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TREATMENT PROTOCOL FOR TEMPOROMANDIBULAR JOINT DERANGEMENT USING AN ANTERIOR REPOSITIONING SPLINT WITH MODIFICATION (ONE YEAR PROSPECTIVE STUDY)

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ABSTRACT

Purpose: To study the patient with temporomandibular joint derangement concerning the subjective response and clinical outcome to a modified splint treatment protocol.

Materials and Methods: 12 patients were included with disc displacement with reduction (DDwR). The treatment protocol was initiated using an anterior repositioning splint (ARS) for 3 months and later completed with ARS modification into a stabilizing splint (SS) for the next 9 months. Follow-up was made over one year (6 weeks, 12 weeks, and 1-year intervals). The follow-up included the patient's self-evaluation, clinical examination, and MRI.

Results: In comparison to the base-line a significant improvement was recorded in the tested parameters; A) in 12 weeks follow up, the subjective data were; the pain frequency (0.41±0.51), the pain degree (0.25±0.45), the modified pain by chewing, movement, para-function, and other parameters were 0.08±0.28, 0.25±0.45, 0.25±0.45, and 0.16±0.38 respectively. B) in 6 & 12 weeks follow-ups the clinical parameters were; MCPS 0.58±0.51, and 0.25±0.45, the MYS 0.58±0.51, 0.25±0.45, the MD 1.91±0.66, 0.58 ±0.51, C) the VAS scores, the mandibular movement range in the maximum opening, protrusive and both lateral directions, and the Helkimo's disability index scores were improved. In 3 & 12 months follow-ups the complete disc recapture diagnosed by MRI were 66% and 83% respectively.

Conclusion: There is a positive impact of the ARS on all criteria of patient subjective and clinical outcomes. The improvement continued after splint modification for the successive 9 months. Within the limitation of this study, and upon literature comparison, this treatment protocol is recommended in DDwR cases.

KEYWORDS : Anterior repositioning splint – temporomandibular disorders – disc derangement with reduction

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INTRODUCTION

The Mandible is connected to the skull through two bilateral synovial joints or temporomandibular joints (TMJ). The physiologic anatomy of these joints combined with the associated muscles and ligaments allows a multi-axis jaw movement necessary for various functional activities [1].

Temporomandibular disorders (TMDs) is a famous orofacial pain (OFP), it refers to musculoskeletal disorders affecting the masticatory muscles, ligaments, and/or the TMJ components (disc, capsule, and/or osseous components) integrity and function [2, 3]. TMDs were described with multiple etiologic and/or perpetuating factors [4,5].

TMDs' common presenting symptom is pain (in-joint and pre-joint area), which is usually triggered by emotions, stress [6], and it is aggravated by chewing or other jaw muscle activities [7]. Thus it can limit, modify, interfere or hinder the normal jaw physiologic functions [8].

Depending on the onset, not the severity, the pain is either acute or chronic, the main categories of chronic type are; a) somatic (dull, achy pain in soft or hard tissues), b) neurogenic (burning or stabbing neuropathic / nerve damage pain), and c) Psychogenic (emotional/ mood-related and lacks organic origins) [9,10,11]. A patient may present a combination of two of these categories or even all combined [12].

Ongoing orofacial pain (OFP) for more than three months was considered chronic [13].

TMDs etiology may be; a) muscle disorders (myalgia [14] or nonspecific pain of masticatory muscles), b) disc displacement (DD) with reduction (DDwR), or without reduction (DDwoR) [15]. the DD may be accompanied or not by locking in opening or closure [16]. DD is also termed in literature "internal derangement" which refers to "a peripheral separation of the disc from its capsular, ligamentous, or osseous attachments" [17], c) degenerative joint disease (DJD), it includes osteoarthrosis, osteoarthritis, capsulitis, synovitis, and degenerative articular disc thinning or even perforation [18,19].

Occlusion-related problems was claimed related or etiologic to TMD [21, 22, 23, 24, 25,26]. But this cause-effect relation was long considered a field of controversy [27]. nevertheless, the lack of consistency even among those studies that support such assumption [28]. And it was reported as a consequence rather than the origin [29].

MRI findings coupled with careful interdisciplinary diagnosis may point out the TMD type [30]. The TMD with DD, especially DDwR, may include a myalgia (2ry myalgia) [31], occlusal deviation [32,33], facial asymmetry (displacement asymmetry) [34], a TMJ site pain component [35], clicking or crepitus [15], or a combination of these symptoms.

The TMD non-surgical approach consists of a recognized health care protocol set that includes; a) cognitive-behavioral therapy aiming for relaxation and habit-breaking [36,37], b) pharmacological approach (using Anti-inflammatories and muscle relaxants or anti-depressants in severe cases) [38,39], c) modalities of physical therapy (electro-physical, massage, or physical exercise) [40,41], d) Wearing an oral appliance (OAs) or an occlusal orthotic (splint) [42], e) a combination of these approaches.

The occlusal splint therapy is a common worldwide accepted TMDs management [43]. The commonly used types in DD cases are [44,45,46]; 1) stabilization splints, which are used in the treatment of nocturnal bruxism, and usually covers all teeth and prescribed to be worn at night to prevent clenching and grinding of teeth, 2) repositioning splints, which are used to alter the occlusal relation and mandibular relation as the anterior repositioning splint (ARS), it fits on the teeth occlusal surface (maxillary or mandibular), and these splints are typically instructed for a day and night use and

usually prescribed al for a short period (not to exceed 3 - 4 months or up to 6 months).

Efficacy of oral appliances used in DD management was hypothetically related to [47,48,49]; 1) dental causes as, a) altering the occlusal relation, b) altering the condylar relation, c) controlled increase in the vertical dimension. 2) non-dental causes, a) altering the cognitive awareness, b) decreasing the related muscles' motor activity, c) placebo effect.

If the short-term use of ARS (2-3months) was combined with relatively long-term use of stabilizing splint, the benefits of both may offer better effect and clinical results. Thus this study aimed to test the null hypothesis that the modified ARS into a stabilization splint will offer a good patient outcome and clinical response in cases of TMD that demonstrates DDwR especially in cases with radiographic signs of moderate disc changes.

MATERIAL AND METHODS

This work was processed and approved according to ethical guidelines of the academic ethics committee, college of dentistry, Mansoura University (A12051021), then each patient was informed about the treatment plan and follow-up regime and asked to sign informed consent according to the college regulations before the clinical procedures.

Patient selection

From the subjects diagnosed with OFP [50], twelve patients were selected according to Kuc et al [51] controlled inclusion and exclusion criteria. The selected cases were diagnosed as TMD, internal derangement patients (anterior disc displacement with reduction), in addition to MRI reported unilateral moderate degenerative changes and mediolateral deviation upon opening (*detailed in next section*). The patients' pre-treatment life table (baseline data) was presented in table 1.

pre-treatment radiographic examination

Pre-treatment cone-beam computed tomography (CBCT) was made to disclose any osseous morphology and pathology [52,53] (figure 1a,b).

Pre-treatment sagittal MRI imaging (figure 1a,b,c) were made in; 1) closed mouth (maximum intercuspation), and in 2) open mouth where the patients maintained in maximum opening that was assessed as follows; open-mouth MRI images was more than (10-15mm measured at an inter-incisal distance) and reach the maximum opening without pain beyond the last opening click (approximately 40-45mm measured at an inter-incisal distance).

TABLE (1) Pre-treatment life table (base line data) of the study subjects based on preliminary diagnosis and MRI reports.

Cases	1	2	3	4	5	6	7	8	9	10	11	12	N=12
Gender (M/F)	F	F	F	F	F	F	F	F	M	M	M	M	1 : 2
													X±SD (Max/Min/R)
Age (Years)	33	33	34	42	36	39	38	37	43	46	49	47	39.7 ± 5.5 (49 /33 /16)
PD (Month/s)	7	9	7	6	13	11	9	8	7	8	11	12	9 ± 2.2 (6 / 13 / 7)
													Mode /Median (Max/Min/R)
MRI Contra DT	2	3	2	1	1	2	3	2	2	2	2	1	2/2 (3/1/2)
MRI Ipsi DT	1	0	0	0	1	0	1	1	0	1	0	0	1/.5 (1/0/1)

PD = Pain Duration in months Contra= Contralateral, Ipsi= Ipsilateral, DT= disc thickness, (normal=0, moderate=1, thin=2, very thin=3, perforated=4), Mean= X, Standard deviation = SD, Maximum=Max, Minimum= Min, Range=R

The patient's predetermined vertical jaw separation was maintained upon biting on a stack of tongue blades at open mouth scans [54].

The DD was present when the disc posterior band (PB) was located within the articular eminence inferior part, and the DD was partially present when PD was located within the articular eminence middle part, and the DD was considered recaptured when disc PB was located within the articular eminence superior part [55, 56].

pre-treatment (self-evaluation & clinical assessment)

Patient self-evaluation was carried out through "Form 1". This form is a translated, modified short screening instrument from Gonzalez et al [57]. The self-report questionnaires address the pain frequency and degree as well as pain modification by chewing movement, para-function or others [58].

Tow examiners used "Form 2", that was designed according to TMD research diagnostic criteria (RDC/TMD) [58], the form consists of 3 parts as follows; A) first part help to assess pain and disability in terms of a Modified Chronic Pain Disability Scale (MCPS) in which (0= no pain & no disability, 1= low pain & no/ low disability, 2= moderate pain & no/ low disability, 3= moderate pain & low/ moderate disability, 4= high intensity pain & high disability or even severely limiting situation) [57], B) second part helps to assess secondary myalgia in terms of a pain site scale (MYS), in which (0= no pain, 1= local pain at palpation site, 2= pain spreading beyond palpation site within the palpated muscle, 3= pain spreading beyond palpation site and beyond the palpated muscle) [59], C) third part is used to assess the opening deviation from mid line (OD) or the medio-lateral shift that deviates the mandibular closing path, the measurements indicated the deviation of the lower incisors midline in relation to upper incisors mid line from maximum intercuspation and maximum opening.. The difference in millimeters were recorded in terms of (0= no shift, 1 = 1-2mm, 2 = 3-4mm, 3 = 5mm, 4= more than 5mm) [60, 61].

The selected subjects were assessed by different methods as follows;

1) VAS scores

VAS is a visual analog scale score, where 10-centimeter horizontal scale scores were used to denote pain level from patient prospect (0 = minimum and 10 = maximum) [62,63].

2) Mandibular movement assessment

Mandibular movement assessment to extract the mean of three successive measurements using digital caliper for each item of them: a) MMO (maximum mouth opening without pain measured in millimeters between upper and lower central incisors or corresponding level), b) FMO (Dentist controlled maximum mouth opening beyond painful limitation, using thumb moderate pressure on lower incisors while index finger resting on upper incisors, measured in millimeters between upper and lower central incisors or corresponding level), c) lateral movement in relation to affected joint disc based on MRI data were measured as ILE (Ipsi-lateral excursion) and CLE (Contra-lateral excursion), measurements were in millimeters between upper and lower incisors midline by asking the subject to move the slightly opened mouth in maximum non painful lateral direction starting by the affected "ipsilateral" side, d) PE or protrusive excursion, denoting the maximum horizontal distance measurements in millimeters between upper and lower incisal edges from maximum intercuspation till maximum protrusion [64-66].

3) Helkimo index (dysfunction index or Di) [67, 68].

This index the anamnestic function throw grading or symptomatic evaluation for dysfunction at baseline (pre-treatment) and after treatment (post-treatment). The index addresses 5 signs which are; 1) range of jaw movement, 2) smooth movement with no deviation or sounds, 3) movement pain, 4) joint pain, 5) jaw muscles pain. The index scores (Di0,

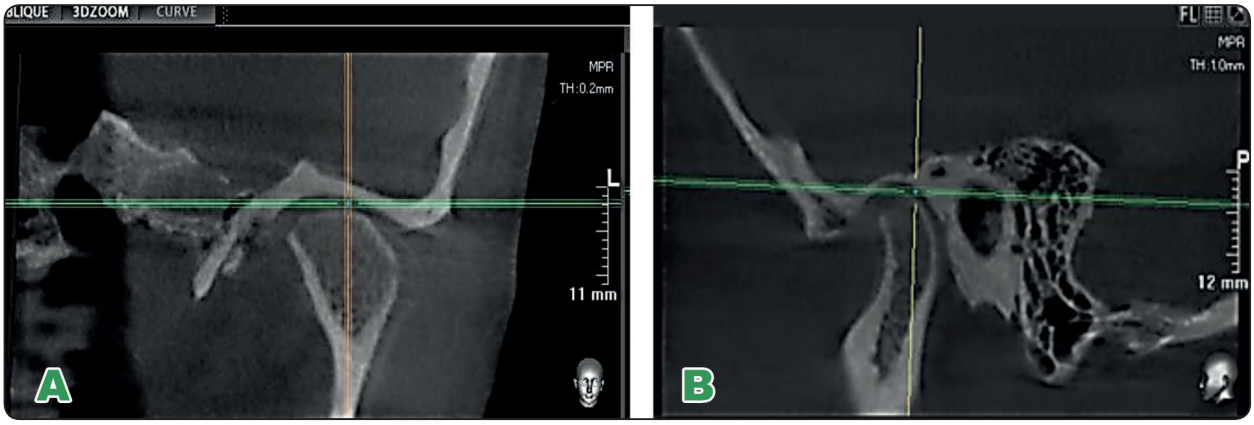

Fig. (1) CBCT of the affected joint side showing a normal joint space and bone integrity in condyle head and fossa, a) coronal view, b) sagittal view.

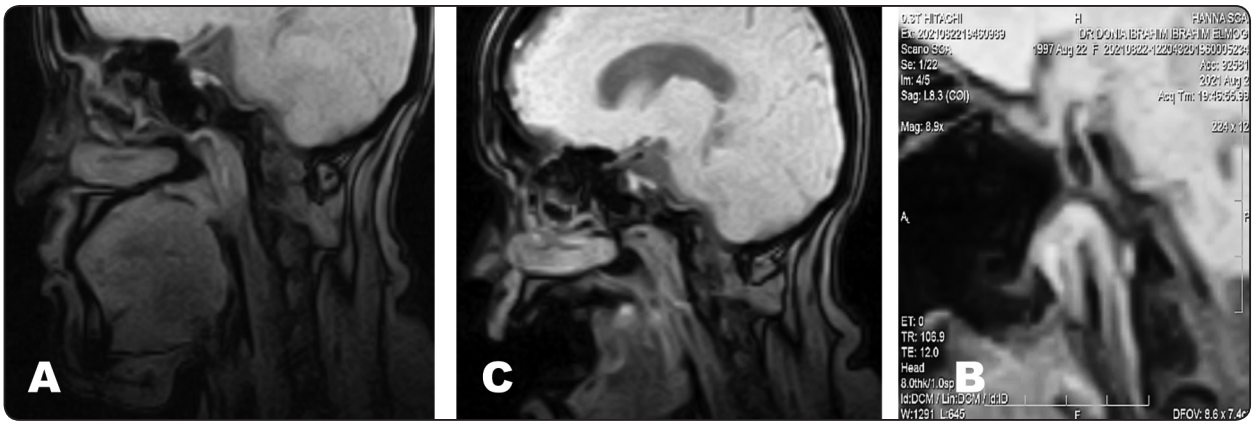

Fig. (2) MRI of the affected joint side in sagittal section, a) closed mouth, b) open mouth, c) anterior disc displacement with no signs of recapture.

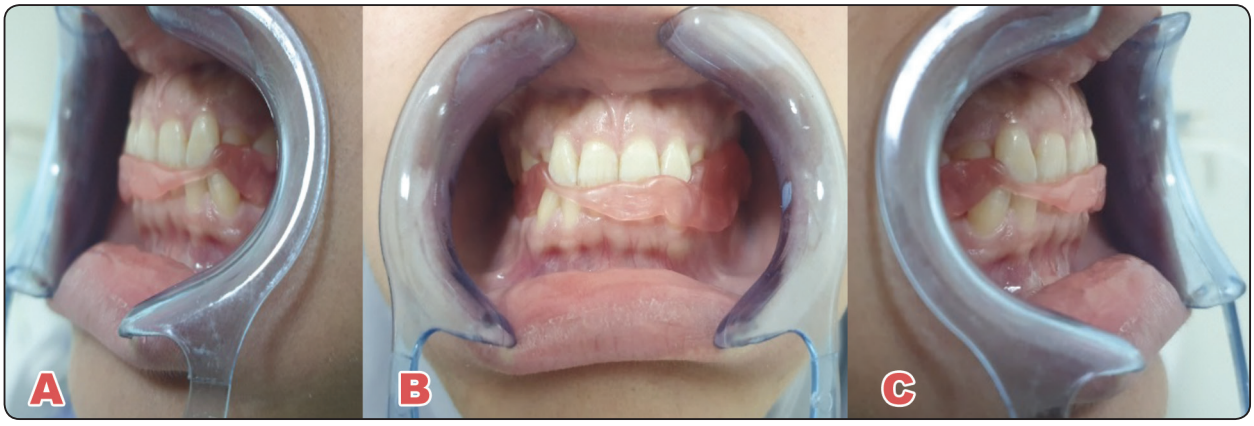

Fig. (3) centric wax inter-occlusal record; a) right side, b) frontal view, c) right view.

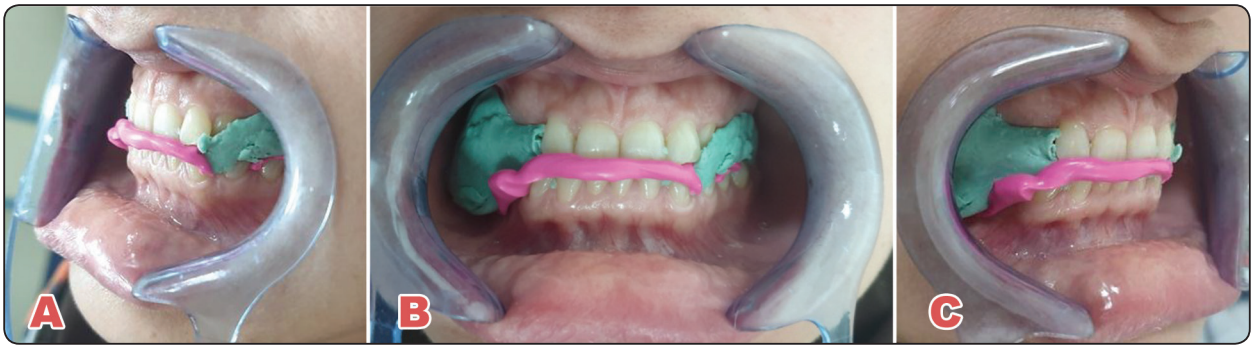

Fig. (4) protrusive rubber base occlusal record; a) right side, b) frontal view, c) right view.

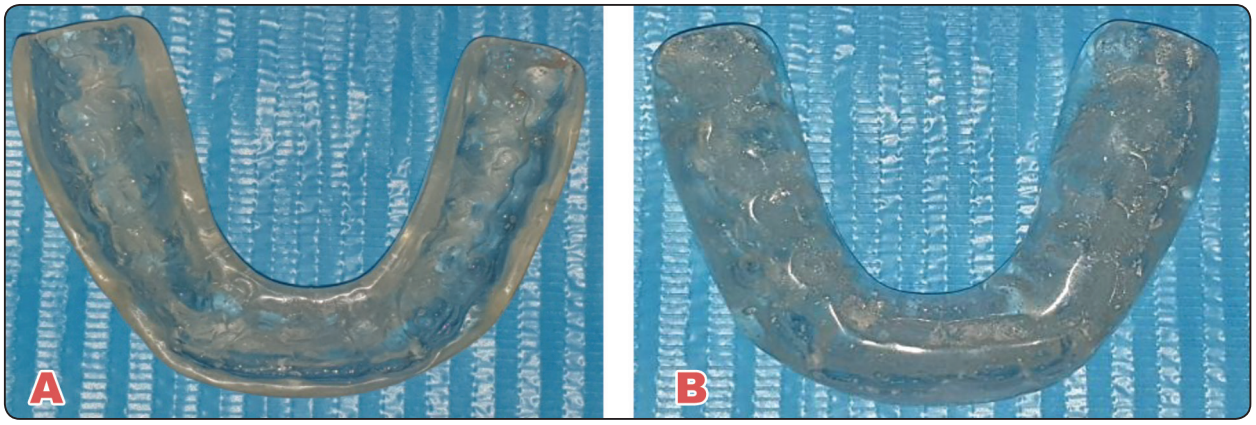

Fig. (5) clear acrylic maxillary A-P splint a) right side, b) frontal view, c) right view.

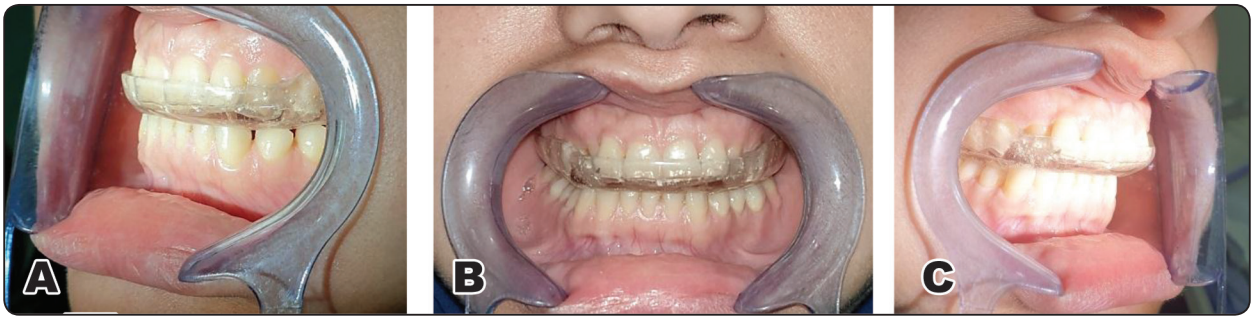

Fig. (6) clear acrylic maxillary A-P splint; a) intaglio surface, b) polished surface with indentation for mandibular anterior teeth.

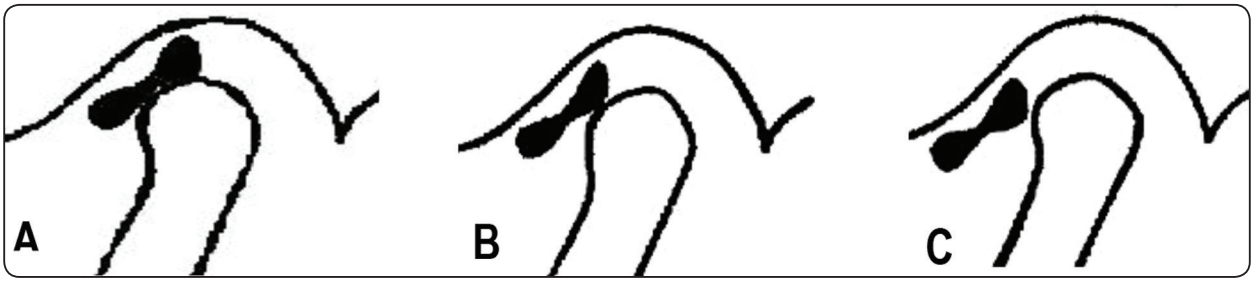

Fig. (7) Diagrammatic presentation for the status of disc-condyle relationship, a) complete recapture, b) partial recapture, c) no recapture.

Di1, Di2, Di3) were as follows; a) 0 points score refers to Di0 or "No symptoms", b) 1-4 points score refers to Di1 or "Mild symptoms", c) 5-9 points score refers to Di2 or "Moderate symptoms", d) >9 points score refers to Di3 or "Sever symptoms".

ARS construction and modification protocol

Maxillary and mandibular impressions were made and poured to produce working models. For each patient, the following records were made: 1) Guided centric, rubber base, 2-3mm thickness, wax inter-occlusal record (figure 3a,b,c). 2) controlled protrusive, edge to edge, rubber base record (figure 4a,b,c) (4-6mm anterior to centric occlusal position) [69].

In both records, the maxillary and mandibular midline were assured to superimpose each other. Records were used for semi-adjustable articulator mounting and programming. Clear acrylic maxillary anterior repositioning splint was waxed, processed, finished & polished with 3-4mm thickness (or slightly more) at the thinnest portion (figure 5a).

Form 1; Patient Self-Evaluation Form **Temporomandibular pain disorder screening instrument**
1. In the last month (approximately) is there a pain in jaw or pre-joint area (in one sides or both sides) **o A- no pain** **o B- Limited time pain** **o C- continuous pain**
2. In the last month (approximately) is there a limited jaw movement in the morning. **O A. no** **O B. yes**
3. In the last month (approximately) is there a pain modification (improved, provoked or worsen the pain) by any of these activities affecting the jaw or pre-joint area (in one sides or both sides) • In chewing hard food **O A. no** **O B. yes** • In chewing gum or clenching **O A. no** **O B. yes** • In other activities (i.e. yawing) **O A. no** **O B. yes**

Modified Short screening instrument with 3 questions (A= 0, B= 1, C= 2)

The used version was translated and edited from (Gonzalez YM, Schiffman E, Gordon SM, Seago B, Truelove EL, Slade G, Ohrbach R. Development of a brief and effective temporomandibular disorder pain screening questionnaire: reliability and validity. J Am Dent Assoc. 2011 Oct;142(10):1183-91.)

Form 2; Diagnostic Pain/ Disability/ Occlusion assessment **Temporomandibular pain disorder screening instrument**	
A- Modified Chronic Pain/ disability Scale	
0- No pain, No disability	o
1- low pain, No/ low disability	o
2- Moderate pain, No/ low disability	o
3- Moderate pain, low/ moderate disability	o
4- High intensity pain, high disability, severely limiting	o
2- Secondary Myalgia Scale	.
0- No pain	o
1- local pain at palpation site	o
2- pain spreading beyond palpation	o
3- site within the palpated muscle	o
4- pain spreading beyond palpated muscle & palpation site	o
3- Med-line deviation in maximum opening	
0- no deviation	o
1- 1mm	o
2- 2mm	o
3- 3mm	o
4- 4mm	

MCPS = ***Modified Chronic Pain Disability Scale*, *(0= No pain, No disability, 1= low pain, No/ low disability, 2= Moderate pain, No/ low disability , 3= Moderate pain, low/ moderate disability, 4= High intensity pain, high disability, severely limiting)***

MYS = ***secondary myalgia pain/extension scale, (0= no pain, 1= local pain at palpation site, 2= pain spreading beyond palpation site within the palpated muscle, 3= pain spreading beyond palpation site and beyond the palpated muscle)***

MD = ***Mid-line deviation in maximum intercuspation (0= no shift, 1 = 1mm, 2 = 2mm, 3 = 3mm, 4= 4mm*).**

Teeth indentations were faint posteriorly (indefinite occlusal stop) or nearly flat, while definite indentation (stops) for the lower incisors (figure 5b) [70,71].

Major occlusal interferences were checked first then the finished ARS was delivered (figure 6a,b,c). occlusal contacts were checked at least 2 times in the next 2 weeks. Patients were instructed for day and night use [72] and to comply with scheduled follow-up.

After 3 months of use the splint was converted to a stabilization splint through; preserving 2-3mm thickness for posterior disclosure, creation of posterior simultaneous contacts and canine guidance anterior contact, and the removal of anterior indentation. The patient was instructed to continue use during the night and for one year [73]. Form 1, 2, and examination procedures were used to collect data presented in tables 2, 3, and 4.

Post-treatment radiographic examination

After 3 months and 1 year periods, a post-treatment MRI was made for all cases in closed moth (maximum intercuspation) to disclose the presence or absence of "disc recapture" (figure 7a,b,c). Comparison with pre-treatment MRI was done by the same examiner to disclose the disc recapture sequence achievement [54- 56].

Statistical analysis

Descriptive and inferential statistics were calculated using IBM® SPSS® 25. Repeated-measures ANOVA is used at significance level P≤ 0.05, to compare changes in the same group with the same variables in successive periods of the study.

TABLE (2) 12 weeks pre-/post-treatment subjective data based on the output of "Patient self-evaluation Form 1".

Categories	Item	Period	Cases												Statistics		
			1	2	3	4	5	6	7	8	9	10	11	12	X ± SD	*CV*	P
Pain & discomfort	Frequency	pre	2	2	3	1	1	1	2	1	1	1	2	2	1.58±0.66	0.42	*P**
		post	1	1	1	0	0	1	1	0	0	0	0	0	0.41±0.51	1.23	
	Degree	pre	2	2	2	1	1	0	1	1	0	0	1	1	1.00±0.73	0.73	*P**
		post	1	1	1	0	0	0	0	0	0	0	0	0	0.25±0.45	1.80	
Pain modification	Chewing	pre	0	0	1	0	1	1	1	1	1	0	0	1	0.58±0.51	0.88	*P**
		post	0	0	0	0	0	0	1	0	0	0	0	0	0.08±0.28	3.46	
	Movement	pre	1	1	1	0	0	0	1	0	0	1	1	0	0.50±0.52	1.04	*P**
		post	1	0	1	0	0	0	0	0	0	0	1	0	0.25±0.45	1.80	
	Para-function	pre	1	1	1	0	1	1	1	0	0	1	1	1	0.75±0.45	0.60	*P**
		post	1	0	1	0	0	0	0	0	0	0	0	1	0.25±0.45	1.80	
	Others	pre	1	1	0	0	1	1	1	1	1	1	1	1	0.83±0.38	0.46	*P**
		post	0	1	0	0	0	1	0	0	0	0	0	0	0.16±0.38	2.33	

Mean= X, Standard deviation = SD, P= comparison with pre-treatment status, P*= statistically significant difference when value is (<0.001)

TABLE (3) 6 weeks and 12 weeks pre-/post-treatment subjective data based on the output of " Clinical Examination Form 2".

Categories	Periods	Cases												Statistics		
		1	2	3	4	5	6	7	8	9	10	11	12	X ± SD	*CV*	P
MCPS	pre	2	3	2	1	1	2	3	2	2	2	2	1	1.91±0.66	0.34	
	Post (6w)	1	1	1	1	0	1	0	1	0	1	0	0	0.58±0.51	0.88	*P**
	Post(12w)	0	1	0	0	0	0	1	0	0	1	0	0	0.25±0.45	1.80	*P**
MYS	pre	1	2	1	0	1	1	2	2	2	2	1	1	1.33±0.65	0.48	
	Post (6w)	1	1	1	0	0	0	1	1	1	1	0	0	0.58±0.51	0.88	*P**
	Post(12w)	1	1	1	0	0	0	0	0	0	0	0	0	0.25±0.45	1.80	*P**
MD	pre	3	4	4	3	3	3	3	3	3	3	3	2	3.08±0.51	0.16	
	Post (6w)	2	3	2	1	1	2	3	2	2	2	2	1	1.91±0.66	0.34	*P**
	Post(12w)	1	1	1	1	1	1	1	0	0	0	0	0	0.58 ±0.51	0.88	*P**

MCPS = Modified Chronic Pain Disability Scale, (0 = No pain, No disability, 1= low pain, No/ low disability, 2= Moderate pain, No/ low disability, 3= Moderate pain, low/ moderate disability, 4= High intensity pain, high disability, severely limiting)

MYS = secondary myalgia pain/extension scale, (0 = no pain, 1 = local pain at palpation site, 2 = pain spreading beyond palpation site within the palpated muscle, 3 = pain spreading beyond palpation site and beyond the palpated muscle)

MD = Mid-line deviation in maximum opening (0= no shift, 1 = 1mm, 2 = 2mm, 3 = 3mm, 4= 4mm).

Mean= X, Standard deviation = SD, P= comparison with pre-treatment status, P*= statistically significant difference when value is (<0.001)

CV = coefficient of variation (ratio of the standard deviation to the mean)

RESULTS

The patients' examination outcomes (table2) were significantly (P≤ 0.05) improved in Pain & discomfort for both frequency and degree. The pain was significantly reduced in frequency from the pre-operative (1.58±0.66) when compared to post-operative (0.41±0.51) with a coefficient of variation (CV) of 0.42 and 1.23 respectively. The pain was significantly reduced in degree from the pre-operative (1.00±0.73) when compared to post-operative (0.25±0.45) with a coefficient of variation (CV) of 0.73 and 1.80 respectively. The pain modification was significantly reduced by chewing, movement, para-function, and others (this refers to psychological stress or anger attacks and sometimes other physical pain) from the pre-operative (0.58±0.51, 0.50±0.52, 0.75±0.45, and 0.83±0.38) when compared to post-operative (0.08±0.28, 0.25±0.45, 0.25±0.45, and 0.16±0.38). Pre-operative CVs were 0.88, 1.04, 0.60, and 0.46 and the post-operative CVs were 3.46,1.80, 1.80, and 2.33 respectively.

The patients' examination outcomes (table3) were significantly (P≤ 0.05) improved in MCPS,

MYS, and MD. The MCPS was significantly (P≤ 0.05) improved in 6 weeks (0.58±0.51) and 12 weeks period (0.25±0.45) in comparison to the starting point (1.91±0.66). but the coefficient of variance was increased in the examination results for the pain/ disability scale and myalgia pain scale, especially in 12 weeks period. The MYS was significantly (P≤ 0.05) improved in 6 weeks (0.58±0.51) and 12 weeks (0.25±0.45) in comparison to the starting point (1.33±0.65). The MD was significantly (P≤ 0.05) improved in 6 weeks (1.91±0.66) and 12 weeks period (0.58 ±0.51) in comparison to the starting point (3.08±0.51).

In table 4; **A)** the VAS results were significant between the starting point (7.00-7.85) and both 6 weeks (2.1-3.6) and 12 weeks (1.8-2.4) in a male/ female order, **B)** the range of mandibular movement results was significantly (P≤ 0.05) improved in MMO, FMO, ILE, CLE, PE. i) the MMO range (in a female/ male order) was significantly improved in 12 weeks (34.3-39.7) in comparison to the starting point (29.2-33.5). ii) the FMO range (in a female/ male order) was significantly improved in 12 weeks (35.4-41.6) in comparison to the starting point (30.5-35.3). iii) the CLE range (in a female/ male order) was significantly improved in 12 weeks (3.80-4.80) in comparison to the starting point (5.00-6.50). iv) the ILE range (in a female/ male order) was significantly improved in 12 weeks (3.6-4.2) in comparison to the starting point (4.9-5.9). v) the PE range (in a female/ male order) was improved significantly in 12 weeks (6.20-6.20) in comparison to the starting point (8.40-8.70). **C)** Helkimo's disability index was significantly improved (in a female/ male order) in comparison to the starting point (6.75-6.30), the score was (2.75-1.80) in the 6 weeks and (1.55-1.50) the 12 weeks. Also, significant improvement in 6 months (1.80-1.60) compared to the 3 months point (1.70-1.46) but no significant improvement in 12 months (0.80-0.20) when compared with the 6 months.

TABLE (4): comparing pre- and post-treatment effect on study subjects (by gender) showing; VAS, maximum active and PMO, Contra LE, Ipsi LE, PE, Helkimo anamnestic and clinical dysfunction index.

Categories Per period	Gender	X ± SD		P
		Pre	Post	
VAS pain (0-6) weeks	Female	7.85±0.93	3.6±3.05	0.000*
	Male	7.00±1.05	2.1±1.85	0.000*
VAS pain (0-12) weeks	Female	7.85±0.93	2.4±1.84	0.000*
	Male	7.00±1.05	1.8±1.65	0.000*
VAS disability (0-6) weeks	Female	7.76±1.39	4.17±1.18	0.004*
	Male	6.76±1.42	4.07±1.18	0.006*
VAS disability (0-12) weeks	Female	7.76±1.39	3.11±1.02	0.002*
	Male	6.76±1.42	2.07±1.22	0.001*
MMO (0-12) weeks	Female	33.2±7.35	40.3±8.81	0.000*
	Male	36.5±8.44	42.7±7.85	0.000*
FMO (0-12) weeks	Female	33.5±7.72	42.4±9.40	0.000*
	Male	36.3±9.25	44.6±8.02	0.000*
ILE (0-12) weeks	Female	3.6±1.18	4.9±1.97	0.000*
	Male	4.2±1.39	5.9±1.37	0.000*
CLE (0-12) weeks	Female	3.80±1.49	5.00±1.74	0.000*
	Male	4.80±1.30	6.50±0.97	0.001*
PE (0-12) weeks	Female	6.20±0.95	8.40±1.63	0.000*
	Male	6.20±0.91	8.70±0.87	0.001*
Helkimo's Di (0-6weeks)	Female	6.75±1.20	2.75±2.46	0.000*
	Male	6.30±1.25	1.80±2.06	0.000*
Helkimo's Di (0-12weeks)	Female	6.75±1.20	1.55±1.66	0.000*
	Male	6.30±1.25	1.50±1.44	0.000*
Helkimo's Di (12-24weeks)	Female	1.80±0.36	1.70±0.46	0.000*
	Male	1.60±0.51	1.46±0.51	0.000*
Helkimo's Di (24-52weeks)	Female	1.80±0.36	0.80±0.89	0.082
	Male	1.60±0.51	0.20±0.63	0.163

**** significant when p<.05, VAS = Visual analog scale, MMO = maximum mouth opening, FMO = dentist assessed mouth opening, CLE = contra-lateral excursion, ILE = Ipsi-lateral excursion, PE = Protrusive excursion, Helkimo's Dysfunction index (Di).***

DISCUSSION

Based on statistical interpretation of results, the null hypnosis was accepted. The diagnosis protocol is according to the original RDC/TMD [56] and its updates [74]. The incorporated categories were; a) history (self-evaluation with minor staff assistance in "form1"), b) examination (clinical examination by the same examiner using "form 2"), c) radiographic examination (MRI images produced by the same machine and examined by the same radiologist) [75, 76].

The treatment protocol started with ARS instead of a centric splint. In literature, the centric splint was reported as a treatment modality in TMD cases [77] to decrease symptoms of OFP more efficiently than distraction splints [78]. Nevertheless, the centric mandibular splint reduced pain by altering the pain processing and anticipation [79], and it was not confirmed to assess disc-condyle spatial relation enhancement [80].

Although, some reports questioned the effectiveness of the splint therapy and claimed a low quality confirming evidence of that treatment protocol [79]. MCPS, MYS, and MD showed a significant reduction in 6-weeks and 12-weeks follow-up. Those results support the positive effect of the ARS on the cases of this study. And agrees with the ARS reported to efficient control & reduction of all symptoms of OFP in most TMD cases [82]. Also, patients' improvement of 88% and 92% treatment efficiency proved through MRI examination [54, 55, 56, 72].

ARS with positive anterior teeth indentation in protrusive mandible position and faint posterior indentation used in the first three months, before transformation to a stabilization splint for the successive nine months. The ARS positive indentation was reported superior to the flat-plane splints (stabilization splints) in myalgia and joint clicking and tenderness reduction [72, 73, 83]. In the first few days, some patients reported difficulty maintaining the protrusive position recorded by anterior indentations. The splint thickness was not less than 3mm in all treatment phases to assure better results [84].

Patient self-evaluation outcome.

All the patients were committed to the scheduled follow-up with no dropouts. The short period of ARS use (3 months) helped to enhance the case generally and the reduction of muscle pain, joint pain, clicking, pain modification factors, and jaw dysfunction. The patient's 12-weeks self-evaluations significantly improved.

These findings agreed with other studies that used the ARS for 2-3 months, considering it a highly recommended non-invasive approach[85-87]. Patient-reported pain frequency and degree significantly decreased. The pain evoked by a modification was reduced as well.

Those results agree with other studies that reported comparable outcomes in 3 months [44,45,88,89,90]. And with Raphael. et al. [91]. They found a reduction in pain evoked by a modification (swallowing, speaking, emotional stress, .etc) by the use of ARS in 6 weeks use. But the reduction was more significant in localized pain.

Nilner. et al.[92] reported a 50% worst pain reduction in 55% of patients after 6-weeks ARS use and a 61% worst pain reduction in 69% of patients after 10-weeks. Oliveira et al.[93] and Wahlund K. [94] reported a 60% worst pain reduction in 50% of patients, and Others found a better outcome regarding pain intensity and frequency.

Madani. et al. [88] reported a 60% disappearance and 35% modification of subjective pain with a 50% reduction of perceived pain and disability caused by pain [95]. Behr. et al. [96] reported a pain reduction in 66% of patients after 1-year of therapy. In 5 months ARS use, Daif ET.[97] reported an 85% improvement (either completely recovered 35% or clinically improved 50%).

Patient examination outcome

Pain/disability

The pain/disability scale results, mandibular deviation results, and myogenic pain results decreased significantly. That agrees with other clinical reports on the used clinical examination parameters improvement [98,99,100,101]. Al Quran. et al. [102] reported 56.66% pain/disability reduction. Fernandes. et al. [103] also reported a pain/ disability reduction by oral splint use.

Myalgia

Myogenic pain (muscle-related pain) is usually a primary finding that leads (after comprehensive diagnosis) to reach the final, precise diagnosis of TMD and its type [104]. TMD and myalgia are co-existing, interrelated components, in which myalgia may be the second TMD's main ingredient [105]. In TMD cases, the etiology of masticatory muscles myalgia is still unclear.

Muscles' parafunction and harmful oral habits are a suggested cause of muscles tissue injury [15]. The results showed the myogenic pain score (range from 0-2) at the pre-treatment phase, which indicated a maximum pain localized within the palpable muscle (within or beyond the palpated area). According to Raphael. et al. [91], the oral splint is effective in localized myogenic pain reduction than the widespread pain type.

Mandibular Deviation

The mandibular deviation was improved significantly by ARS. In literature, the hypothesized etiology of the mandibular deviation or the modified jaw movement path results from myalgia due to; a) abnormal function which modifies the muscle action to least painful alternative [15,106], or b) a modified muscle action in response to impulses from TMJ load receptors [107,108, 109].

Occlusion

The stomatognathic system usually adapts to early asymptomatic pathologic changes of TMD [110].

Some study subjects showed a) defective posterior maximum intercuspation, b) mediolateral occlusal deflection/slide, or c) mid-line deviation. presented at the beginning and the end of the masticatory cycle during condyle-disc translator part of mouth opening.

No occlusal adjustments were considered for any patient. A statistically significant decrease in midline deviation was apparent during the successive study periods. The occlusal slide/deflection decreased by the progress in treatment and the decrease of symptoms and pain.

The deviation on opening may have created the illusion of occlusal slide upon closure, thus the decrease in deviation consequently made the slide/ deflection less noticed by the progress of treatment. Also, during the active disease course, the myogenic pain and the muscle spasm usually alter the mandibular path upon opening and alter the posterior teeth contact pattern. Usually the patient shelters to the least painful path of opening and closure and seeks the least painful pattern of teeth contact and masticatory cycle.

In literature, the occlusal adjustments in symptomatic TMDs were seldom advised, because; 1) occlusal slide may be a consequence of TMD rather than an etiology, 2) occlusal variables are of low relative risk in TMD development [111]. Also, there was no statistically confirmed cause-effect relation between occlusal features and TMDs [112].

Also, 3-month use of ARS was recommended by Conti. et al. [73] to avoid the development of posterior open bite [113], thus the conversion to partial time use with a stabilization splint is recommended and justified.

Clinical follow-up results.

VAS score

The used VAS was a 10-centimeter scale, VAS of pain showed an improvement from 7 to 2.1 in 6 weeks and reached 1.8 in 3 months.

Many studies reported a significant VAS improvement after ARS use [90,114,115]. Although changes were significant. This could be accepted because, in subjective-score templates, the results could be affected by social status, economic status, educational level, and gender-wise. According to Linton & Gotestam [116], patients have a general tendency to overestimate the pain VAS scores regarding duration and intensity, especially in the baseline.

In literature, some studies used a 10-points scale while others used a 100-points scale. Madani et al [88], reported a similar VAS enhancement from 61 to 36.5 in 3 months treatment period. Also, Sousa BM et al. [117], reported an improved VAS, started at 7.1 and reached 1.4 & 0.7 in 1 month and 6 months respectively. Di Paolo et al [118], reported VAS scores improvement from 63 to 8.32, and 70% of their patients considered themselves healed.

Zhigui et al.[82], reported pain VAS of 3.89 ± 1.80, 2.23 ± 1.77, and 1.37 ± 1.57 in baseline, 3months, and 1 year respectively. Badel T. et al [100], reported a pain VAS scores reduction from 5.589 (at baseline) to 2.054 and 0.41 at 4 weeks and 16 weeks respectively. Dao et al. [119] found a decrease in VAS of pain intensity at rest and after exercise in 8 weeks ARS use.

VAS disability scores showed an improvement from 6.7-7.7 to 4, and 2-3 in 6, and 12 weeks. Zhigui et al. [82] reported a mean disability VAS reduction from 4.42 to 3.66 and 2.50 in 3months, and 1 year respectively. Riley P et al. [120] reported a pain VAS reduction of 1.40 to 2.01 at the end of treatment.

Range of motion

MMO has changed significantly from 33-36mm up to 7-8mm improvement. The mandibular functional range showed a significant increase in other studies [115,121,122]. These results agreed with Zhang C. et al.'s [82] results that found a 5-5.4mm increase in cases with an initial MMO < 37mm. Sousa BM. et al. [117] reported a change of 8-9mm in pain-free MMO started at 26.8mm to became 34.7mm and 35.6mm in 1-month and 6-months.

According to De Felicio et al. [123], the MMO had a minor change (1-2mm), but the ILE, CLE, and PE were changed from (42.33, 6.26, 7.33, and 5.08) to (43.96, 6.84, 8.55, and 6.99) respectively. While Zhigui. et al. [82] reported no improvement in the tested parameters of the mandibular functional range.

Helkimo's Di

In 123 TMD cases (93 females, 30 males), Polso HL. et al. [124] reported a significant decrease in Helkimo's Di after the ARS treatment. Daif. et al. [97] also mentioned better clinical dysfunction indices on 6-months with splint therapy.

Magnusson T. & Syren M. [125] also reported a significant improvement in Di over a 6-months use of stabilization splint. And Ekberg. et al. [126] inferred a better Di index in 10 weeks of stabilization splint at night only. The reports agreed with the Di indices improvement concerning the short-term ARS use and stabilization splint in the short-& long-term. Although the Di index offered a supportive piece of information with significant results and agreed with other studies, most of the studies lacked a precise description of treatment and follow-up times.

Clicking sounds

Tallents. et al. [113] reported clicking-sound categories based on the timing and the amount of vertical jaw separation.

Accordingly, the cases contributed in this study were as follows; A) according to vertical jaw opening (a 60% of the patients had an early clicking and 40% had a mid-click), and B) according to clicking timing during jaw opening (an 83% early-type and 17% and mid-type).

All the patients reported a clicking TMJ sound (at least unilaterally). A 75% of the patients reported the disappearance of clicking sounds in the first

two weeks of treatment, and 100% mentioned the complete absence of the clicking in ≤ 4 weeks.

Conti. et al. [127] reported a 100% improvement of clicking sound with ARS use within the first 2-weeks and only 67% for another splint type.

Some authors explained the resolution of sounds by the disc morphological alterations [128], while others considered it a progressive adaptation or natural healing process [93,129].

MRI

During the MRI follow-up in 3 months and one year, the MRI demonstrated the signs of disc recapture (return to normal position) in 66% of cases, while nearly 34% attained a partial recapture (especially in the TMJ affected side). The backward movement of the disc can result from the condyle forward and downward position, so the ARS helped maintain a normal disc-condyle relationship. The one-year MRI revealed 83% disc recapture and 17% resistance cases of partial recapture. According to the results, the conversion of ARS did not disturb the course of treatment or jeopardize the disc recapture process.

Some authors described the progressive splints as a short-term solution for DDwR and reported a risk of disc recapture failure and recurrence upon the ARS removal [130,131]. Contrarily, a stabilized case was reported and confirmed through MRI after 2-year treatment. Hence the long period disc recapture stability helps to encourage the adaptation tissues synthesis (formation of extra fibrous tissues and increased the thickness of the disc tissues) [129].

In this work, the splint was not removed (withdrawn) after three months. Instead, it was modified (as a stabilization splint) for part-time use in the successive nine months. Therefore, disc recurrence possibility [130] and the risk of keeping the mandible in anterior displacement reduced [72,73], securing a better result. According to Zhigui. et al. [82] a 92.31% disc-recapture success was reported after 3-months of ARS treatment. That decreased to 72.53% after 1-year of treatment stop and ARS removal.

Also, the ongoing improvements in all clinical parameters in 6-months and 1-year therapy could have resulted from a) elimination of pressure on disc tissues, b) stretching of joint-associated ligaments and muscles, c) reduction of motor activity in masticatory muscles [47,48,49,132].

A 2-month use of the ARS reported accomplishing MRI proved a 70% displaced-discs reduction [133]. Kurita. et al. [134] reported a 50% disc-recapture at the end of the treatment and resolution of all signs and symptoms. Liu. et al. [80] also mentioned a more posterior disc movement (2.23 mm) in the ARS group and less (0.75mm) for the stabilization splint.

Some cases showed resistance in disc-recapture. Other reports also investigated the use of ARS in severe cases of joint derangement and found a reduction of OFP symptoms with no MRI signs of normal disc-condyle relationship [135]. Severe disk displacement is not necessarily pure anterior and may contain a transverse component which renders the ARS much less effective [56, 136, 137, 138,139].

According to Kurita. et al. [140] the DD joints with persisting non-recapture discs were usually associated with; A) deformed, flattened articular eminence, and B) condylar deformation or size regression. The disc-recapture resistance occurs despite being irrelevant to the resolution of all signs and symptoms. In severe joint internal derangement, Katzberg. et al. [141] and Ronquillo et al. [142] reported an abnormal condylar position (posterior dislocation) even in centric occlusion.

CONCLUSION

In conclusion, the day and night use of ARS provided an improvement in all investigated parameters and was considered a successful treatment for DDwR. The continuous use of modified ARS into a stabilizing splint is beneficial

to the patient with no recorded patient complaint or any adverse effect on jaw function.

MRI (complete or partial) disc-recapture through the ARS therapy and its modification achieved. Nevertheless, the regression of signs and symptoms was not directly associated with and sometimes preceded that recapture.

Also, a further investigation is required to disclose the possibility of recurrence of signs and symptoms, or disc-recapture failure, after modified ARS removal.

Conflict of interest

The authors declare no conflict of interest.

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