard to the MMO at baseline, after 7 days, and after 30 days. However, after 90 days, MMO was significantly lower in Group C than in groups A and B. Consistent with our results, Seifeldin et al. [18] compared soft splints with 2mm thickness to hard occlusal splints with 2-3mm thickness and reported that MMO increased significantly in both groups after 1 month. Suvinen et al. [39] also reported an increase in MMO by 7.4mm after splint therapy. In our study, the initial improvement in MMO in groups C and D (soft occlusal splints), especially at the first week of delivery can be due to the flexibility of the splint, which promotes

the optimal distribution of heavy occlusal forces and subsequently relieves spasms. However, in Group C, MMO did not increase after 90 days compared to 30 days. Given the small thickness of soft splint in Group C, it appears that application of heavy parafunctional forces over time caused deformation and distortion of the splint, reducing its efficacy. On the other hand, the deformation of soft occlusal splints appears to prevent the blockage of afferent neural impulses to the central nervous system. Therefore, and in contrast to other groups, TMD symptoms did not decrease in this group. However, hard splints alter the occlusal balance and consequently the afferent impulses to the central nervous system, improve the vertical dimension of the face, correct the condylar position and thus alleviate TMD symptoms [20,21,24 and 25].

In this study, the four groups did not differ significantly in terms of click frequency at different durations. However, Group B showed the best effectiveness in this regard, reducing the frequency of clicks by 50% compared to baseline after 90 days, followed by Group A with a 20% reduction. However, for groups C and D, no success in was recorded in eliminating the clicks. Soni et al. [29] showed the positive effectiveness of soft occlusal splints in reducing articular sounds. However, Seifeldin et al. [18] reported only a primary improvement in clicking with hard occlusal splints compared to soft splints. The reason was the increased TMJ space, which would allow the meniscus to return to its original position more easily and reduce clicks. Other studies discussed that the effectiveness of anterior repositioning splints in reducing articular sounds was higher than that of occlusal splints, which may be because the normal position of the condylar disc is achieved after the dislocated articular disc returns through an anterior condyle displacement using anterior repositioning splints [40,41]. Chen et al. [41] reported that a period of 6 months is required for optimal effectiveness of anterior repositioning splints in eliminating articular sounds. Considering the 3-month follow-up in this study, studies with longer follow-ups are required to make a definitive judgment on this. However, it appears that hard occlusal splints may be more effective than soft splints in eliminating articular sounds in TMD patients. Future studies with larger sample sizes are required to evaluate the effectiveness of other conservative approaches such as counseling in combination with occlusal splints.

Study Limitations

The limitations of this study included the strict inclu-

sion and exclusion criteria that limited the sample size and incomplete follow-ups, which is a common problem in long-term clinical studies. In addition, the study lacked a voluntary control group, which admittedly limited the results.

Conclusion

No significant difference was found between the groups in terms of MMO, TMJ pain at rest or in function, and short-term masticatory muscle pain, i.e. after 7 and 30 days. However, 3-mm hard occlusal splints had the greatest success in reducing TMD symptoms after three months, while 1-mm soft splints had the least success.

Conflict of Interest

There is no conflict of interest to declare.

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