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Comparison of Modified Occlusal Splint, Standard Splint Protocol, and Conventional Physical Therapy in Management of Temporomandibular Joint Disc Displacement with Reduction and Intermittent Locking: A Randomized Controlled Trial

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Abstract: Background: Temporomandibular joint disc displacement with reduction is one of the most common types of TMJ arthropathy. This single-blinded, randomized clinical study aimed to evaluate the effectiveness of three different therapeutic methods. Methods: Standard splints (Group 1), modified occlusal splint (Group 2), and conventional physical therapy with exercises (Group 3). A total of 48 patients were randomly assigned by a computer-generated allocation sequence to receive rehabilitation. The outcome was defined as improvements in pain and intermittent locking episodes. The follow-up visits were scheduled as one month and a long-term evaluation at one (T1), two (T2), three (T3), and four years (T4). Magnetic resonance images were also taken to evaluate each patient before treatment and at one year. Image analysis involved the evaluation of morphology and the function of intra-articular structures. Variables such as age, gender, and pre- vs. post-treatment values of VAS and TMJ locks between the three intervention categories were compared for statistical evaluations. p values ≤ 0.05 were taken as being significant. Results: A total of 16 subjects were allocated to each group. At T1, a decrease in pain and TMJ locking episodes was observed, which was maintained throughout the course of the study for four years of follow-ups, with no statistically significant differences. However, there was a tendency for better outcomes in favor of Group 2, with less clicking of the TMJ at opening. Conclusions: The modified mandibular splint seems to be successful as an effective alternative for the management of temporomandibular joint disc displacement with reductions in intermittent locking.

Keywords: TMJ disorders; temporomandibular joint diseases; temporomandibular joint; temporomandibular joint syndrome; splint therapy

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1. Introduction

Temporomandibular joint (TMJ) disorders encompass a heterogeneous group of musculoskeletal and neuromuscular conditions that affect the temporomandibular joint complex [1]. Temporomandibular disorder (TMD) is the term that is used to define TMJ dysfunction and pain [2]. Disc displacement with reduction (DDwR) is one of the most commonly diagnosed intracapsular biomechanical disorders in patients involving the condyle-disc complex, with a collective prevalence of at least 41% of the general population [1]. It is typically characterized by clicking or popping sounds on mouth opening [3–6]. It has also been reported as a physiological accommodation without clinical significance [7]. Females were found to be more predisposed to develop DDwR than males [8]. According

to the "Diagnostic Criteria for Temporomandibular Disorder (DC/TMD) and the DDwR Diagnostic Criteria and Symptomatology of DDwR", a diagnosis of DDwR relies on the presence of the abnormal positional relationship between the disc and the condyle, articular eminence, and/or articular fossa [3–5,9].

Magnetic resonance imaging (MRI) is supportive in determining the position, movement, and integrity of the temporomandibular articulation, and it is performed to detect joint effusion and mandibular condyle marrow abnormalities [10–12]. However, MRI is not sufficient for the diagnosis of disc displacement, and it must be combined with clinical examination and anamnestic data [13,14].

Diagnostic signs of DDwR are clicking, snapping, or popping sounds during opening, closing, or both (i.e., reciprocal click), either described by the patient or detected by the clinician [2–13]. Disc displacement with reduction may persist for several years and can migrate anteriorly, and as a result, disc displacement without reduction (DDwoR) may occur. Under physiological conditions, the position of the condyle at maximum mouth opening is generally found beyond the summit of the articular eminence. In patients with DDwR, although pathological displacement of the disc can occur in any direction, anterior and anteromedial displacements are the most common [13]. In DDwR with intermittent locking (DDwRwIL), similar to DDwR, in the closed mouth position, the disc is in an anterior position relative to the condylar head, and the disk intermittently reduces with the opening of the mouth. In DdwRwIL, compared to DDwR alone, in the clinical history of the last 30 days, there are repeated episodes of momentary locking that spontaneously resolve without the need for manual reduction maneuvers either by the patient or the operator [9]. MRI images are not different from those of the DDwR unless, at the time of the open-mouth examination, the patient is in a locked position; in this case, the disc appears completely dislocated even with the mouth open [13]. Furthermore, diagnostic criteria for DDwRwIL include the following: In the last 30 days, any TMJ noises present with jaw movement or function or patient reports of any noise present during the exam; in the last 30 days, the jaw locks with limited mouth opening even for a moment and then unlocks. Clicking, popping, and (or) snapping noise detected during both opening and closing movements, detected with palpation during at least one of the three repetitions of jaw opening/closing, right/left, and lateral or protrusive movement(s) [14,15].

The etiopathogenesis of disk displacement remains unclear, and it might be multifactorial [15–19]. Previous studies concerning the etiology of DDwR, including advanced MRI imaging studies, have been limited to detecting group differences between DDwR patients and healthy controls. This condition is partially attributed to abnormal biomechanical forces related to occlusion and excessive articular friction coefficient that reduces the fluency of movements, joint hypermobility, direct or indirect whiplash trauma, degenerative articular disorder, bacterial infection, abnormal articular eminence inclination, height, and thickness of the roof of the glenoid fossa (RGF) [20]. Disc displacement may be detected in asymptomatic individuals because of the adaptative tissue capacity. The fibrosis of retro-discal tissue, which occurs with aging, is most frequently associated with the later stages of disc displacement. This explains the painless and the diminishing incidence of painful disc displacement with age. For some patients, the pain appears to develop slowly and worsen in a fluctuating pattern [21]. Treatment of these taxonomic entities could also be achieved with different treatment modalities [22,23].

Existing studies on DDwRwIL are very limited, and some do not use MRI, which is the gold standard examination method for TMJ pathologies [24]. The focus of this work was to test an occlusal device that was developed specifically for DDwRwIL patients who have intermittent locking episodes and/or pain. Although improvements with conventional methods are mentioned in scientific publications, limitations of such traditional approaches have been experienced clinically in terms of problems such as pain and TMJ locking episodes in the management of DDwRwIL patients [3,14,23]. For this purpose, pain and TMJ locking outcomes for a novel treatment method known as "modified occlusal splint protocol (MOSP)" were compared to a standard splint protocol and conventional physical

therapy with exercises. These results were assessed with a follow-up period of four years to test the efficiency of this proposed novel protocol.

The research hypothesis was decided as "Therapy with modified mandibular splint protocol can be more effective than conventional treatment protocols for DDwRwIL". The null hypothesis was "Therapy with modified mandibular splint protocol is as effective as conventional protocols for DDwRwIL". For this purpose, this single-blind, randomized, controlled clinical trial study aimed to evaluate and compare the effectiveness of three different therapeutic methods in the management of disc displacement with reduction and intermittent locking in terms of a decrease in pain and TMJ locking episodes with four years of follow-up.

2. Materials and Methods

2.1. Ethical Considerations

This study was evaluated and approved by the Ethics Committee of Area 2 Milano (Prot. No. 575-2018- Date: 17 July 2018) and complied with the Declaration of Helsinki (last updated: October 2013) [25]. Informed consent was obtained from all participants before starting the study. This study was registered as a clinical trial with Clinical Trial registration number ISRCTN15536327. Date registered: 9 September 2024. Link: https://www.isrctn.com/ISRCTN15536327 (accessed on 15 June 2024).

2.2. Study Design and Participants

The study was a single-blind, randomized, controlled trial comparing therapy with conventional splint therapy with modified mandibular splint (MOS) and physical therapy with exercises to reduce the frequency of DDwRwIL. Potential participants were identified during routine outpatient clinic visits, and a pre-assessment was performed by the local clinical team. The recruitment phase was from September 2018 to March 2020. The diagnosis of DDwRwIL was carried out according to the Diagnostic Criteria and Symptomatology of DDwR [3].

The anamnesis, clinical diagnosis, MRI assessments, and treatments were performed by the same researcher (S.P.). Table 1 shows the diagnostic tool for DDwRwIL [14].

Table 1. Diagnostic tool for DDwRwIL.

An intracapsular biomechanical disorder involving the condyle-disc complex. In the closed mouth position the disc is in an anterior position relative to the condylar head, and the disk intermittently reduces with opening of the mouth. When the disk does not reduce with opening of the mouth, intermittent limited mandibular opening occurs when limited opening occurs, and maneuver may be needed to unlock the TMJ. Medial and lateral displacement after disc may also be present clicking popping or snapping noises occur with disc reduction.
Positive for the following:
1A—In the last 30 days any TMJ noises present with jaw movement or function, or
1B—Patient report of any noise present during the exam; and
2—In the last 30 days jaw locks with limited mouth opening even for a moment and then unlocks.
Positive for at least one of the following:
1—Clicking, popping and or snapping noise detected during both opening and closing movements, detected with palpation during at least one of the three repetitions of jaw opening and closing.
2A—Clicking popping add or snapping noise detected with palpation during at least one of 3 repetitions of opening or closing movement(s) and
2B—Clicking popping add or snapping noise detected with palpation during at least one of 3 repetitions of right left, lateral or protrusive movement(s)

Data Collection

Inclusion criteria: (a) joint sounds and problems with TMJ movements such as pain, restrictions in range of movement, and locking; (b) a positive diagnosis of TMJ DDwRwIL based on clinical inspection; (c) patients of DDwRwIL on one side or both sides that was confirmed by MRI examination; (d) adults ($\geq$18 years); (e) able to give informed consent; (f) TMJ pain; (g) no previous TMJ treatment.

Patients were excluded if they presented (a) contraindication for MRI (such as patients with any metallic prosthesis or artificial pacemakers), (b) TMJ disc displacement without reduction (DDWoR), or (c) previous facial bone fractures.

In this study, outcomes of standard splint protocol, modified occlusal splint protocol (MOSP), and conventional physical therapy with exercises were compared in terms of pain and TMJ locks with a follow-up period of four years.

2.3. Randomization and Masking

Patients were randomly assigned by a computer-generated allocation sequence to receive rehabilitation by using conventional therapy approaches or MOSP or disc remodeling exercises. Participants were randomly assigned (1:1) with a computer-generated allocation, and all baseline data were collected before randomization, which was carried out by the recruiter. Due to the nature of the intervention, neither participants nor clinicians were masked to the intervention. The data analyst was blinded until the entire analysis was completed.

2.4. Clinical and Image Assessments

The following clinical and image assessments were performed by the same examiner at the time of diagnosis and during the follow-up period for both groups:

- Maximum mouth opening in mms (without any assistance for opening);
- Pain at rest and mastication [assessed by a Visual Analogue Scale (VAS) from 0 to 10, the extremes of which were 'no pain' and 'pain as bad as the patient ever experienced'];
- TMJ locking evaluation: In the last 30 days, (1) less than three episodes of TMJ locking, (2) three to 15 episodes of TMJ locking, or (3) more than 15 episodes of TMJ locking.

2.5. MRI Analysis

MRI was performed with all subjects instructed to lie in a supine position with both arms adducted using the special TMJ dual coil. The static images were acquired in the closed and open mouth positions. Magnetic resonance imaging was executed at two time points: before functional treatment and 1 year after the treatment (in cases when the patient had occlusion modified, an additional third MRI was taken upon completion of treatment).

The MRI was performed with devices with a power equal to 1.5 Tesla with dedicated TMJ coils. In all patients, they were performed with the mouth closed and open.

Only in the MOSP group was the first MRI performed with a bite (made of wax) in an occlusal position. In the splint group, MRIs were performed (before treatment and at one year with the device inserted).

2.6. Splint Fabrication and Therapeutic Intervention

The experimental Group 1 received a treatment MOS. Groups 2 and 3 were both control groups. The patients in Group 2 were given a conventional splint, while Group 3 consisted of performing a home exercise known as the "disc remodeling exercise". Further details about groups can be found written below:

2.6.1. Group 1—MOS Group

The modified mandibular splints had the same characteristics as the conventional version, but the production methodology was completely different:

(1) At the time of the first visit, a wax construction bite was placed in the therapeutic position in addition to the standard positions, and the MRI was performed (the therapeutic

position was simply achieved by protruding the jaw into a position where the joint noise and intermittent locks disappeared).

(2) If the images with an occlusal bite showed a complete reduction in the disc on the head of the condyle, the same bite was used for the construction of the splint. If the mandibular advancement was excessive, a new, less protruding therapeutic position was to be found.

(3) At the control appointment that was scheduled for about 40 days after the first visit, the mandibular splint was controlled in the dental clinic. Adjustments of the splint were carried out to check the progressive retrusion of the mandible. Adaptations were made to the splints according to the occlusion and needs of each patient (modifications for repositioning the jaws, such as removal or adding adjustments to improve occlusion and to rehabilitate TMD).

(4) At one year, another MRI was performed with the splint inserted, and the following factors were obtained:

(A) Complete reduction in the disc on the condyle

(B) Anatomically acceptable condylar position

In the meanwhile, clinically, the patient could not have restrictions during TMJ movements and sleeping with no pain experienced due to TMD.

(5) If these conditions were satisfied, the occlusion was modified with fixed artifacts in the position of the splint (Again with patient-specific adjustments in the occlusion).

2.6.2. Group 2—Therapy with Conventional Splint

A first MRI was obtained without a wax bite using traditional methods. The therapeutic position was identified by simply protruding the jaw into a position where the joint noise and intermittent locks disappeared. The splint was produced accordingly, made of hard resin and without metal hooks. It was made for the upper arch and equipped with an extension that intercepted the jaw during closure, bringing it into the therapeutic position. A second MRI was obtained with a splint in the mouth.

2.6.3. Group 3—Physical Therapy with Exercise Named "Remodeling Exercise"

The group who was prescribed home exercises (until problems disappeared; however, they were continued whenever needed), which included opening their mouth to reduce the disc and then closing and opening again, repeated 10 times × 4 times a day, keeping the jaw in a protruded position where the noise disappears.

2.6.4. Collection of Data

Pre- versus post-treatment values of VAS scores and TMJ locking frequency were analyzed by comparing the baseline (T0) and the T1 after one year, 2 years (T2), 3 years (T3), and 4 years (T4).

2.7. Sample Size Calculation

The sample size calculation was based on a one-way ANOVA model with a 1:1:1 scheme, with significance level (alpha) = 0.05, power = 0.80, delta = 0.5, 3 groups, between-group variance = 0.025, and error (within-group) variance of 1, which provided an estimated sample size of N = 42 (N = 14 per group). Assuming a 10% dropout, we decided to enroll two additional patients per group.

2.8. Statistical Analysis

Statistical analysis of data was carried out using the 11.0 version of SPSS statistical software. The normality of quantitative data was checked using the D'Agostino and Pearson omnibus normality test. A comparison of age among groups was performed using ANOVA, followed by Bonferroni's multiple comparison test. A comparison of gender was made using Pearson's chi-square test. Pre- vs. post-treatment values of VAS and TMJ locks amount were analyzed using a non-parametric approach using the Friedman test

followed by the Dunn post hoc compute. The VAS and TMJ locks comparisons between the three intervention categories have been made through the Kruskal–Wallis test, followed by Dunn's test to compare all pairs of groups. Prevalence of pain among patients in the three groups, considering only the presence/absence of pain, was also provided. p values ≤ 0.05 were accepted as being significant.

3. Results

Figures 1–4 show representative before and after treatment MRI images from one of the DDwR with intermittent locking patients that was rehabilitated utilizing MOS protocol. Figure 5 shows a representative view of a modified mandibular splint on the anatomical cast of one of the patients.

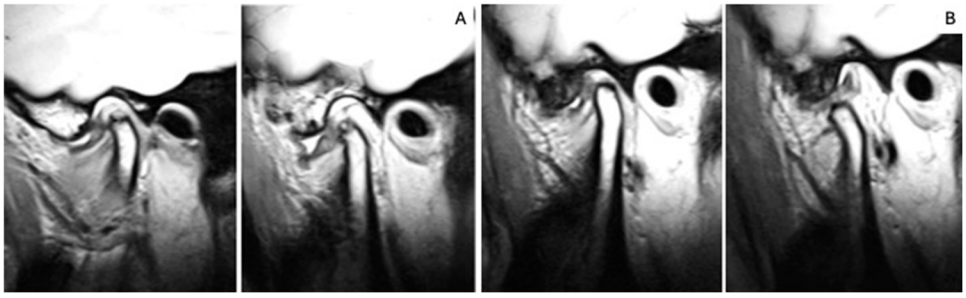

Figure 1. MRI taken at beginning of treatment (A patient with bilateral DDWR but at the time of the initial exam there was an evident DDwRwIL on the right side that did not reduce at maximum opening). (**A**): right TMJ, (**B**): left TMJ.

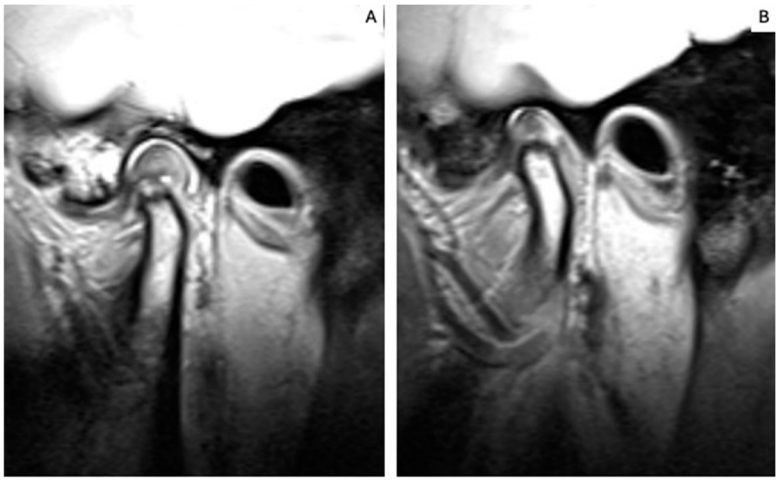

Figure 2. MRI with wax in the therapeutic position: the normal condyle-disc relationship was restored, and the condyles were not particularly advanced with respect to the glenoid cavity. Later, this position of the bite was used for the construction of the MOS. (**A**): right TMJ, (**B**)**:** left TMJ.

A total of 48 patients were included in this study (16 subjects for each group). Table 2 describes the age, gender, and affected side of the mandible in the three different treatment groups.

For age, a one-way ANOVA ($p = 0.39$). Using Bonferroni's multiple comparison test: there was a non-significant difference among groups in any comparison.

For gender, Pearson's Chi-square was a non-significant difference among groups ($p = 0.25$)

For VAS, a one-way ANOVA Kruskal–Wallis non-parametric test was non-significant ($p = 0.48$). Dunn's multiple comparison tests showed non-significant differences among groups in any comparison.

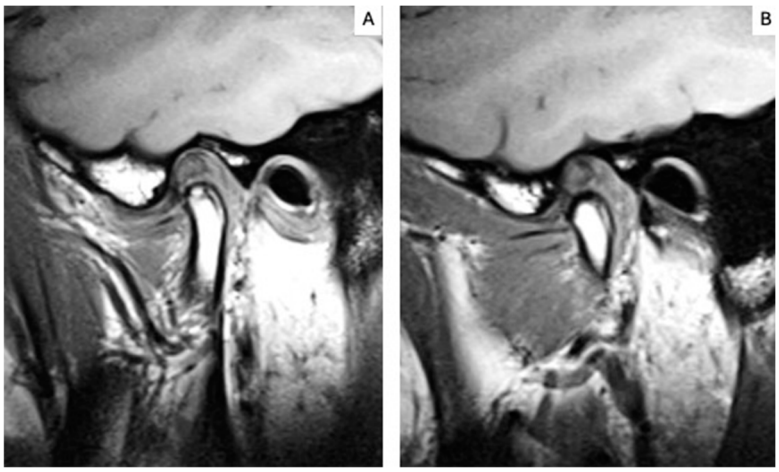

Figure 3. MRI at the end of treatment with splint at 1 year follow-up that shows that normal condyle-disc relationship has been restored and an improvement in the bone profile of the right condyle was achieved. (**A**): right TMJ, (**B**): left TMJ.

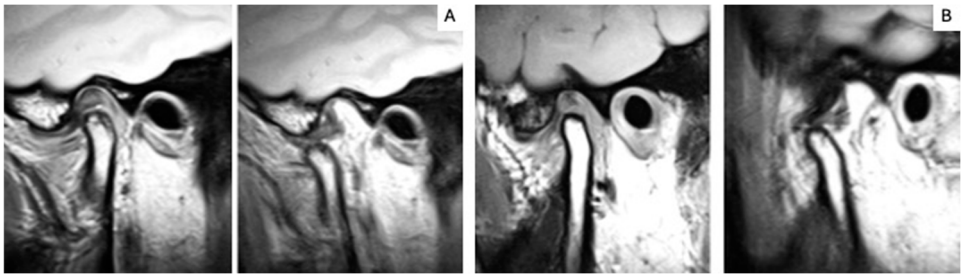

Figure 4. Control MRI 4 years follow-up which shows the changes in the occlusion and interruption of splint use, anatomical and clinical healing with normal findings. (**A**): right TMJ, (**B**): left TMJ.

Figure 5. Modified mandibular splint (MOSP).

One hundred and sixty-seven patients were screened over a period of 48 months, and eighty-six met the inclusion criteria (Figure 6 shows the selection and workflow of patients).

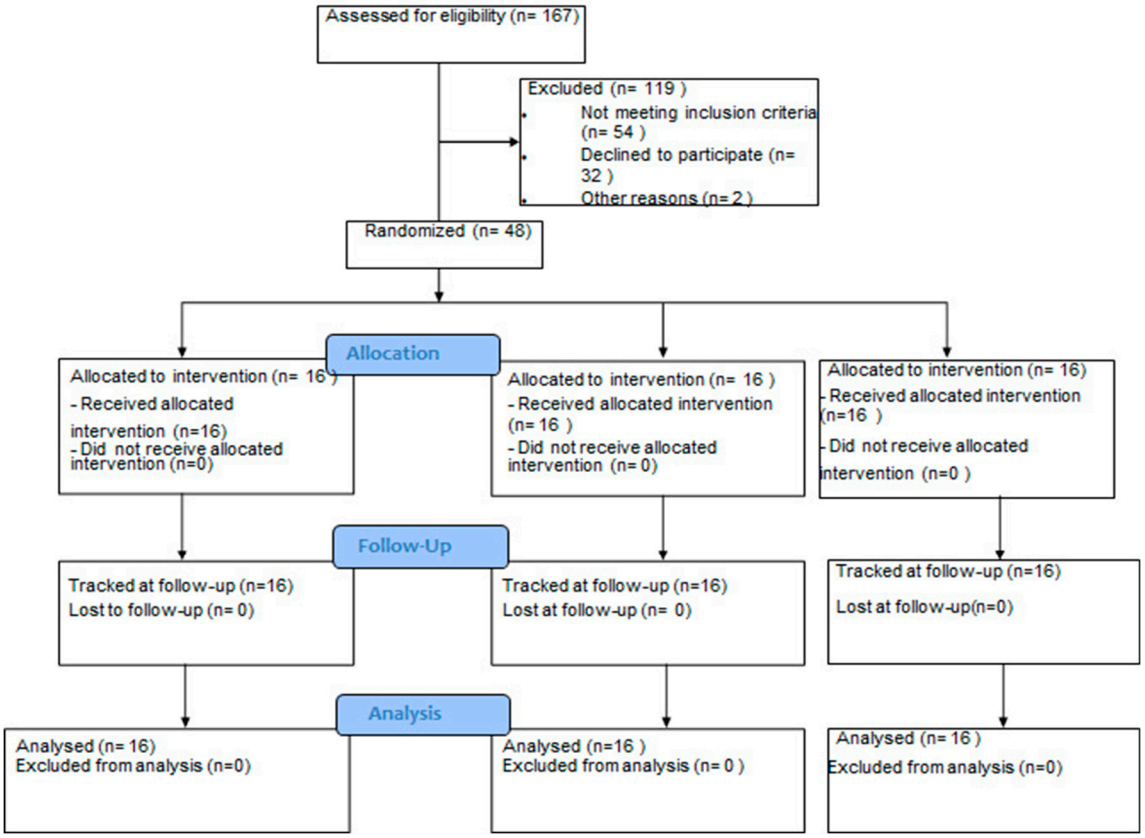

Figure 6. The workflow of patients through the study, according to CONSORT criteria.

Table 2. Patient demographics of the study groups.

Groups	Gender (F/M)	Age (Mean ± SD)	Affected Side
Conventional Splint	11F/5M	27.06 ± 10.60 years	3 Bilateral 6 Right 7 Left
Modified Occlusal Splint	10F/6M	22.25 ± 10.65 years	7 Bilatera l3 Right 6 Left
Remodelling Exercise	14F/2M	26.63 ± 11.39 years	7 Bilatera l3 Right 6 Left

3.1. Pain VAS Score

3.1.1. Modified Occlusal Splint Protocol (Group 1)

At the baseline, the pain prevalence was 75% (12/16) in each group.

At four years, the resolution of pain and locks was 13/16 (81%) with the modified occlusal splint protocol, 8/16 (50%) with conventional treatment, and 4/16 (25%) with a remodeling exercise.

A significant difference in the VAS score was documented by comparing the baseline (T0) and the T1 after one year ($p = 0.0026$). At the baseline, the mean and standard deviation were 3.1 ± 2.4, while at T1, the VAS score was zero. No significant differences were detected when comparing the VAS scores at T2, T3, and T4 ($p > 0.05$). After 2 years (T2), the mean and standard deviation were 0.44 ± 1.3, and after 3 years (T3), the score was zero for all subjects. After 4 years (T4), the mean and standard deviation were 0.13 ± 1.5.

3.1.2. Conventional Treatment (Group 2)

A significant difference in the VAS score was documented when the baseline (T0) and the T1 scores were compared after one year ($p = 0.0005$). At the baseline, the mean and standard deviation were 2.8 ± 1.9, while at T1, the VAS score was zero. No significant differences were detected when comparing the VAS scores at T2, T3, and T4 ($p > 0.05$). After 2 years (T2), the mean and standard deviation were 0.13 ± 0.5, and after 3 years (T3) the score was 0.5 ± 0.97. After 4 years (T4), the mean and standard deviation were 0.5 ± 0.97.

3.1.3. Remodelling Exercise (Group 3)

A significant difference in the VAS score was documented by comparing the baseline (T0) and the T1 after one year ($p = 0.0032$). At the baseline, the mean and standard deviation were 2.3 ± 1.7, while at T1, T2, T3, and T4, the VAS score was zero.

3.1.4. Treatments Comparison

At the baseline, no significant difference was detected comparing the MOSP, conventional treatment, and remodeling exercise groups ($p > 0.05$). At T1, no significant difference was detected where all the groups presented no VAS score of pain for all subjects treated ($p > 0.05$). At T3, no significant difference was detected ($p > 0.05$); a sensible increase in pain scoring means of the conventional treatment group. Also, at T4, no significant difference was detected comparing treatment groups ($p > 0.05$) (Table 3 and Figure 7).

Table 3. VAS score Summary.

	MOSP					Conventional Treatment					Exercise				
	T0	**T1**	**T2**	**T3**	**T4**	**T0**	**T1**	**T2**	**T3**	**T4**	**T0**	**T1**	**T2**	**T3**	**T4**
Mean	3.1	0	0.44	0	0.13	2.8	0	0.13	0.5	0.5	2.3	0	0	0	0
Std. Deviation	2.4	0	1.3	0	0.5	1.9	0	0.5	0.97	0.97	1.7	0	0	0	0
Std. Error of Mean	0.59	0	0.33	0	0.13	0.48	0	0.13	0.24	0.24	0.41	0	0	0	0
Lower 95% CI of mean	1.8	0	−0.26	0	−0.14	1.7	0	−0.14	−0.015	−0.015	1.4	0	0	0	0
Upper 95% CI of mean	4.3	0	1.1	0	0.39	3.8	0	0.39	1	1	3.1	0	0	0	0

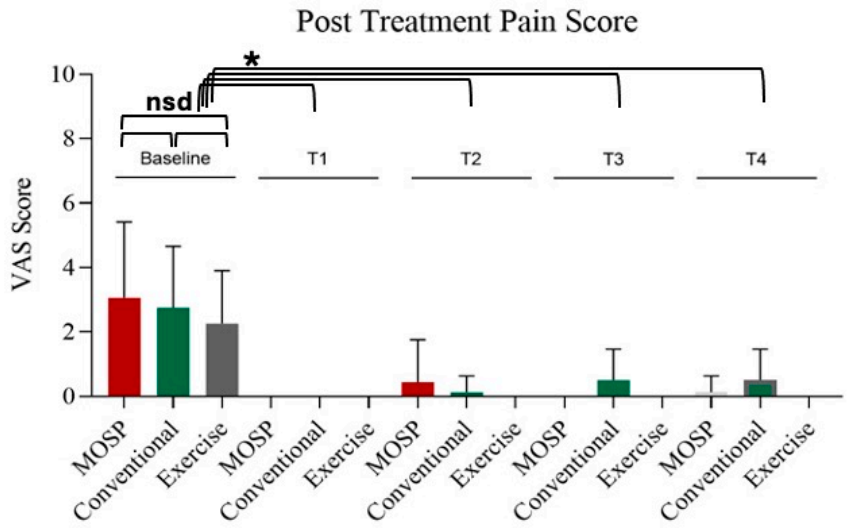

Figure 7. VAS SCORE at different timelines for comparison of 3 testing groups (The horizontal bars just indicate no significant difference (nsd) among the 3 groups at baseline, and significant difference is highlighted with "*" between baseline and subsequent assessments for each group).

3.2. TMJ Locking

3.2.1. Modified Occlusal Splint Protocol

A significant difference in the TMJ locking score was documented by comparing the baseline (T0) and the T1 after one year ($p < 0.05$). At the baseline, the mean and standard deviation were 2.9 ± 0.34, while at T1, the TMJ locking score was zero. No significant differences were detected when comparing the TMJ locking scores at T2, T3, and T4 ($p > 0.05$). After 2 years (T2), the mean and standard deviation were zero, and after 3 years (T3), the score was 0.063 ± 0.25. After 4 years (T4), the mean and standard deviation were 0.063 ± 0.25.

3.2.2. Conventional Treatment

A significant difference in the TMJ locking score was documented by comparing the baseline (T0) and the T1 after one year ($p < 0.005$). At the baseline, the mean and standard deviation were 2.8 ± 0.4, while at T1, the TMJ locking score was zero. No significant differences were detected when comparing the TMJ locking scores at T2, T3, and T4 ($p > 0.05$). After 2 years (T2), the mean and standard deviation were 0.13 ± 0.5, and after 3 years (T3), the score was 0.5 ± 0.97. After 4 years (T4), the mean and standard deviation were 0.5 ± 0.97.

3.2.3. Remodelling Exercise

A significant difference in the TMJ locking score was documented by comparing the baseline (T0) and the T1 after one year ($p < 0.00001$). At the baseline, the mean and standard deviation were 2.3 ± 0.86, while at T1, the TMJ locking score was zero. No significant differences were detected when comparing the TMJ locking scores at T2, T3, and T4 ($p > 0.05$). At T2, T3, and T4, the means and standard deviation were, respectively, 0.25 ± 0.58, 0.19 ± 0.54, and 0.19 ± 0.54.

3.2.4. Treatments Comparison

At the baseline, no significant difference was detected comparing the MOSP and conventional treatment methods' means ($p > 0.05$). At T1, no significant difference was detected, where all the groups presented no TMJ locking scores for all subjects treated ($p > 0.05$). At T3, no significant difference was detected, considering a sensible increase in pain scoring means of the conventional treatment group ($p > 0.05$). At T4, no significant difference was detected comparing all treatment groups ($p > 0.05$) (Table 4 and Figure 8).

Table 4. TMJ locking score summary.

	MOSP					Conventional Treatment					Exercise				
	T0	**T1**	**T2**	**T3**	**T4**	**T0**	**T1**	**T2**	**T3**	**T4**	**T0**	**T1**	**T2**	**T3**	**T4**
Mean	2.9	0	0	0.063	0.063	2.8	0	0.13	0.5	0.5	2.3	0.0	0.25	0.19	0.19
Std. Deviation	0.34	0	0	0.25	0.25	0.4	0	0.5	0.97	0.97	0.86	0.0	0.58	0.54	0.54
Std. Error of Mean	0.085	0	0	0.063	0.063	0.1	0	0.13	0.24	0.24	0.21	0.0	0.14	0.14	0.14
Lower 95% CI of mean	0.0	0.0	−0.071	−0.071	2.6	0.0	−0.14	−0.015	−0.015	0.0	1.8	0.0	−0.058	−0.10	−0.10
Upper 95% CI of mean	0.0	0.0	0.20	0.20	3.0	0.0	0.39	1.0	1.0	0.0	2.7	0.0	0.56	0.48	0.48

Based on TMJ locking analyses, the proportion of successful cases in three different groups can be listed as follows: exercise group 62.5%, traditional therapy 68.8%, and MOS 93.8%.

The findings of this study demonstrated no significant difference comparing the three groups at the study time points. The TMJ locking frequency of the conventional treatment was slightly higher when compared to the MOSP and the exercise group, but no significant difference was detected ($p > 0.05$). All of the treatments were efficient in reducing the pain score and the TMJ locking frequency from the baseline to the T1 timepoint.

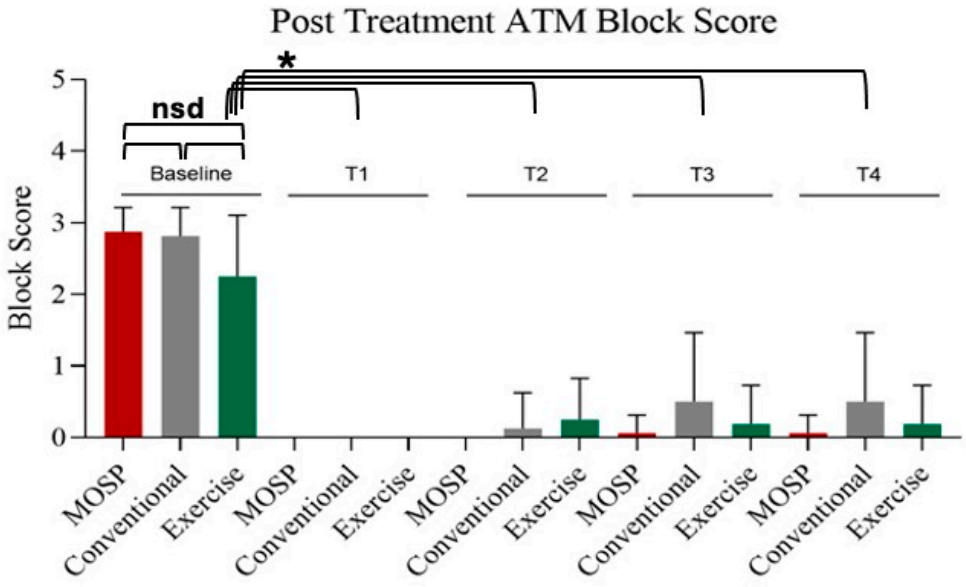

Figure 8. TMJ locking frequency at different timelines for comparison of 3 testing groups (Block score shows results of TMJ locking evaluations ". (In the last 30 days, 1—less than three episodes of TMJ locking; 2—three to 15 episodes of TMJ locking; 3—more than 15 episodes of TMJ locking"). (The horizontal bars just indicate no significant difference (nsd) among the 3 groups at baseline, and significant difference (*) between baseline and subsequent assessments for each group).

4. Discussion

The treatment for patients suffering from a clicking joint, including DDwR with intermittent locking, is dictated primarily by the presence of pain or dysfunction and leads to a more favorable mechanical TMJ load [26–30]. Non-surgical options are proposed for the treatment and include a combination of splinting with physical therapy [31,32]. Currently, occlusal splint rehabilitation is the standard method to treat disc displacement with reduction. Types of occlusal splints include the stabilization splint, modified Hawley splint, and repositioning splint. Outdated evidence shows that the occlusal stabilization splint is effective in patients with DDwR, and occlusal appliances are the most common therapy, even though there are no guidelines to provide specific recommendations to support clinical practice and decisions. Furthermore, there is often a discrepancy between the findings [33–40].

In DDwR, the treatment objectives are multiple: the restoration of muscle–articular balance proprioception and recovery of the relation of the condyle with a disc. However, clinical responses to available therapies remain variable and unpredictable, making it difficult to select patients who could benefit from these types of treatments [39]. Furthermore, there is currently no conclusive evidence that biomechanical conditions cause the healthy disc to become a disc with problems, such as TMJ displacement without reduction [40–45].

Modified mandibular splint therapy as a term was also used in literature by researchers; however, the protocols used were different from the ones presented in this paper [24,46]. In a recent study, modified mandibular splint therapy was evaluated for TMD. For that research, the authors aimed to present an MOS splint with a specific treatment regimen, and improvements in joint sounds were assessed as an outcome [24]. As a result, they reported that a modified mandibular splint can be used to treat reciprocal clicking of the TMJ effectively. Furthermore, the study did not use any magnetic resonance imaging examination for evaluation, which was one of the major limitations [24]. In this present study, different from that, MOS therapy was tested for DDwRwIL, and MRI images were used for evaluation. Another study by Gidon et al. reported outcomes of MOS to treat bruxism and related cranio-mandibular-myofascial pain in post-traumatic stress disorder patients [46]. However, their MOS appliance was different from the one used in this work,

as it was a thicker mandibular splint. In conclusion, they reported that MOS therapy provided an effective therapy for reducing nocturnal pain and bruxism symptoms in such patients [46].

Various designs of appliances are utilized for the management of TMD, including stabilization splints (Michigan Splints) and anterior repositioning appliances (such as Tanner appliances, Fox appliances, or centric relation appliances) [47–49]. Mostly, these appliances are made of hard acrylic, which looks like orthodontic retainers in design. The aim of such therapies is to provide a temporary and ideal occlusion, minimize abnormal muscle function, and protect teeth from clenching [47–52]. On the other hand, the purpose of the anterior positioning appliances is more concentrated on the improvement of the disk-condyle relationship with joint function by repositioning the mandible and condyle anteriorly [49]. A recent meta-analysis evaluated the effectiveness of splint therapy in patients with temporomandibular disorders and reported moderate-quality evidence that splint therapy has a substantial effect on reducing pain among patients with TMDs [48]. Even though they are mentioned in the literature with successful outcomes, some limitations of the traditional approaches are being experienced clinically in terms of pain and TMJ movement restrictions, especially for DDwRwIL patients. The proposed protocol in this research is represented as an alternative to conventional treatments. Although not statistically significant, the results of this study showed a tendency for reduced scores in terms of pain and TMJ locking episodes.

MRI studies evaluating treatment-dependent changes have documented disc displacement in ~35% of asymptomatic patients, showing no long-term effect on snap [15,33]. The purpose of a splint for DDwR of TMJ is to recapture the disc anteriorly and reposition the condyle downward; improve jaw function; correct the relationship between the glenoid fossa, articular disc, and condyle; reduce joint pain and sounds; prevent the development of the TMD [31]. The modified splint used in this study was designed to reduce pain and TMJ locks. MRI is the gold standard method for diagnosis of DDwRwIL, and research in this field should use this diagnostic tool, whenever possible, to confirm and check the outcomes, which is also one of the strong points of this study. Another strong point was the four-year follow-up period, which can be considered a long-term follow-up with control visits when compared to other research papers [48–54]. The outcomes of this study demonstrated no significant difference comparing the three groups. The TMJ locking frequency of the conventional treatment was slightly higher when compared to the other groups, but no significant difference was detected. All of the treatments seem to be efficient in reducing the pain score and the TMJ locking frequency from the baseline to the T1 timepoint.

In the literature, there are various studies evaluating the outcomes of TMD treatments with splint therapy [48–54]. However, the number of randomized clinical trials is limited (54). The majority of the studies assess the outcomes such as pain, restriction in TMJ movements, and pain [48–54]. In a recent network meta-analysis of randomized controlled trials, the effectiveness of occlusal splint therapy was investigated for the management of temporomandibular disorders with forty-eight randomized studies. According to the results, there was a significant decrease in post-treatment pain intensity in arthrogenous TMDs after anterior repositioning splints, counseling therapy with hard stabilization splints, mini-anterior splints, and hard stabilization splints alone, when compared to the control groups. Outcome variables were pain improvement, post-treatment pain intensity, improvement in mouth opening, and disappearance of TMJ sounds. Based on their results, they reported moderate to very low-quality evidence confirming the effectiveness of occlusal splint therapy in the treatment of TMDs [53]. The results of this present work, in accordance with the literature, highlight an obvious enhancement of the symptoms with successful results in splint therapy (both with conventional splints and MOS). These outcomes show that splint therapy is a successful treatment for DDwRwIL patients.

One of the limitations of this study is that it included a small number of patients in groups. Further prospective studies with larger groups and longer follow-ups are needed in

the literature to confirm these results. Within the limitation of the present study, the findings seem to encourage a non-surgical approach to temporomandibular joint disc displacement through both occlusal splint and reduction exercises. Modified occlusal splint for treating disc displacement with reduction and intermittent lock of the articular disc seemed to show no statistical difference when compared to conventional treatment alternatives.

5. Conclusions

According to the results of this study, although not statistically significant, a modified occlusal splint seemed to be a successful treatment method for DDwRwIL patients with promising results in terms of clinical efficacy for a reduction in pain with a drastic decrease in the TMJ joint locking episodes. Furthermore, a tendency for better outcomes was observed in favor of the modified occlusal splint approach for the patients who experienced a clicking sound at TMJ during mouth opening. Although not statistically significant, the results of this study showed a tendency for reduced scores in terms of pain and TMJ locking episodes.

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