Comparative evaluation of soft and hard splints in treatment of clenching disorder

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ARTICLE INFO	ABSTRACT

Introduction: The aim of this study was to compare the efficiency of soft and hard splints in treating patients with clenching.

Materials and Methods: In this clinical study, 26 patients with clenching disorder randomly divided to two equal group of treatment: hard and soft splint. The amount of masticatory muscle pain and maximum mouth opening were measured at the delivery time and 3, 6, 9, and 12 weeks later by a blind examiner. Data were analyzed by independent T and repeated measure ANOVA tests with significance level of p=0.05.

Results: Hard and soft splints were resulted in significant reduction of masticatory muscle pain (hard: P<0.001, Soft: p<0.001) and increase in maximum opening (hard P<0.001, Soft p<0.003), but there was no significant difference between them in pain relieving (P=0.848) and maximum opening (P=0.622).

Conclusion: This study showed that efficacy of hard and soft splints in treating patients with clenching is same.

Keywords: Masticatory muscle; Maximum mouth opening; Occlusal splint; Pain.

Introduction

Masticatory system activities can be divided into functional and parafunctional habits, which are differentiated by: 1) the force type; 2) force direction; 3) situation of the mandible; 4) type of muscle constriction; and 5) the effect of the protective reflex [1]. Parafunctional activities could be either diurnal or nocturnal activities. Diurnal parafunctions occur without the awareness of the patient including clenching, grinding, thumb sucking, tongue thrust, cheek biting or other occupational habits. Nocturnal parafunctions have been reported to be very common, and include monophase (i.e., clenching) or rhythmic (i.e., bruxism) contractions [1]. Clenching is a continuous or intermittent mouth closing

with vertical forces. It is a centric bruxism in which teeth are impacted against each other [2]. Clenching may cause complications such as muscle pain, attrition, headache, tooth mobility, limitation in mouth opening (particularly upon waking), and temporomandibular joint clicking [1]. There are two main approaches to treat temporomandibular disorders: reversible (non-aggressive) and irreversible (aggressive) treatments. Reversible treatments consist of medical therapy, physical therapy, and splint therapy. Irreversible treatments include permanent changes in tooth occlusion and temporomandibular joint surgery [3]. Several theories have been proposed to explain the therapeutic effect of splints (such as occlusal deprogramming, joint

unloading, relaxation of muscles, and reposition of TMJ) [5,6], but none of them could be considered predominant because the occlusal disharmony is not the only cause of TMD and multiple effects of splints cannot be justified by occlusal correction [7]. Splints are used to provide occlusal stability, treat temporomandibular disorders [8], or prevent dental attrition [9]. Stabilization splints as a first line of treatment and a beneficial diagnostic tool are conservative and eliminate occlusal discrepancies, stabilize painful conditions, normalize precise body movements, decrease the trauma incurred in a damaged temporomandibular joint and accelerate its repair [10,11,12,13]. Okeson [1] has suggested that the use of an occlusal appliance increases the patient's knowledge of jaw habits and helps to change the mandibular resting position to be more relaxed and open.

Different types of splints in term of material are used:

1- Soft.

2-Hard.

3- Dual laminated (occlusal surface hard and inner surface soft) [4].

4- Hydrostatic appliance (containing liquid) [14].

Soft and hard splints are more common in dental practice. The soft splint is an appliance made from flexible elastic materials that conform to the maxillary teeth. Soft splint could be made rapid, easy, with lower cost [11], and is appropriate treatment for patients with clenching but it is not a good choice in following conditions:

1- Significant occlusal discrepancy due to insufficient thickness.

2- Missing teeth because of inability to provide occlusal contacts for opposing teeth.

3- Moderate to severe tooth attrition from nocturnal parafunctional habits (tooth grinding or bruxism).

In other side, hard splints provide a precise occlusal mark; can be fabricated with additional material in specific locations (like edentulous areas, cross bites and other large discrepancies); and bond with self-curing acrylic. Disadvantage of hard splint include uncomfortable nature, rocking or pressure on the supporting teeth [15]. While the advantages and disadvantages of both soft and hard splints have been widely discussed in the literature, there is no consensus that which one could be more beneficial. The purpose of this study was to compare the efficacy of hard and soft splint therapy in the treatment of clenching problems. The null hypotheses is assumed that hard and soft splints have no significant difference in the efficacy of treating clenching problem.

Materials and Methods

Study Sample

This prospective interventional clinical study had been performed in Department of Prosthodontic of Tehran University of Medical Sciences. Participants were selected among patients referred to the TMJ subdivision. All potential participants completed written questionnaires to assess whether they are qualified to be included in the study and to gather information about the symptoms they experienced. Selected patients had either diurnal or nocturnal clenching, but not bruxism. Diurnal clenching was diagnosed by assessing whether the patient impacted the teeth against each other. Nocturnal clenching was diagnosed based on extent of muscular pain and limitation of mouth opening upon waking. The absence of bruxism was established by ensuring that the symptoms of tooth grinding and attrition were absent. Also, internal derangement and other intra capsular defects were rolled out through exact examination.

The specific criteria for inclusion in this study were: subjects had only a clenching problem; they were 20-45 years old; and they had not received any previous treatment such as splint therapy, physiotherapy, or medical therapy. Patients who did not use the splint regularly and/or who did not participate in all follow-up sessions were excluded. Those with symptoms such as joint inflammation and disc displacement, osteoarthritis, systemic arthritis and ankyloses were not included in the study [1]. A pilot study had been performed with five patients per group and decreasing pain from the baseline at 1 month visit was 1.25±0.96 in soft and 4.5±2.5 in hard group.

The sample size calculated 13 in each group with considering the $\alpha=0.01$, $\beta=0.05$ with following formula:

$$N= \frac{2((Z_{\alpha/2}+Z_{\beta})^2 +(S^2_1+S^2_2)^2)}{(\overline{x}_1-\overline{x}_2)^2} = \frac{2[(2.57+1.645)^2+(6.33+0.917)^2]}{(4.5-1.25)^2} \sim 13$$

26 Participants were randomly divided into two groups of 13 subjects each based on treatment by soft (Group S) or hard (Group H) splints. The sample size was calculated according to pilot study and similar articles [14,16,17]. The randomized couple blocks method was used to divide the patients into the two groups.

Splint properties and use

Alginate impression making performed from maxilla and mandible arches. Polyurethane was used to fabricate the soft splints (Durasoft® pd, Scheu-Dental, GmbH, Germany) and hard polycarbonate (Imprelon 'S' , Scheu-Dental, GmbH, Germany) was used to manufacture the hard splints. Fabricated splints were 2-4 mm thick and were adapted to maxillary arch. The patients were instructed to use splint (both type) during sleep time. Patients were not aware of the splint type they received, because of the similarity of soft and hard splints. The only individual aware of the type of splint used in each patient's treatment was the senior author. Researchers who gathered pain degree and amount of maximum opening and assisted in questionnaire completion were not aware of splint type and they just signed the records according to patient coding numbers, the such that this study was double blinded (patients and assessors).

Data collection and analysis

After delivering the splints, the amount of pain was measured with a pain ruler using a visual analog scale (VAS), and amount of maximum mouth opening (MO) was registered. These values constituted each patient's baseline measurements. Follow-up examinations were carried out at 3, 6, 9 and 12 weeks in which amount of pain and MO were repeatedly measured (Table 1). Independent and dependent t tests were used to compare the effects on pain alleviation and MO increase within each splint group and between the two groups. The repeated measures ANOVA was used for quantitative comparison of the two splint types and for controlling the effect of the baseline values and the age of subjects on the degree of pain and MO. P values of less than 0.05 were considered significant. All analyses was performed using SPSS software (SPSS for Windows Inc. Version 22. Chicago, Illinois, IBM Corporation, USA).

Results

A total of 26 patients (13 in each group) participated in the study. Average age in Group H and S were 29.87 ± 7.83 and 33.15 ± 8.92 years, respectively. According to T test average age of two groups revealed no statistically significant differences (P=0.325). Each group contained one man and twelve women. The baseline pain value in Group H and S were 6.62±1.71cm and 6.69 ± 2.14 cm in contrary. There was no significant difference between the two groups (P=0.920). The baseline MO value in Group H and S were 37.92 ± 6.15 (mm) and 34.92 ± 9.15 (mm). There was no significant difference between the two groups (P=0.337). The baseline records were same in both groups. A repeated measurements test using age as an auxiliary variable showed no significant difference in amount of pain between the two groups (P=0.848). The small number of male participants in this sample prevented the use of sex as a variable. To compare the effect of splint type on the degree of pain alleviation at various follow-up times, the differences in pain values from the baselines were calculated and compared in the two groups. The amount of pain relief in comparison to the baseline at the 3rd week follow-up was 5.85 ± 2.73cm in the soft splint group and 5.92 ± 1.97cm in the hard splint group. There was no statistically significant difference in pain alleviation between the two groups. A coupled t test comparing follow-up values with baseline values showed similar results in both groups. In Group H and S, the degree of pain in the 6th, 9th and 12th weeks was significantly reduced in comparison to baseline pain, but the reduction level was not significant in the 3rd week (Table 2).

MO changes during the follow-up period were compared to the baseline MO values in both groups. A coupled t test comparing baseline values with follow-up values showed that the amount of MO increased significantly in both groups. The repeated measure ANOVA showed no significant difference in MO between the two groups (Table 3). There was no significant difference between hard and soft splints in pain relieving: P=0.848 and maximum opening: P=0.622 (Table 4).
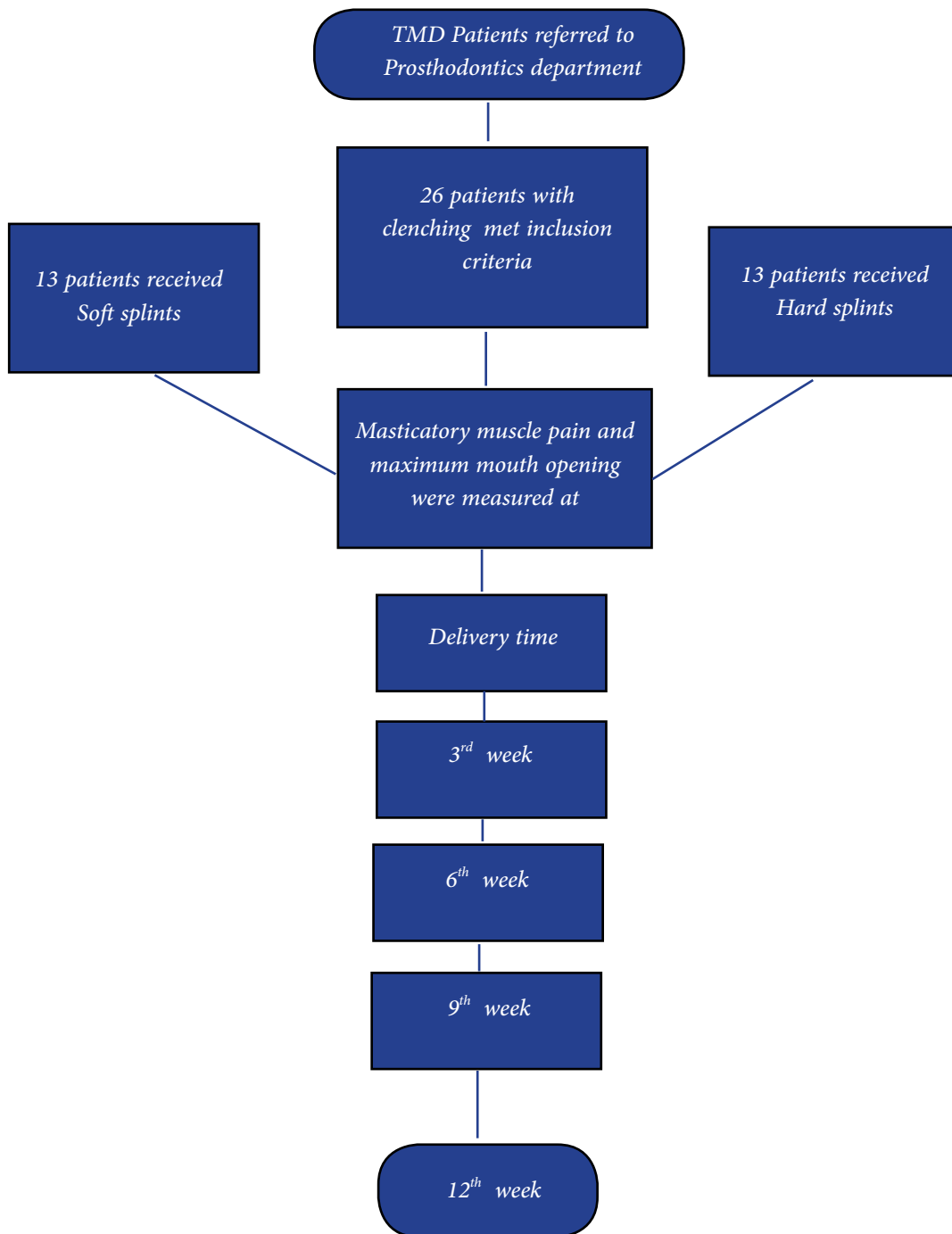
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│  TMD Patients referred to │
│  Prosthodontics department│
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│     26 patients with      │
│  clenching  met inclusion │
│         criteria          │
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│ 13 patients received │   │ 13 patients received │
│   Soft splints   │   │   Hard splints   │
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┌─────────────────────────┐
│ Masticatory muscle pain and │
│  maximum mouth opening      │
│      were measured at       │
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│       Delivery time       │
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│        12th  week         │
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Table 1. Trial profile of comparison between soft and hard splints.

Time (week)	Hard Splint		Soft Splint	
	Mean Pain level (cm)± Standard deviation	P value of comparison to base line	Mean Pain level (cm)± Standard deviation	P value of comparison to base line
Base line	6.62±1.71	----	6.69±2.14	----
3rd week	5.92 ±1.97	0.168	5.85±2.73	0.076
6th week	4.77±1.64	<0.001	4.92±2.69	0.007
9th week	4 ±1.47	<0.001	4±2.51	0.001
12th week	3.62±1.55	<0.001	3±2.61	<0.001

Table 2. The comparison of the pain level in different periods in hard and soft splint groups.

Time (week)	Hard Splint		Soft Splint	
	Mean MIO (mm) ± Standard deviation	P value of comparison to base line	Mean MIO (mm) ± Standard deviation	P value of comparison to base line
Base line	37.92±6.15	----	34.92±9.15	----
3rd week	39.92±6.95	0.036	38.77±7.46	0.008
6th week	40.92±6.82	0.002	39.15±7.77	0.025
9th week	42.23±6.58	<0.001	40.85±6.59	0.003
12th week	42.62±6.18	<0.001	41.69±6.34	0.003

Table 3. The comparison of the MOI in different periods in hard and soft splint groups.

Time (week)	Groups	Mean Pain level decrease (cm)±Standard deviation	P value of comparison between groups	Mean MIO increase (mm)±Standard deviation	P value of comparison between groups
3rd week	Hard Splint	0.69±1.70	0.813	2±3.05	0.222
	Soft Splint	0.84±1.57		3.84±4.33	
6th week	Hard Splint	1.84± 0.98	0.901	3±2.64	0.502
	Soft Splint	1.76±1.96		4.23±5.94	
9th week	Hard Splint	2.61 ±1.04	0.909	4.30±3.03	0.388
	Soft Splint	2.69±2.17		5.92±5.89	
12th week	Hard Splint	3±0.91	0.378	4.69±2.95	0.301
	Soft Splint	3.69±2.62		6.76±6.44	

Table 4. The comparison of the pain level decrease and MIO increase in different periods between hard and soft splint groups.

Discussion

In present study, the null hypothesis is accepted that both soft and hard splints improved TMJ symptoms and there were no significant difference between them. Hick [11] has concluded that the soft splint was not intended to replace hard splint therapy. He argues that the soft splint can be used for patients with less severe problems, those who are in immediate need of a splint, and as a night guard for patients wearing a hard splint during the day. No description of methodology or evaluation process were presented in this study. Okesons study [18] comparing the effect of soft and hard splints on bruxism demonstrated that hard splints significantly decreased muscle activity, while soft splints actually increased muscle activity in most instances. These findings are in contrary to the results we obtained in this study. The study, however, was limited by the short duration of the treatment (seven nights). Also, the different methodology of this study with ours makes comparison difficult. In Okeson's study, patients had weared a hard splint for seven days, then muscle activity was registered. They had a rest period of five days, after which muscle activity was again registered. Then, they had weared a soft splint for seven days, muscle activity was registered, and the results

were compared. The researchers were not blinded to splint type. In assessing the effect of the splint types on bruxism, they found that the soft splint may increase eccentric activities, because of tooth wear and eccentric parafunctional activity. In another study, Pettingill et al [12]compared the efficacy of hard and soft splints to treat temporomandibular disorders. Their results suggested that soft and hard splints similarly reduced masticatory muscle pain, which confirm the results of the present study. Comparison between studies is difficult, however, since types of temporomandibular disorder are not same in all patients.

Another study [19] compared the immediate effects of hard and soft splints on the activity of the masseter and anterior temporalis muscles, demonstrating that the use of hard splints decreased the electromyographic activity of the muscles. The use of soft splints, however, led to a slight increase in the activity of both muscles, particularly the masseter, because of the convenience of inducing bite force on the soft material. The limitations of this study include the short treatment duration and lack of evaluation of long-term effects. Also, each patient was treated first with a hard splint and then with a soft splint, and thus it is possible that the effect of the hard splint influenced the effect of the soft splint. Cruz-Reyes et al [16] assessed the influence of hard stabilization and soft splints on electromyographic (EMG) pattern in bruxer patients. In their study, EMG was used as an indicator of masseter and temporalis activity before and after the treatment. Patients used the splints 24 hours for 46-60 days. According to their findings, hard stabilization splints resulted in neuromuscular recovery in comparison to soft splints and were preferred.

Meshramkar et al [17] evaluated the effect of hard and soft splints for Management of Myofascial Pain with a 90 days follow up. Their results showed both types were effective and subjective and objective signs were reduced but, hard splints were more efficient. Seifeldin and Elhayes [20] compared soft and hard splints in treatment of myofacial pain dysfunction (MPD) or internal derangement (ID) of TMJ with reciprocal clicking in a 4 months follow up. Patients had visited monthly and pain, muscle tenderness, clicking and mouth opening were evaluated. Based on the findings, both types of splints improved the TMJ parameter but the soft splints were more effective after 4 months. Amin et al [14] evaluated the clinical performance of hard, soft and liquid oral splints in management of myofascial pain. They monitored patients for 1 week, 1, 2, and 3 months and found that all types of splints are effective in decrease of pain. However, hard splints were relieved the pain in shorter time period, then liquid and finally soft splints. Algabri et al [21] in a meta-analysis review compared the efficacy of hard and soft splints in reduction of pain and muscle tenderness in a time period of 3 months. Based on the inclusion criteria, three studies were evaluated and reveled no significant difference between soft and hard splints in terms of relief of pain and muscle activity.

Conflict could be observed in different studies. It is noteworthy that splint therapy is a treatment that requires patient cooperation to achieve its goal and it can be a reason of different result. In this study, it was supposed that the patients used the splint as instructed; disuse or irregular use of the splint may have influenced the treatment results. While patients were fully informed about irregular splint use and its consequences, this assumption forms one limitation of this study.

Finally, given the lack of significant difference in the effects of soft and hard splints on clenching therapy, and since the use of a soft splint is more convenient for patients because of its flexibility, this article authors recommend the use of soft splints. This is also the case because a soft splint does not require adjustment, avoiding the possibility of exacerbation by a dentist's incorrect adjustment. Moreover, to achieve the aim of splint therapy, patient cooperation is necessary; therefore, patients should be fully educated before treatment and be aware of complications caused by disuse or improper use.

Conclusion

Based on this study and by considering of its limitation can be concluded: Splint therapy causes significant decrease in pain and increase in mouth opening. There were no significant differences between the hard and soft splints.

Acknowledgment

Conflict of Interest

There is no conflict of interest to declare.

Refrences

[1] OKeson JP: Management of temporomandibular

disorders and occlusion. 7th ed. St. Louis:C V Mosby Co, 2012.

[2] Alqutaibi AY, Aboalrejal AN. Types of occlusal splint in management of temporomandibular disorders (TMD). J Arthritis. 2015 Nov; 4(176):2.

[3] Glickman I: Clinical periodontology. 6th ed. Philadelphia:W.B. Sunders Company, 1984.

[4] Hupp JR, Ellis E,Tucker M:contemporary oral and maxillofacial surgery. 6th ed. St.louis:Mosby, 2013.

[5] Rashid R. Soft occlusal splint therapy in the management of myofascial pain dysfunction syndrome: A follow-up study in Kashmiri population. International Journal of Applied Dental Sciences 2017; 3(4): 82-88.

[6] Clark GT:A critical evaluation of orthopedic interocclusal appliance therapy, design, theory and overall effectivenss. J Am Dent Assoc 1984; 108(3):359-64.

[7] Klasser GD, Greene CS. Oral appliances in the management of temporomandibular disorders. Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology. 2009 Feb 1; 107(2):212-23.

[8] Stock still JW, Bowley JF, Dunning D, Spalding P, Stafford K, Erickson L: Prevalence of temporomandibular disorders (TMD) in children base on physical signs.J dent child 1998; 65(6):459-67.

[9] The Academy of prosthodontics: The Glossary of prosthodontic terms. J Prosthet Dent 1999; 81:41-110.

[10] Nelson SJ:Principles of Stabilization bite splint therapy. Dent Clin North Am 1995; 39:403-21.

[11] Hicks NA:An efficient method for constructing a soft interocclusal splint.J Prosthet Dent 1989; 61:48-50.

[12] Pettengill GA, Growney JR, Schoff R,Kenworthy CR:A pilot study comparing the efficacy of hard and soft stabilization appliances in treating patients with temporomandibular disorders. J Prosthet Dent 1998; 79(2):165-68.

[13] Ash MM, Ramfjord SP: An introduction to functional.

[14] Amin A, Meshramkar R, Lekha K. Comparative evaluation of clinical performance of different kind of occlusal splint in management of myofascial pain. The Journal of the Indian Prosthodontic Society. 2016 Apr; 16(2):176.

[15] Edward F Wright: Manual of Temporomandibular Disorders.1rd ed. Blackwell publishing Co, 2005.

[16] Cruz-Reyes RA, Martínez-Aragón I, Guerrero-Arias RE, García-Zura DA, González-Sánchez LE. Influence of occlusal stabilization splints and soft occlusal splints on the electromyographic pattern, in basal state and at the end of six weeks treatment in patients with bruxism. Acta odontologica latinoamericana: AOL. 2011; 24(1):66-74.

[17] Meshramkar RD, Guttal K, Roque AL, Nadiger RK, Lekha K. Comparative Evaluation of Clinical Performance of Different Kind of Occlusal Splint Therapy in the Management of Myofascial Pain. Journal of Dental and Medical Sciences. 2015; 14(8):54-7.

[18] Okeson JP:The effect of hard and soft occlusal splints on nocturnal bruxism. JADA 1987; 114:788-91.

[19] Al Quran FA,Lyons MF:The immediate effect of hard and soft splints on the EMG activity of the masseter and temporalis muscles.J Oral Rehabil 1999; 26(7):559-63.

[20] Seifeldin SA, Elhayes KA. Soft versus hard occlusal splint therapy in the management of temporomandibular disorders (TMDs). The Saudi dental journal. 2015 Oct 1; 27(4):208-14.

[21] Algabri RS, Alqutaibi AY, Keshk AM, Alsourori A, Swedan M, El Khadem AH, Kaddah AF. Effect of hard versus soft occlusal splint on the management of myofascial pain: Systematic review and meta-analysis. Indian J Sci Technol. 2017 Apr; 10:10-6.