

# Efficacy of hard and soft occlusal splint therapy in the management of temporomandibular disorders: a comparative study

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## ABSTRACT

**Background:** A consensus regarding the effectiveness of soft and hard occlusal splint therapy for Temporomandibular Disorders (TMDs) is lacking. Different studies have reported contradictory results.

**Objective:** To evaluate the effectiveness of hard and soft occlusal splints in the management of temporomandibular disorders.

**Materials & Methods:** A comparative study was conducted at the Prosthodontics Department, Rawal Dental Hospital, Islamabad, Pakistan, from November 2022 to March 2024 on 94 patients who were evaluated to reach the diagnosis of temporomandibular disorder. Patients were given a hard or a soft stabilization splint by random sampling. Each patient was reviewed after 3 weeks interval for a duration of 6 months. The modified Fonseca's questionnaire was filled on each subsequent visit to record the effect of the occlusal splint on the existing condition and compare it from baseline data. SPSS 25 was used for data analysis; comparison between the groups were made using the Chi square test, and a  $p \leq 0.05$  was considered significant.

**Results:** In terms of comparing Group A and B at 6-month follow up, there was no significant difference reported while comparing most of the outcome variables. A significantly smaller number of participants reported clicking at 6-months who underwent hard-splint therapy as compared to those who underwent soft-splint therapy (2.1% vs 21.2% respectively,  $p=0.013$ ).

**Conclusion:** Significant improvement in TMJ pain, joint sounds, muscle tenderness and mouth opening was observed with hard occlusal splints following 3 months of therapy.

**Keywords:** Temporomandibular Joint; Occlusal Splints; Mastication; Bruxism; Arthralgia; Arthroplasty.

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## INTRODUCTION

Temporomandibular Disorders (TMDs) are conditions affecting the Temporomandibular Joint (TMJ), masticatory muscles, and associated structures. These conditions are associated with a variety of signs and symptoms that range from pain in preauricular region, dysfunction in terms of joint sounds, and/or inability to perform routine functions.<sup>1</sup> TMD was earlier considered a single entity; today, it is a collective term embracing a broad spectrum of joint and muscle problems in the orofacial area.<sup>1,2</sup> TMDs have a multifactorial etiology, with bruxism, traumatic bite, psychological illness, extreme mouth opening, occlusal disharmony, and anatomic variations being leading causes.<sup>2</sup>

Several treatment modalities have been employed for the management of TMDs, including reversible and irreversible therapies. Successful reversible options include occlusal splints, physiotherapy, muscle-relaxing appliances, and pharmacological interventions.

Similar to other repetitive motion disorders, Physical Self-Regulation (PSR) instructions routinely encourage patients to rest their masticatory muscles by voluntarily limiting their use by avoiding hard or chewy foods, and restraining from activities that overuse the masticatory muscles (clenching teeth, holding tension in masticatory muscles, chewing gum, and yawning wide).<sup>3,4</sup> Alternate treatments include ultrasound, soft laser, diathermy, infrared radiation, and acupuncture. Severe cases that do not respond to conservative management might require surgical interventions of arthrocentesis and arthroplasty.<sup>5</sup>

Occlusal splint therapy is hypothesized to work by optimizing occlusal contacts without having to alter the mandibular rest position or changing occlusion irreversibly.

Both soft and hard splints have been used in the treatment of temporomandibular disorders.<sup>5</sup> The soft splints might help distribute the heavy loading force associated with parafunctional habits such as bruxism and clenching; these splints might also have a placebo effect.

The hard occlusal splints alleviate the symptoms by altering the occlusal equilibrium, by raising the vertical dimension of occlusion, changing the condylar position, changing impulses to the central nervous system and aiding cognitive awareness.<sup>6</sup>

This study was conducted to evaluate the efficacy of hard versus soft stabilization appliance therapy for the treatment of temporomandibular disorders by assessing comparative improvement in muscle pain, joint sounds, limitation in mouth opening, difficulty in chewing and parafunction. The results will help to select an effective treatment modality in the management of TMDs so that relevant treatment can be provided to patients.

## MATERIALS & METHODS

This cross sectional comparative study was carried out at Prosthodontics Department, Rawal Dental Hospital, Islamabad, Pakistan, after approval from the ethical committee (Ref no. 918/Trg, dated 13/May/2020). A total of 94 subjects were evaluated both clinically and radiographically. All patients, both males and females diagnosed with myofascial pain dysfunction and internal derangement disorders reporting to the Prosthodontics department from November 2022 till March 2024 were included. Patients between the ages of 15-50 years having complete dentition were included. Patients with bone diseases (Osteoporosis, Osteopetrosis, Osteomalacia), suffering from debilitating diseases (Rheumatoid Arthritis, Poliomyelitis, Chronic Obstructive Pulmonary Disease), Dyskinesia, and those with a history of orthodontic treatment, or orthognathic surgery were excluded from the study.

A thorough history was obtained from each patient and detailed oral examination was carried out to diagnose TMD. Each subject was interviewed using modified Fonseca's questionnaire.<sup>7</sup> Patients were evaluated concerning facial pain, TMJ tenderness, joint sounds, limitations in mandibular movement, locking, stiffness or tenderness of jaw muscles, and difficulty in chewing. Those reporting with one or more of these symptoms were asked further questions regarding their severity and functional consequences in order to reach the diagnosis of the type of TMD. Upon reaching the diagnosis, patients were given a hard or a soft stabilization splint based on simple random sampling. Each patient was reviewed after 3 weeks interval for a duration of 6 months. The questionnaire was filled on each subsequent visit to record the effect of the occlusal splint on the existing condition and compare it with baseline data.

Data were entered and analyzed using IBM SPSS 25. Descriptive statistics were calculated for quantitative variables; comparisons for the effect of occlusal splints on TMDs were done between the two study Groups using Chi square test, and outcomes were compared at baseline, 3-months, and 6-months follow ups. A  $p \leq 0.05$  was considered statistically significant.

## RESULTS

Of the 94 TMD patients enrolled in the study, 59(62.8%) were males and 35(37.2%) females; the majority, 57(60.6%) belonging to the age group of 20-40 years. There were 47 patients each in

soft occlusal splint (Group A) and hard stabilization splint (Group B) study arms. There were 29(61.7%) males and 18(38.3%) females in Group A, compared to 30(63.8%) males and 17(36.2%) females in Group B. The comparison of baseline demographic and clinical factors is given in Table 1.

At baseline, pain was present in 45(95.7%) participants in Group A and 43(91.5%) participants in Group B ( $p=0.399$ ); clicking was present in 35(74.4%) participants in Group A and 30(63.8%) participants in Group B ( $p=0.079$ ); difficulty in chewing was present in 33(70.2%) participants in Group A and 35(74.5%) participants in Group B ( $p=0.112$ ); and limitation of mouth opening was present in 31(66.0%) participants in Group A and 33(70.2%) participants in Group B ( $p=0.658$ ). In terms of muscle tenderness, masseter tenderness was present in 29(61.7%) participants in Group A and 26(55.3%) participants in Group B ( $p=0.530$ ); temporalis tenderness was present in 38(80.9%) participants in Group A and 37(78.7%) participants in Group B ( $p=0.797$ ), as given in Table 1.

The comparison of functionality elements at baseline, 3-months and 6-months among participants undergoing soft-splint therapy is shown in Figure 1. The figure shows a significant improvement in pain, clicking, difficulty in chewing, and limitation in mouth opening among participants belonging to Group A at both follow ups.

Similarly, the comparison of functionality elements at baseline, 3-months and 6-months among participants undergoing hard-splint therapy is shown in Figure 2, where significant improvement in pain, clicking, difficulty in chewing, and limitation in mouth opening was observed among participants at both follow up time points.

At 3-months and 6-months post-splint therapy, the functionality and muscle tenderness were assessed for all participants belonging to the two study arms.

At 3-months follow up (Table 2), a significant difference in pain among participants of two study groups was found, where greater number of patients of Group A reported pain as compared to those of Group B (51.1% vs 21.3%,  $p=0.003$ ). Similarly, clicking was also more commonly observed among patients belonging to Group A compared to Group B (38.3% vs 19.1%,  $p=0.019$ ); tenderness of TMJ was also more commonly reported by participants in Group A compared to Group B (17.0% vs 4.3%,  $p=0.045$ ). It was also observed that limitation of mouth opening was more likely to be reported by patients of Group A compared to Group B (42.6% vs 17.0%,  $p=0.007$ ). In terms of muscle tenderness, there was no significant difference between two Groups at 3-months follow up.

In terms of comparing Groups A and B at 6-months follow up (Table 3), there was no significant difference reported while comparing most of the outcome variables. However, a significantly smaller number of participants of Group B reported clicking at 6 months when compared to Group A (2.1% vs 21.2% respectively,  $p=0.013$ ).

**Table 1: Comparison of baseline characteristics among soft and hard splint therapy Groups (n=94).**

Characteristics	Overall (n=94)	Group A (n=47)	Group B (n=47)	p value
<b>Demographics</b>				
Age Groups				
• <20 years	18 (19.1%)	12 (25.5%)	06 (12.8%)	0.012
• 20-40 years	57 (60.6%)	31 (66.0%)	26 (55.3%)	
• >40 years	19 (20.2%)	04 (8.5%)	15 (31.9%)	
Gender				
• Male	59 (62.8%)	29 (61.7%)	30 (63.8%)	0.831
• Female	35 (37.2%)	18 (38.3%)	17 (36.2%)	
<b>Functional problems</b>				
Pain				
• Absent	06 (6.4%)	02 (4.3%)	04 (8.5%)	0.399
• Present	88 (93.6%)	45 (95.7%)	43 (91.5%)	
Clicking				
• Absent	29 (30.9%)	12 (25.5%)	17 (36.2%)	0.079
• Present	65 (60.1%)	35 (74.4%)	30 (63.8%)	
Tenderness				
• Absent	24 (25.5%)	13 (27.7%)	11 (23.4%)	0.112
• Present	70 (74.4%)	34 (72.3%)	36 (76.5%)	
If present, site of tenderness				
• Unilateral	57 (81.4%)	31 (91.1%)	26 (72.2%)	0.112
• Bilateral	13 (18.5%)	03 (8.8%)	10 (27.7%)	
Difficulty in chewing				
• Absent	26 (27.7%)	14 (29.8%)	12 (25.5%)	0.645
• Present	68 (72.3%)	33 (70.2%)	35 (74.5%)	
Parafunction				
• Absent	63 (67.0%)	31 (66.0%)	32 (68.1%)	0.826
• Present	31 (33.0%)	16 (34.0%)	15 (31.9%)	
Limitation of mouth opening				
• Absent	30 (31.9%)	16 (34.0%)	14 (29.8%)	0.658
• Present	64 (68.1%)	31 (66.0%)	33 (70.2%)	
<b>Muscle tenderness</b>				
Masseter tenderness				
• Absent	39 (41.5%)	18 (38.3%)	21 (44.7%)	0.530
• Present	55 (58.5%)	29 (61.7%)	26 (55.3%)	
Temporalis tenderness				
• Absent	19 (20.2%)	09 (19.1%)	10 (21.3%)	0.797
• Present	75 (79.8%)	38 (80.9%)	37 (78.7%)	
Lateral Pterygoid; superior head				
• Absent	27 (28.7%)	10 (21.3%)	17 (36.2%)	0.111
• Present	67 (71.3%)	37 (78.7%)	30 (63.8%)	
Lateral Pterygoid; inferior head				
• Absent	10 (10.6%)	03 (6.4%)	07 (14.9%)	0.181
• Present	84 (89.4%)	44 (93.6%)	40 (85.1%)	
Pterygoid tenderness; medial				
• Absent	17 (18.1%)	03 (6.4%)	14 (29.8%)	0.003
• Present	77 (81.9%)	44 (93.6%)	33 (70.2%)	

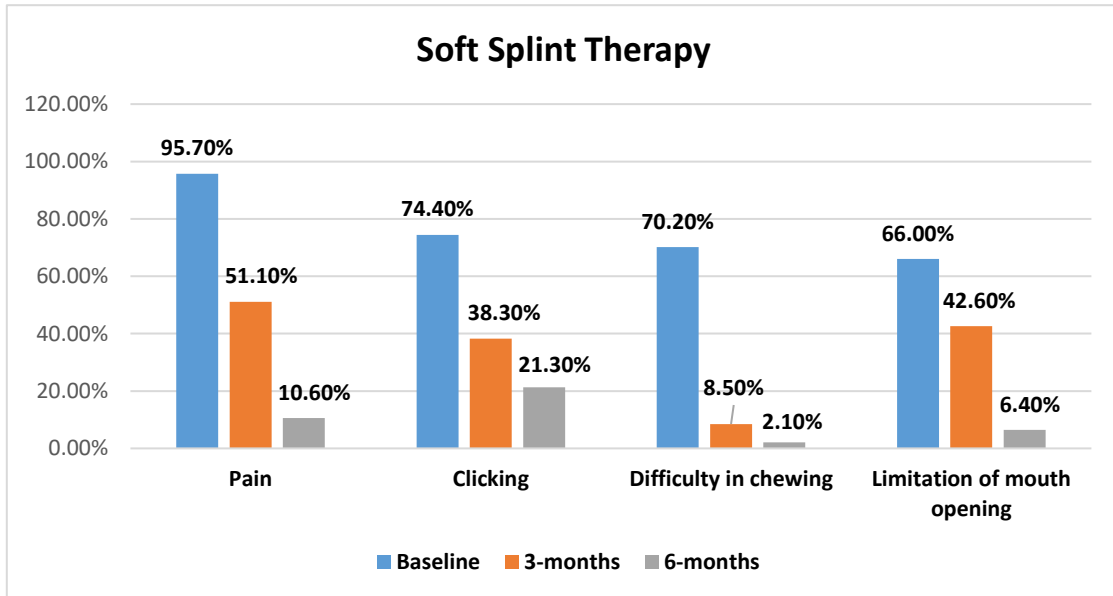


Figure 1: Comparison of functionality in participants undergoing soft-splint therapy (Group A) at baseline and 6-months (n=47).

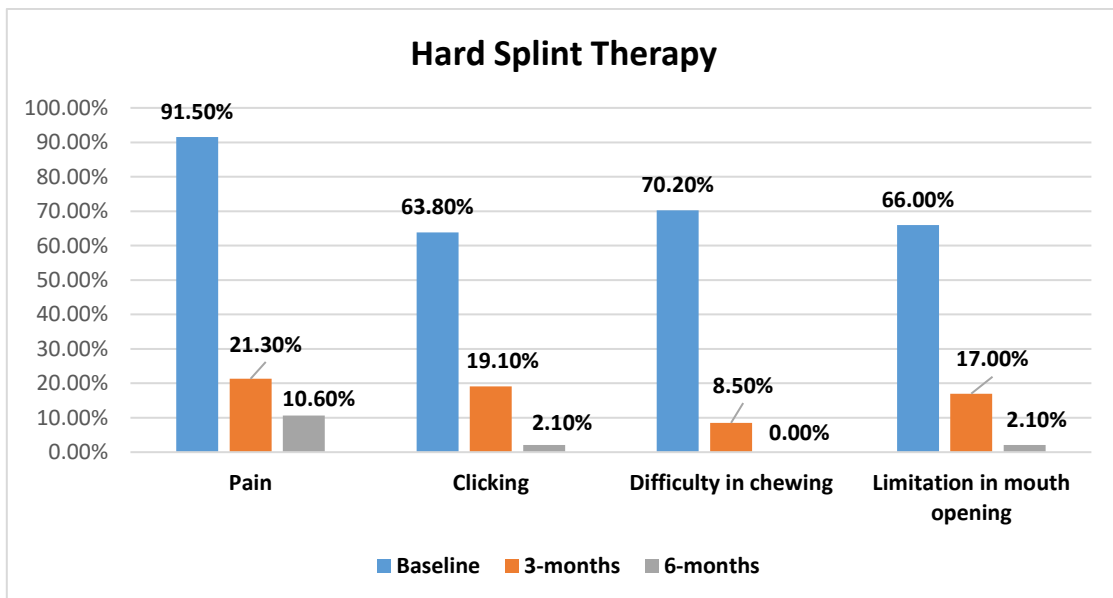


Figure 2: Comparison of functionality in participants undergoing hard-splint therapy (Group B) at baseline and 6-months (n=47).

**Table 2: Comparison of functionality and muscle tenderness after 3-months of split therapy among two study Groups (n=94).**

Characteristics	Overall (n=94)	Group A (n=47)	Group B (n=47)	p value
<b>Functional problems</b>				
Pain				
• Absent	60 (63.8%)	23 (48.9%)	37 (78.7%)	0.003
• Present	34 (36.2%)	24 (51.1%)	10 (21.3%)	
Clicking				
• Absent	67 (71.3%)	29 (61.7%)	38 (80.9%)	0.019
• Present	27 (28.7%)	18 (38.3%)	45 (40.4%)	
If present, site of clicking				
• Unilateral single click	09 (33.3%)	08 (44.4%)	01 (5.2%)	
• Bilateral single click	14 (51.8%)	09 (50.0%)	05 (26.3%)	
• Unilateral reciprocal click	01 (03.7%)	01 (05.5%)	0 (0.0%)	
• Bilateral reciprocal click	03 (11.1%)	0 (0.0%)	03 (15.7%)	
Tenderness				
• Absent	84 (89.4%)	39 (83.0%)	45 (95.7%)	0.045
• Present	10 (10.6%)	08 (17.0%)	02 (4.3%)	
Difficulty in chewing				
• Absent	86 (91.5%)	43 (91.5%)	43 (91.5%)	1.000
• Present	08 (08.5%)	04 (08.5%)	04 (08.5%)	
Limitation of mouth opening				
• Absent	66 (70.2%)	27 (57.4%)	39 (83.0%)	0.007
• Present	28 (29.8%)	20 (42.6%)	08 (17.0%)	
<b>Muscle tenderness</b>				
Masseter tenderness				
• Absent	90 (95.7%)	45 (95.7%)	45 (95.7%)	1.000
• Present	04 (04.3%)	02 (04.3%)	02 (04.3%)	
Temporalis tenderness				
• Absent	94 (100%)	47 (100%)	47 (100%)	-
• Present	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Lateral Pterygoid; superior head				
• Absent	90 (95.7%)	44 (93.6%)	46 (97.9%)	0.307
• Present	04 (43.0%)	03 (06.4%)	01 (02.1%)	
Lateral Pterygoid; inferior head				
• Absent	90 (95.7%)	45 (95.7%)	45 (95.7%)	1.000
• Present	04 (04.3%)	02 (04.3%)	02 (04.3%)	
Pterygoid tenderness; medial				
• Absent	87 (92.6%)	45 (95.7%)	42 (89.4%)	0.239
• Present	07 (07.4%)	02 (04.3%)	05 (10.6%)	

**Table 3: Comparison of functionality and muscle tenderness after 6-months of split therapy among two study Groups (n=94).**

Characteristics	Overall (n=94)	Group A (n=47)	Group B (n=47)	p value
<b>Functional problems</b>				
Pain				
• Absent	86 (91.5%)	42 (89.4%)	44 (93.6%)	0.460
• Present	08 (08.5%)	05 (10.6%)	03 (06.4%)	
Clicking				
• Absent	83 (88.3%)	37 (78.7%)	46 (97.9%)	0.013
• Present	11 (11.7%)	10 (21.2%)	01 (02.1%)	
If present, site of clicking				
• Unilateral single click	05 (45.4%)	05 (50.0%)	0 (0.0%)	
• Bilateral single click	06 (54.5%)	05 (50.0%)	01 (100%)	
Tenderness				
• Absent	91 (96.8%)	45 (95.7%)	46 (97.9%)	0.557
• Present	03 (03.2%)	02 (04.3%)	01 (02.1%)	
Difficulty in chewing				
• Absent	93 (98.9%)	46 (97.9%)	47 (100%)	0.315
• Present	01 (01.1%)	01 (02.1%)	0 (0.0%)	
Parafunction				
• Absent	89 (94.7%)	45 (95.7%)	44 (93.6%)	0.646
• Present	05 (05.3%)	02 (04.3%)	03 (06.4%)	
Limitation of mouth opening				
• Absent	90 (95.7%)	44 (93.6%)	46 (97.9%)	0.307
• Present	04 (04.3%)	03 (06.4%)	01 (02.1%)	
<b>Muscle tenderness</b>				
Masseter tenderness				
• Absent	94 (100%)	47 (100%)	47 (100%)	-
• Present	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Temporalis tenderness				
• Absent	94 (100%)	47 (100%)	47 (100%)	-
• Present	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Lateral Pterygoid; superior head				
• Absent	93 (98.9%)	47 (100%)	46 (97.9%)	0.315
• Present	01 (01.1%)	0 (0.0%)	01 (02.1%)	
Lateral Pterygoid; inferior head				
• Absent	94 (100%)	47 (100%)	47 (100%)	-
• Present	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Pterygoid tenderness; medial				
• Absent	94 (100%)	47 (100%)	47 (100%)	-
• Present	0 (0.0%)	0 (0.0%)	0 (0.0%)	

## DISCUSSION

The results of this study support the hypothesis of hard splints being more effective than soft stabilization splints in patients of temporomandibular disorders over a period of 3 months. At 3-month follow up, a significant difference in pain among participants of two study Groups was found, where greater number of patients belonging to soft splint occlusal therapy Group reported pain as compared to those belonging to hard stabilization Group (51.1% vs 21.3%,  $p=0.003$ ). These results contradict a study by Aldrigue RH et al.,<sup>7</sup> which showed no difference between soft and hard occlusal splint therapy ( $p=0.9$ ). A study done by Harkins et al.,<sup>8</sup> concluded that soft splints reduced facial myalgia in 74% of the patients while 26% reported

with more or no change. Amin A, et al., and Wieckiewicz M, et al., on the other hand, concluded hard splints to be significantly effective within 30 days of splint therapy while soft splints took 90 days ( $\alpha \leq .05$ ).<sup>8,9</sup> Singh BP, et al., stated that soft splint therapy was ineffective,<sup>10</sup> and Hazra R<sup>11</sup> concluded as hard splints being significantly effective in patients of craniomandibular disorders ( $p < 0.01$ ). Harkins S,<sup>12</sup> and Amin A,<sup>13</sup> found significant reduction in pain in patients of both soft and hard occlusal splints, while no significant difference was found in between the two Groups at any interval. ( $p=0.6$ )

Similarly, according to our study, clicking was also more commonly observed among patients belonging to soft splint therapy Group as compared to hard splint therapy Group (38.3%

vs 19.1%,  $p=0.019$ ). Amin A, et al.,<sup>13</sup> summarized clicking scores as a significant decrease in both Groups, with the decrease in clicking starting from 2 months in patients wearing hard occlusal splint and from 3 months in those wearing soft splint. However, no statistically significant difference was found between the two Groups at any follow-up interval. Zhang SH et al.,<sup>14</sup> concluded a significant reduction in frequency of joint sounds in the sample. They mentioned a pronounced improvement in the patients wearing splints with canine guidance rather than those with bilateral balanced occlusion. Okeson JP and colleagues<sup>15</sup> compared the treatment outcomes of occlusal splint therapy with pharmacological therapy. TMJ clicking in those wearing soft occlusal splints showed significant reduction as compared to pharmacologic treatment during the three months of follow-up. Espí-López GV et al.,<sup>16</sup> also found that after six weeks of using soft splints, 74% patients had complete or almost complete remission of their TMD symptoms including joint sounds.

Limitation of mouth opening is one of the important markers of TMDs. It was observed that limitation of mouth opening was more likely to be reported by patients undergoing soft splint therapy as compared to hard splint therapy (42.6% vs 17.0%,  $p=0.007$ ). Seifeldin SA et al<sup>17</sup> conducted a similar study and

concluded no significant difference between the two Groups, one treated with the occlusal appliance and the other educated regarding the condition ( $\alpha = .325$ ). In a few other studies by Zhang SH,<sup>15</sup> and Poorna TA,<sup>18</sup> a significant difference was seen in both the Groups following three months of their respective treatments. ( $p=0.001$ )

## CONCLUSION

Significant improvement in TMJ pain, joint sounds, muscle tenderness, and mouth opening occurred with hard occlusal splints following 3 months of therapy, though these differences became non-significant at six months post-therapy. Appliance therapy has marked improvement on symptoms of TMDs.

## LIMITATIONS

A small sample size and short duration of study may not allow generalization of the results.

## RECOMMENDATIONS

Further research needs to be carried out on larger sample sizes and longer durations of study to confirm hard splint therapy as the treatment of choice for TMDs.

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