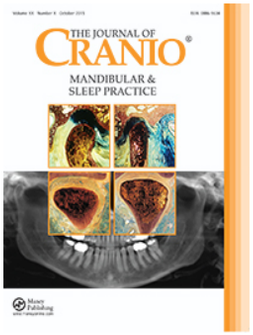

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Intra-articular and Muscle Symptoms and Subjective Relief During TMJ Internal Derangement Treatment with Maxillary Anterior Repositioning Splint or SVED and MORA Splints: A Comparison with Untreated Control Subjects

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ABSTRACT: Discomfort associated with wearing an intraoral splint represents a problem in the management of temporomandibular joint (TMJ) internal derangement. This study evaluated whether the use of a mandibular splint during the day and a maxillary splint at night could be more comfortable and therefore as efficacious in internal derangement treatment as a maxillary splint (AR splint). Fifty (50) patients (average age 28.8; range 14-63) with confirmed internal derangement in at least one TMJ were divided into three groups: 20 patients treated with AR splint (Group I); 20 patients treated with a SVED (Sagittal Vertical Extrusion Device) and a MORA (Mandibular Anterior Repositioning Splint) (Group II); and 10 patients who underwent no treatment (Control Group). Joint noise, pain intensity and its character (as constant or chewing/biting pain), muscular pain, and subjective relief were evaluated monthly before treatment began (T0) and for six months thereafter. The following results were found: 1. Subjects in Group I and Group II displayed a significant decrease in joint pain ($p<0.001$), constant pain ($p<0.001$), chewing/biting pain ($p<0.001$), joint noise and muscle pain from the beginning through the sixth month follow-ups; 2. At T1 and T2, subjects in Group II reported significantly lower discomfort associated with the devices than subjects in Group I. The use of two splints seems to be as efficacious as the use of an AR maxillary splint; however an AR splint is considered more comfortable by patients, especially during the first months of therapy.

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Displacement of the disk in one or both of the temporomandibular joints (TMJ) is found in a majority of patients with symptoms of temporomandibular disorders (TMD).[1] In about half of these patients, the displaced disk can be held in a normal (reduced) relationship with the condyle by anterior positioning of the mandible. With the mandible held in anterior position, clicking and locking are eliminated, and pain relief is usually obtained within a few days. Consequently, anterior mandible repositioning using maxillary appliances with pull-forward ramps has been used to treat reducing disk displacement.[2-3]

In a literature review of long-term treatment findings, the anterior repositioning splint (AR splint) proved superior to flat occlusal splints and when compared with a control group in reducing or eliminating joint noise (clicking), joint pain, and associated muscle symptoms.[4]

However, one of the most important clinical problems with this type of therapy is the discomfort during swallowing, talking, eating, and drinking. Since the splint must be worn daily for many hours, especially during the first months of therapy, the discomfort is a serious clinical problem. Therefore, at the University of Chieti, Italy, subjects were treated using two different splints constructed with the same wax in an advanced mandible position. Since the most important symptoms associated to TMD are joint noises and/or pain and muscular pain, the authors wanted to investigate the frequency and intensity of the symptoms in subjects treated with the two splints.

The SVED (Sagittal Vertical Extrusion Device)[5] and the MORA (Mandibular Anterior Repositioning Splint),[6] were used alternatively during night and day, respectively, and the results were compared with an untreated group of subjects and a group of patients treated using an AR splint.[2] The authors also evaluated psychological and/or physical stress associated with wearing the devices and experienced by the subjects at baseline and during the treatment. Psychological and/or physical stress experienced by a patient leads to increased activity of the masticatory muscles,[7-8] and masticatory muscle activity increases with stress, often resulting in, or exacerbating, symptoms of craniomandibular disorder.[9] This hypothesis is supported by a stress-related concept of myofascial pain dysfunction (MPD), based on studies which have found a high incidence of other "psychosomatic" disorders in MPD subjects. It was found that 135 MPD subjects had more frequent low back and neck pain, nervous stomach, asthma, and a history of ulcers than control subjects.[10]

Material and Methods

The sample was selected from a group of subjects referred for evaluation of complaints of TMJ pain and dysfunction. Symptoms included: joint tenderness and pain on palpation; joint pain during masticatory movements and abnormal noises, such us popping and clicking; tenderness and pain in masticatory muscles during palpation. Subjects were included based on the following criteria: 1. if they presented joint pain and joint noise in at least one TMJ; and 2. if suspected internal disk derangement was confirmed on magnetic resonance images (MRI). Fifty (50) subjects were included, 28 males and 22 females (average age 28.8; range from 14.0 to 63.0). Internal disk derangement was assessed with MRI with two sequences using dual coil capability. The sequences were performed using a proton density image technique. The MRI was read by an oral radiologist, blind to the study, and suspected internal derangement in the subjects was confirmed. Where internal derangement was clinically diagnosed on both sides (32 subjects), the radiologist did not always confirmed this data. In 21 subjects, internal derangement was confirmed by MRI on one side only; however, these subjects were included in the sample because the clinical examination confirmed the presence of TMJ sounds. It was assumed that TMJ disk displacement was present.

Occlusal splints are often used in the management of TMD. The intent of this study was to evaluate the influence of the type of occlusal splint used in these cases. Ten patients were chosen as a control group. Forty (40) patients were randomly divided into two homogeneous groups, based on the criteria of the Kolmogorov-Smirnov test, in age distribution (**Table 1**). No significant differences were found in the variables considered among the three groups before treatment began. Since there is no literature on a standard therapeutic method for the management of internal derangement, the authors used SVED and MORA in Group II and an AR splint in Group I. In both Group I and Group II, the treatment consisted of anterior mandibular repositioning by means of oral orthopedics. No drugs or physical therapy were prescribed. The patients were not instructed in exercises or home care and were not told to change their diets. The primary reason for the lack of adjunctive therapies was to more accurately assess the effects of one treatment made at a time.

Group I: Anterior Repositioning Splint

An anterior repositioning splint is commonly used in the management of anterior disk displacement with reduction to re-establish the normal condyle-disk relationship (**Figure 1**). The primary goal in protrusive splint treatment is the elimination of joint sounds by recapturing the disk. A smooth, coordinated, painless range of motion often can be obtained if the disk is recaptured. In this way, mandible deviation, joint noises, and pain can be eliminated.[11-12] For each patient, a full-coverage AR splint was constructed for the maxillary arch using clear self-curing acrylic resin as described by Okeson.[13] The base of the occlusal splint is prepared on a model and fitted to the maxillary teeth. An acrylic ramp is placed in the anterior palatal area so that during normal occlusion, the mandibular anterior teeth contact with the protrusive guiding ramp. Occlusal contacts are constructed positioning the mandible forward to a jaw position that is effective in decreasing pain and to where the joint noise disappears. The later the opening clicking sound occurred, the less the trend for mandibular protrusion to obtain acceptable condyle-disk position. The subjects were

Table 1
Mean Distribution of Age and VAS Assessments of Joint Pain (Mean, SD, Median and Range) According to the Type of Therapy

	Group I (N=20)					Group II (N=20)					Control group (N=10)				
	Mean	SD	Median	Range	Vs Grp II	Mean	SD	Median	Range	Vs Cont Grp	Mean	SD	Median	Range	Vs Grp I
Age	26.70	5.8	28.5	14.2-58.8	NS	28.20	6.5	27.5	18.2-63.4	NS	27.8	7.2	28.4	15.3-58.2	NS
T0	66.00	15.94	67.5	35-90	NS	67.25	15.09	67.5	40-90	NS	64.5	18.77	60.0	40-95	NS
T1	37.75†	17.28	40.0	0-85	*	20.25†	23.92	12.5	0-85	***	60.5§	17.71	55.0	40-50	*
T2	19.25†	17.64	22.5	0-50	NS	14.00‡	17.29	0	0-50		60.0	15.63	55.0	40-85	***
T3	13.70‡	13.46	17.5	0-39	NS	11.20§	13.45	0	0-39	***	58.5	16.67	55.0	30-85	***
T4	4.75‡	8.66	0	0-25	NS	4.00‡	8.37	0	0-25	***	51.5	23.46	55.0	0-80	***
T5	3.50	7.27	0	0-20	NS	3.50	7.27	0	0-20	**	46.5§	22.86	50.0	0-75	**
T6	1.50	4.62	0	0-15	NS	1.50	4.62	0	0-15	**	46.0§	22.83	47.5	0-75	**

*p<0.05; **p<0.01; ***p<0.001 in the transversal analysis
†p<0.001; ‡p<0.01; §p<0.05 in the longitudinal analysis

instructed to wear the same splint both at night and during the day. The proper instructions for wearing the AR splint were given during each of the monthly appointments. The importance of wearing the splint at all times, as instructed, was impressed on the patients in order to guarantee the correct repositioning of the mandibular condyle.

Group II: SVED and MORA

Subjects in Group II were treated using two types of appliances: a SVED and a MORA (**Figure 2a**, **2b**). The MORA was worn during daytime, while the SVED was worn alternatively, at night. At the initial examination, a polyvinylsilozane putty construction bite was established in mandibular position, which effectively eliminated clinical signs of disk displacement and reduction by forcing the mandible to open and close along an anterior trajectory. Contact of the natural anterior teeth was maintained so that increases in occlusal vertical dimension were kept to a minimum. The amount of anterior repositioning in bites averaged 4.5 mm, with a range of 2-6 mm, measured in anterior teeth. During the treatment, all patients were fitted with removable day and night appliances. They were told to wear the MORA or SVED at all times and to be very careful not to bite down when changing appliances. Proper instructions for wearing the AR splints were given during each of the monthly appointments. The importance of wearing the splint at all times, as instructed, was impressed on the patients in order to guarantee the correct repositioning of the mandibular condyle.

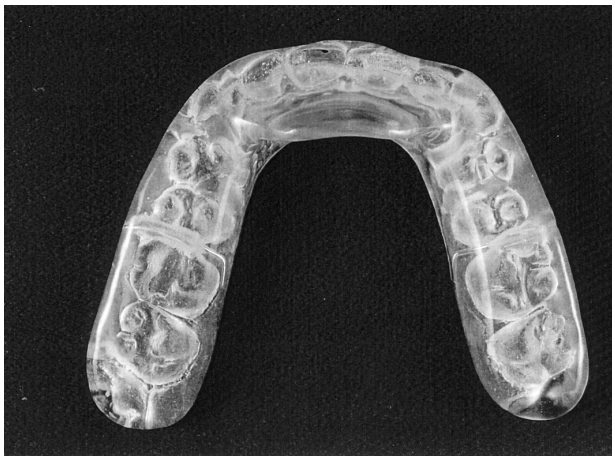


Figure 1
Example of AR splint used in Group I

The MORA (**Figure 2a**) is a frequently used partial coverage splint positioned on the maxillary or mandibular teeth that has high patient acceptance because of the relatively comfortable design. When used on the lower arch, it is a modified Gelb splint.[14-15] Acrylic covers the occlusal and lingual surfaces of the mandibular posterior teeth, from the canines to the most distal molar bilaterally. There is a lingual anterior metal bar. The incisal edges of the lower anterior teeth are left uncovered, and the upper incisors do not contact the splint. Total occlusal contact of the posterior teeth, including canine guidance, is established with the appliance. The use of two posterior segments allows incisal function of the natural anterior teeth and avoids interfering with tongue position. The appliance is made with prominent pull-forward inclines located over the lingual side of the premolar area (so that they engage the mesial facing slope of the lingual cusp of the maxillary first premolar) and the lingual side of the most distal mandibular molars (so that they engage the mesial facing slope of the palatal cusp of the terminal maxillary molar). In this study, all subjects had the mandible advanced to approximately an edge-to-edge

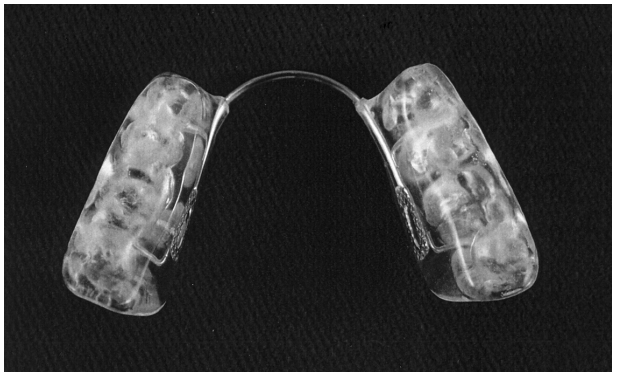
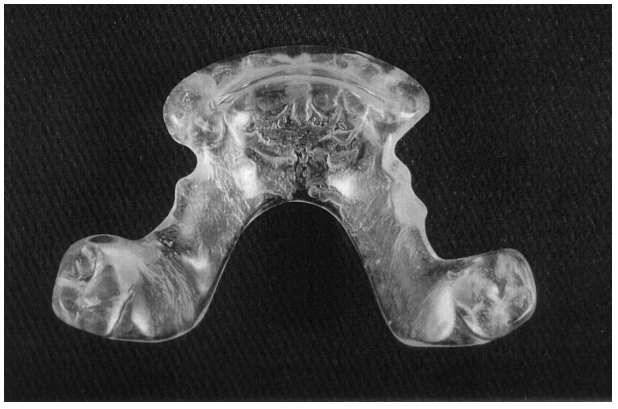


Figure 2
Examples of appliances/splints used in Group II: **a**. (above) Mandibular Anterior Repositioning Splint (MORA), occlusal view; **b**. (below) Sagittal Vertical Extrusion Device, occlusal view.



incisal relationship, with a mild anterior open bite created by the minimal thickness of the acrylic required to cover the posterior teeth. Gelb[14] notes that the mandibular orthopedic repositioning appliance, which is constructed to cover only the lower posterior teeth has a lot of advantages: 1. it provides the patient with functional comfort in the shortest period of time; 2. it is hygienic and comfortable; and 3. phonetically, it can be checked to see that it does not invade the freeway space.

In the current study, when the appliance was placed in the patients' mouths, it was balanced in centric occlusion. Centric stops were then incorporated into the occlusal topography of the acrylic appliance, and the patient's bite was guided into right lateral and left lateral excursions. Finally, the patient was instructed to move into a protrusive relationship with optimal contact on the last molar only. Subjects were requested to wear the appliance during daytime. During the first week, the appliance had to be worn for short periods of time, then the time was increased until it became a full day in the second week.

All patients were given a SVED (**Figure 2b**)[5] to use during sleeping. The primary advantage of the SVED is that the anterior ramp is constructed behind the canine area and specifically engages the anterior mandibular teeth, preventing mandibular movement in a posterior direction. Thus the mandible is anteriorly braced even when the mouth is open. The anterior ramp used in this study was carefully adjusted so that it forced the mandible to open and close on the same trajectory supported by the inclines of the daytime appliance. Both appliances were balanced in centric occlusion and into right lateral and left lateral excursions. When the patients first received their appliances, they were instructed to return to the office only if they noticed some dramatic relief of symptoms within a week.

All subjects in the three groups were monitored monthly from the beginning of the treatment (T0) for a total period of six months (Tl, T2, T3, T4, T5, T6).

1. Joint noise. The presence of joint noise (clicking) was investigated by the same clinician using a stethoscope. Each subject was listed as having or not having joint noise each month. Based on clinical evaluation and on the patient's referred history, the patient was classified as having (*yes*) or not having (*no*) joint noises. Patients with a unique joint noise, during the opening or closing of the mouth, were classified as having joint noises.
2. Intensity of joint pain. The intensity of pain was assessed daily by each subject with a 100 mm Visual Analogical Scale (VAS) rated from *no pain* to *worst pain possible*. Each subject was asked to record the intensity of pain (VAS score) daily in a personal daybook. The mean value of the daily scores during each month was used as the VAS scores for that month.
3. Kind of joint pain. Each patient was asked to describe the kind of pain as *constant pain* or *pain when chewing/biting*,[16] using two descriptors based on the McGill Pain Questionnaire. For each type of joint pain, a daily note of the intensity (VAS score) was recorded by patients. The mean value of those daily values during each month was used as the VAS score for that month.
4. Muscle pain. Muscle pain was assessed during palpation using the Travell[17] method. Muscle pain was rated based on a 4-point scale from 0-3.[18] (0: no pain; 1: discomfort, aching or suffering; 2: pain; 3: patient shows lachrymation or asks to the clinician to not palpate that point). Because of the small samples and in order to increase the power of statistical analysis, patients were finally classified as having or not having muscle pain upon palpation.
5. Subjective relief. The VAS was also adapted and employed to assess subjective status associated with disturbing articulation, occlusion, or muscle function

during the follow-up period. Subjects were asked to estimate their mood of nervousness (i.e., depression or aggressiveness), the comfort they felt wearing splints while working or studying, and how they experienced the state of their home life at the baseline and during treatment. The VAS was a 100-mm line with the endpoints of *no complaints* and the *highest possible intensity of complaints*.

Statistical Analysis

This study focused on the distribution and the intensity of pain and joint noises and the influence of the kind of splint on these variables. Variables were used to show the influence of using an orthopedic device and the particular type of device. The three groups were preliminarily screened for homogeneity of age distribution using a Kolmogorov-Smirnov test, resulting in age homogeneity in the three groups (**Table 1**). Simple descriptive statistics were assessed and differences in frequencies between groups were analyzed using Pearson's chi-square. Due to the possibility of skewed data, non-parametric statistics (Kruskal-Wallis and Dunnett's T3) were computed to test significant differences between groups according to the VAS score assessment. In order to investigate the repeated pain assessments, a Friedman's two-way analysis of variance (ANOVA) between measurements was calculated and the differences were estimated with the Wilcoxon's signed rank test. All statistical analyses were performed using the SPSS Ver. 9 (SPSS, Inc., Chicago, IL) and the level of significance was set at $p<0.05$.

Results

All subjects completed the study. Subjects reported joint pain and joint noise in at least one TMJ on average for the past 24 months at mean (range 8 months to 28 months). No statistical analyses were performed in this regard. Occlusal features included different types of malocclusion: 48% showed class II molars at one side or bilaterally; 20% showed class III molars at one side or bilaterally; 12% showed the absence of one or more teeth in the posterior zone; 4% showed a genesis of one or more permanent teeth.

Joint Noises

The frequency of joint noises was investigated by the clinician while the subject was not wearing a splint. The frequency decreased over time in the two study groups. In Group II, the frequency of clicking decreased from 100% of subjects at T0 to 25% of subjects at T6. Interestingly, clicking disappeared in 25% of subjects after the first month of therapy (T1) and in 70% of the subjects after the fourth month of therapy (T4). In Group I, clicking was observed in 100% of subjects at T0, disappeared in 35% of subjects after the third month of therapy (T3), and in 40% of subjects after the fifth month (T5). Clicking disappeared in 20% of subjects soon after the first month of therapy (T1). In the control group, clicking was observed in 100% of patients during the entire period of follow-up. Chi-square analysis revealed that the percentage of subjects reporting clicking was statistically lower in Group II compared with the control Group at T5 and T6 ($p<0.01$), **Figure 3**.

Joint pain: Intensity of Pain on VAS

Descriptive statistics are shown in **Table 1**. The Friedman two-way analysis of variance (ANOVA) showed a highly significant effect over time, and separate Wilcoxon testing between the assessments of months 1, 2, 3, 4, 5, and 6 revealed significant therapeutic effects in the two study groups throughout the assessment period ($p<0.001$). In Group II, the mean value of pain intensity decreased approximately 70% from T0 to T1 ($p<0.001$). It then continued to decrease over time (**Table 1**) with statistically significant differences between T2 and T1 ($p<0.01$); T3 and T2 ($p<0.05$); and T4 and T3 ($p<0.01$). In Group I, the intensity of pain showed a similar pattern (**Table 1**). There was a significant drop of about 45% in mean scores after one month from the start of treatment ($p<0.001$) and also between T2 and T1 ($p<0.001$); T3 and T2 ($p<0.01$); and T4 and T3 ($p<0.01$). After T4, the intensity of pain continued to decrease and the mean score became clinically irrelevant in both Groups I and II. The most important finding regarding joint pain was that a significant difference between groups was observed at T1, as a lower intensity of joint pain was recorded in Group II than in Group I (**Table 1**) ($p<0.05$). However, there was no significant difference between the two study groups at T0 or at the other follow-ups (T2, T3, T4, T5 and T6, **Table 1**). This is why therapy with SVED and MORA seemed to be more efficacious during the first month of therapy than the therapy with the AR splint in decreasing joint pain. Untreated subjects in the control group showed no significant decrease in joint pain from T0 to T6, with the exception of between T1 and T0 ($p<0.05$); T5 and T4 ($p<0.05$); and T6 and T5 ($p<0.05$. These differences were not clinically significant.

Kind of Joint Pain: Chewing-Biting Pain

The intensity of chewing-biting pain significantly decreased over time in the two study groups ($p<0.001$) but not in the control group, **Table 2**. In the control group, the intensity of chewing/biting pain increased over

time (p<0.01) with a statistically significant difference between T1 and T0 (p<0.05). Patients in Groups I and II reported a significantly lower intensity of chewing/biting pain compared with the control group since T1 (p<0.001). These differences were highly significant for the two groups until T6 (p<0.001 both groups). Interestingly, subjects in Group I showed a significantly lower intensity of chewing/biting pain at T1, compared with subjects in Group II (p<0.001), although no significant differences were observed at T2, T3, T4, T5 and T6.

Kind of Joint Pain: Constant Pain

At T0, in each of the three groups, constant pain displayed a lower intensity than chewing-biting pain (p<0.001). The intensity of constant pain significantly decreased over time in the two study groups (p<0.001) but increased in the control group, **Table 3**. There were no significant differences between groups at T0. In Group II, the intensity of pain decreased approximately 85% from 62.5 (mean VAS score at T0) to 4.00 (mean VAS score at T3) after three months of therapy and became clinically irrelevant after the third month of therapy (range from 0.00 to 15.00 at T4, T5 and T6). In Group I, a similar pattern was found as the intensity of pain decreased form 65.0 (mean VAS score at T0) to 5.25 (mean VAS score at T3) after three months of therapy and became clinically irrelevant after the third month of therapy (range from 0.00 to 30.0 at T4, T5 and T6). Although a statistically significant and clinically relevant reduction of pain intensity was observed in both the study groups, this reduction was more evident in Group II, as the mean value of VAS score was significantly lower in Group II than in Group I at T1 (respectively 28.75 and 37.5; p<0.01) and at T2 (respectively 11.0 and 21.5; p<0.05). In the control group, the intensity of constant pain increased over time from T0 (63.5) to T4 (73.0), although Wilcoxon testing revealed a significant decrease between T1 and T0 (p<0.05). After T4, pain intensity (VAS) decreased until T6 (65.5), with a significant difference between T5 and T4 (p<0.01). However, this pain reduction cannot be considered clinically relevant since all the subjects included in the control group asked for all therapy after the sixth month study.

Cross-sectional analysis revealed a significantly lower intensity of constant pain in Group II and Group I compared with the Control Group at T1 (respectively, p<0.001 and p<0.01), and T2, T3 and T4 (p<0.001 for both study groups). In addition, although a significant reduction of constant joint pain between T5 and T4 was recorded in the Control Group (p<0.01), pain intensity in the two study groups continued to be significantly lower at T4 and T5, compared with the control group (p<0.001).

In both study groups, the frequency of muscle pain was significantly lower than that observed in the control group (p<0.05) at T5. At T6, no statistical analysis was performed, since no muscle pain was recorded in either of the two study groups, **Figure 4**.

No significant difference was observed between subjects from the two study groups at T0 when they inserted the splints in their mouths for the first time. All the subjects reported a severe discomfort (**Figure 5**), mostly associated with difficulty in phonetic function and swallowing. They also reported difficulty in maintaining correct oral hygiene. Soon after the beginning of treatment, at T1 and T2, subjects in Group II reported a significant decrease in discomfort (p<0.001). At the same time, sub-

Table 2
VAS Assessments of Chewing-Biting Pain
(Mean, SD, Median and Range) According to the Type of Therapy

	Group I (N=20)					Group II (N=20)					Control group (N=10)				
	Mean	SD	Median	Range	Vs Grp II	Mean	SD	Median	Range	Vs Cont Grp	Mean	SD	Median	Range	Vs Grp I
T0	73.00	8.34	70.0	60-90	NS	73.50	7.27	72.5	65-90	NS	66.5	18.72	62.5	40-95	NS
T1	34.50†	6.67	35.0	20-45	***	43.25†	7.30	42.5	30-60	***	72.0§	16.87	72.5	45-95	***
T2	31.00‡	4.76	30.0	20-40	NS	34.75†	5.95	35.0	25-50	***	73.0	16.87	72.5	45-95	***
T3	28.50‡	4.32	30.0	20-35	NS	29.95‡	5.03	30.0	20-40	***	74.0	15.60	72.5	50-95	***
T4	17.75†	9.66	20.0	0-25	NS	16.50†	9.33	20.0	0-30	***	75.0	14.53	72.5	55-95	***
T5	11.75‡	8.47	15.0	0-20	NS	12.50‡	9.25	15.0	0-25	***	75.5	12.35	72.5	60-90	***
T6	5.25‡	6.17	0	0-15	NS	7.00‡	6.96	10.0	0-20	***	76.5	12.92	75.0	60-95	***

*p<0.05 **p<0.01 ***p<0.001 in the transversal analysis
†p<0.001 ‡p<0.01 §p<0.05 in the longitudinal analysis

Table 3
VAS Assessments of Constant Pain
(Mean, SD, Median and Range) According to the Type of Therapy

	Group I (N=20)					Group II (N=20)					Control group (N=10)				
	Mean	SD	Median	Range	Vs Grp II	Mean	SD	Median	Range	Vs Cont Grp	Mean	SD	Median	Range	Vs Grp I
T0	65.00	8.76	65.0	50-80	NS	62.50	6.59	62.5	50-70	NS	63.5	18.57	62.5	40-95	NS
T1	37.50†	8.81	40.0	20-50	**	28.75†	5.35	30.0	20-40	***	67.0§	16.53	67.5	45-95	**
T2	21.50†	10.53	25.0	0-35	*	11.00†	11.65	7.5	0-30	***	68.0	13.58	70.0	50-95	***
T3	5.25‡	10.06	0	0-30	NS	4.00§	7.54	0	0-25	***	72.0	11.83	72.5	55-95	***
T4	4.25	9.39	0	0-30	NS	2.50	5.26	0	0-15	***	73.0	11.35	75.0	55-95	***
T5	3.75	9.30	0	0-30	NS	1.50	3.66	0	0-10	***	68.5‡	11.80	70.5	50-90	***
T6	3.75	9.30	0	0-30	NS	1.00	3.08	0	0-10	***	65.5	8.64	67.5	50-80	***

*p<0.05 **p<0.01 ***p<0.001 in the transversal analysis
†p<0.001 ‡p<0.01 §p<0.05 in the longitudinal analysis

jects using the AR splint (Group I) continued to describe a severe discomfort caused by difficulties during speaking, probably associated with the presence of the anterior ramp on the splint. However, subjects treated with SVED and MORA described no difficulty in speaking when they wore the MORA (during the day) and said they felt comfortable while wearing the MORA while working or studying. Because of the improvement of adaptation to the devices, subjects in Group II showed a significantly lower discomfort at every follow up from T1 to T4, compared with subjects usng the AR splint (Group I), **Figure 5**. At T3 and T4, subjects using the AR splint showed a significant decrease of discomfort, **Figure 5** ($p<0.05$ between T4 and T3 and $p<0.001$ between T5 and T4), derived from the fact that they experienced a decrease of pain intensity and joint noises and, consequently, began to wear the splints only for a few hours during the day. Because of this decrease, patients in Group I reported significantly less discomfort than in Group II at T5 and T6 ($p<0.05$).

Discussion

Joint pain and joint sounds were strongly associated with joint abnormal morphology. The presence of pain was associated with MRI evidence of joint effusion[19] and reciprocal clicking was consistently associated with disk displacement with reduction.[20-21] Pereira, et al.,[22] in TMJ autopsy studies which correlated symptoms before death to anatomical examination of the joints, concluded that

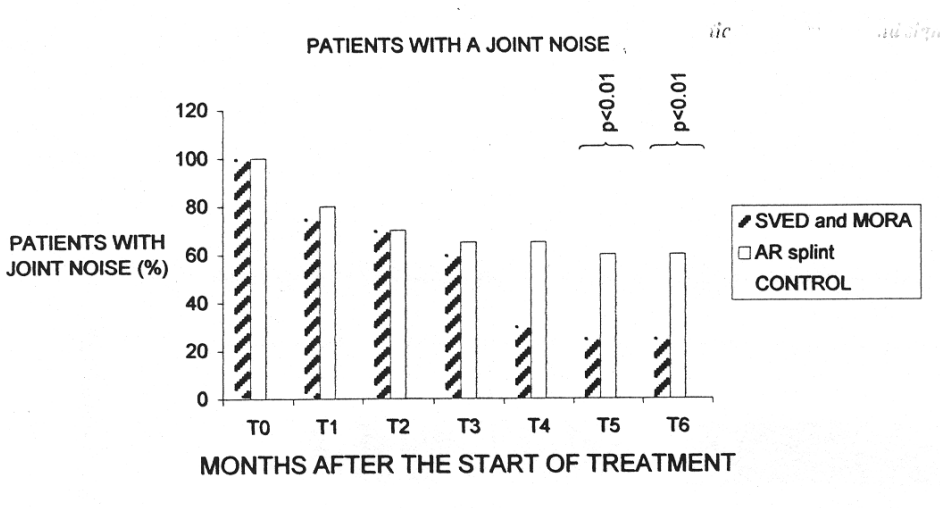


Figure 3
Graphic representation of patients reporting joint noise (as % of the whole sample) treated by using the AR splint (AR: N=20), SVED and Gelb splint (SVED and GELB: N=20) or nontreated control subjects (Control: N=10), from the baseline recording (T0) to month six (T6) after the start of treatment. Significant differences between groups indicated by brackets.

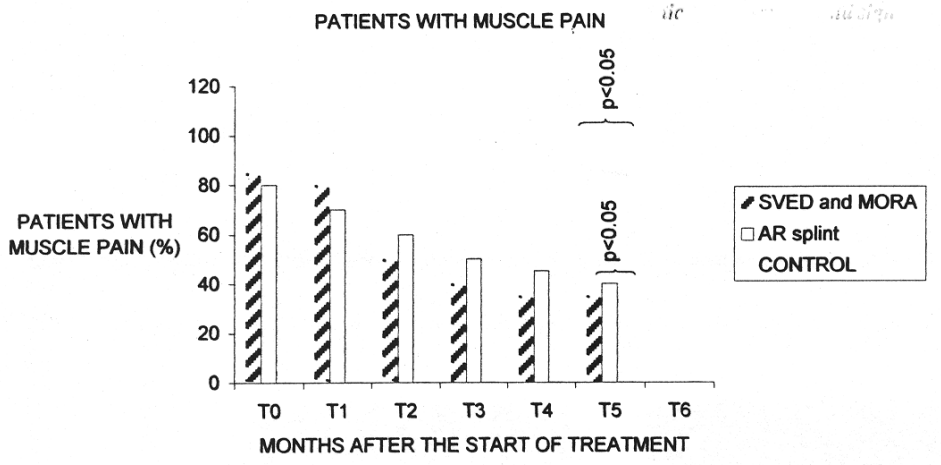


Figure 4
Graphic representation of patients reporting muscle pain (as % of the whole sample) treated by using the AR splint (AR: N=20), SVED and Gelb splint (SVED and GELB: N=20) or nontreated control subjects (Control: N=10), from the baseline recording (T0) to month six (T6) after the start of treatment. Significant differences between groups indicated by brackets.

the association between pain and/or dysfunction and joint morphology is complex and that gross morphologic alterations can be present in the absence of TMD symptoms. However, since the primary symptoms for consulting a clinician are pain and joint noises, in the current study we simply assessed the existence of pain and joint noises and monitored over time the presence of symptoms without assessing any morphological alteration of the TMJ observed on MRI.

In the current study, we included 21 patients with disk displacement confirmed only on one side by MRI and with TMJ sounds in both joints. The primary inclusion criteria in the study was the presence of clinical symptoms (sounds and pain), and these 21 subjects showed severe clinical symptoms, although symptoms were not confirmed by MRI on one side. Additionally, since TMJ displacement on one side is often treated with the same therapeutic program as cases with both disks displaced, we decided to include these patients in our sample.

One difference between this study and other studies of attempted disk recapture is that the SVED was used on all patients at night. The design of the SVED seems better able to maintain the anterior mandibular position. During sleep, the anterior ramp may have served as protection to the retrodiskal tissues against gravitational pulling of the mandible or to relieve the lateral pterygoids of the respon-

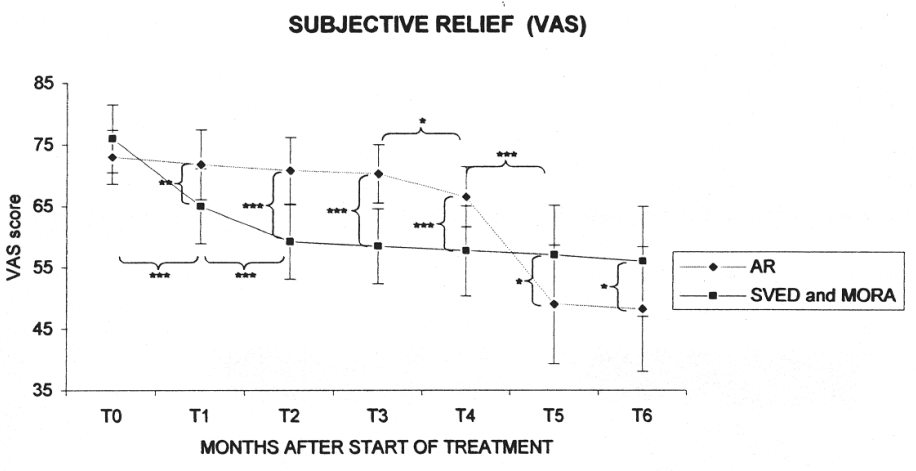


Figure 5
Graphic representation of subject relief (as VAS score) (mean value and SD) reported by patients treated by using the AR splint (AR: N=20), SVED and Gelb splint (SVED and GELB: N=20) or nontreated control subjects (Control: N=10), from the baseline recording (T0) to month six (T6) after the start of treatment. Significant differences between groups indicated by brackets.
*p<0.05 **p<0.01 ***p<0.001

sibility of preventing mandibular retrusion. Reflex neuromuscular protective mechanisms are most quiescent during sleep, and the mandible assumes its most retrusive posture when the body is fully reclined.

The primary finding with regard to joint pain in the current study was that no significant difference was observed in the amount of joint pain in the group of subjects treated with the AR splint or SVED and MORA, except at T1 (one month after the start of treatment). At T1, the subjects treated using the SVED and MORA reported a significantly lower intensity of joint pain ($p<0.05$), compared with subjects treated with the AR splint, **Table 1**. This finding may be due to the fact that subjects treated with the AR splint reported a significantly greater discomfort associated with the device during the first month of therapy than subjects treated with the SVED and MORA ($p<0.01$) **Figure 5**. Subjects treated with the AR splint did not wear the splint all night and day and probably experienced a less evident therapeutic effect. Instead, subjects treated with the SVED and MORA experimented a higher decrease in discomfort at T1 and T2 ($p<0.001$) **Figure 5**. More than likely these patients wore their splints without interruption and obtained a greater therapeutic effect. Discomfort was probably associated with the presence of the anterior ramp on the AR splint, which can make phonetic function and swallowing difficult. Subjects treated using the SVED and MORA had to wear the SVED (with the anterior ramp) only at night, while the MORA (worn during the day) was more comfortable. They reported no difficulty in speaking when they wore the MORA (during the day) and were comfortable while wearing the MORA while working or studying. In conclusion, the use of the SVED and MORA seems to be more efficacious compared with AR splint use in the treatment of joint pain during the first month of therapy because of the more comfortable therapeutic design.

Longitudinal analysis showed that the intensity of joint pain in subjects treated with the SVED and MORA mostly decreased during the first month of therapy (from 67.5 to 20.25; $p<0.001$, **Table 1**). This finding seems to be in accord with the fact that subjects treated with the SVED and MORA experienced a greater therapeutic effect during the first month of therapy. This disputes the importance of subjective relief in the management of TMJ internal derangement.

It must be noted that no significant differences were found between the study groups from T2 to T6 in the intensity of joint pain and that subjects in both of the study groups showed a significantly lower intensity of joint pain from T1 to T6 compared to the control subjects (**Table 1**). This seems to confirm the validity of the anterior repositioning of the mandible in the treatment of TMJ internal derangement.

Subjects treated with the SVED and MORA showed a significantly lower intensity of constant joint pain at T1 and T2, compared to those treated with the AR splint, **Table 3**. Longitudinal analysis showed a highly significant decrease in constant joint pain at T1, T2 ($p<0.001$), and T3 ($p<0.05$), **Table 3**, while no significant decrease was observed at follow-up in subjects treated with the SVED and MORA. This confirms that the greater therapeutic effect of the SVED and MORA mostly occurred during the first months of wearing the device. However, no conclusions could be made, since subjects treated with the AR splint also experienced a highly significant decrease in constant joint pain at T1, T2 ($p<0.001$), and T3 ($p<0.01$), **Table 3**. This finding seems to confirm the validity of that therapeutic device despite its discomfort.

In the group of untreated control subjects, constant pain showed an increase in intensity until T4 (the increase was statistically significant at T1, $p<0.05$, **Table 3**), and this finding was probably due to the absence of a therapeutic program.

In the control group, the intensity of constant pain showed a decrease at T5 and T4 ($p<0.01$), **Table 3**. The mechanism of this improvement of symptoms remains unclear. Perhaps, this was due to the fact that subjects learned a new mode of pain perception. The perception of pain changed and the values became higher than in the first month. However, this finding cannot be considered a sign of recovery as it was not clinically relevant.

The distribution of chewing-biting pain (**Table 2**) showed the same tendency compared with that of constant pain (**Table 3**), since it showed significantly lower intensity in subjects treated with the AR splint or the SVED and MORA compared with the untreated control subjects, from T1 to T6 ($p<0.001$). This finding seems to confirm the validity of jaw repositioning in the treatment of TMJ internal derangement. It must be noted that subjects treated with an AR splint experienced a more efficacious therapeutic effect at T1, compared with those treated with the SVED and MORA ($p<0.001$), since they reported a lower chewing-biting pain intensity, **Table 2**. Subjects in the control group experienced a progressive increase of pain intensity from T1 to T6, **Table 2**. This finding also confirms the validity of both of the compared treatments.

The frequency of joint noise (**Figure 3**) became significantly lower in the groups of patients treated with the SVED and MORA at T5 and T6, compared to subjects treated with the AR splint and with the untreated control patients ($p<0.01$). This seems to suggest that the SVED and MORA were more efficacious in the treatment of

joint noises than the AR splint. However, it must be noted that the frequency of joint noise decreased over time in each of the two study groups, just from T1, while it remained at 100% until T6 in the control group. The difference observed from T1 to T4 between the two study groups and the control group, although not significant, might suggest that an efficacious therapeutic goal could be obtained with the use of each of the two types of therapy. The fact that no differences were observed between the study and the control groups until T5 could be explained as a consequence of the small number of subjects studied.

The findings relative to the frequency of muscle pain, shown in **Figure 4**, confirmed the therapeutic efficacy of treatment with the SVED and MORA, as well as of with the AR splint. Although significant differences were observed at T4 and T5 between the two study groups and the control group ($p<0.05$), a decrease of the frequency of muscle pain was observed from T1 in both the study groups. In the control group, the frequency of muscle pain showed a progressive increase from T0 to T2 and became 100% at T3. It then remained at 100% until T6. This seems to confirm the presence of a closed link between muscular and skeletal apparatus and the presence of joint pain and muscle pain in subjects with internal derangement.

One of the most important findings was that subjects treated with the SVED and MORA experienced significant lower discomfort while wearing the splints from Tl, compared with subjects treated with the AR splint, **Figure 5**. This could suggest that, although clinical therapeutic effect of the two compared types of therapy was almost equal, the SVED and MORA were more easily accepted by the patients. This is probably because the MORA did not interfere with swallowing or phonetic function during the day. Instead, the main of discomfort associated with the AR splint was difficulty during speaking and swallowing.

No definite conclusions with regard to the SVED and MORA therapy were possible. It is difficult to know how many symptoms during treatment were due to a failure of compliance rather than a problem with anatomy or treatment technique. Patients were told they must adhere to a strict protocol for appliance wear. Although they were told to always wear the night appliance to sleep and not remove the day appliances for eating, patients occasionally slept with only the day appliance or ate without any appliance. Some of those patients reported that such compliance failure produced a sudden return of symptoms, and they resumed strict compliance. Even though there were some compliance failures, the results were still improved or normalized symptoms, and no attempt was made to eliminate compliance failures from the study.

Limits of the Study

This study was limited by the time considered. Follow-up was concluded when only a part of the subjects were considered asymptomatic. The study must be considered a preliminary study. We do not know how many subjects became chronic in pathology or how many completely recovered. This interruption of the study was in part due to the fact that control subjects decided to begin the therapy with the splint and were treated with AR splints. Another limit was that VAS was used to assess the quantity of pain. This method was shown to be influenced by subjective perceived levels of pain intensity[23] by McKay and Christensen[24] and therefore, a pseudo-scientific diagnostic technique. Finally, no MRIs were made during the eight months, and the study must be considered only an analysis of the primary symptoms associated with a recently diagnosed TMD.

Conclusions

In the treatment of TMJ internal derangement, anterior jaw repositioning seems to be confirmed as an efficacious therapeutic action, since subjects in the two study groups showed a significant decrease in joint pain, constant joint pain, and chewing-biting pain from the first month after the start of therapy.

In the treatment of TMJ internal derangement, the clinical therapeutic efficacy of the anterior repositioning of the mandible seems to be confirmed at least until the sixth month after the start of treatment, since subjects in the study groups showed a significantly lower intensity of joint pain, constant joint pain, chewing-biting pain, from the beginning to the sixth monthly follow-up.

Regarding the therapeutic protocol, the use of an inferior splint during the day (MORA) and a superior splint during the night (SVED) showed a similar therapeutic effect compared with the use of an AR splint in the management of TMJ internal derangement, and resulted in more comfort to the patient. Since patients tended to wear these types of splints for a greater number of hours because of the comfortable design, the splints seem to be more efficacious during the first months of therapy.

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