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Occlusal appliances – an alternative in temporomandibular disorders' pain treatment

Оклузални сплинт – алтернатива у терапији пацијената са темпоромандибуларним дисфункцијама

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SUMMARY

Introduction/Objective The pain that originate of the musculoskeletal structures of the mastication system is one of the symptoms belonging to the category of temporomandibular disorders or temporomandibular dysfunction (TMD).

The aim of the research was to evaluate the effect of therapy with stabilizing occlusal splint in the control of painful symptoms of TMD in comparison with the effect of drug therapy.

Methods Using a standard diagnostic protocol Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) proposed by Dworkin and LeResche, a group of 44 patients with painful temporomandibular dysfunctions was included. Patients were divided into three treatment groups by random selection. The first group was treated with stabilization occlusal splint for a period of one month. In the two control groups was carried out a combination therapy with non-steroidal anti-inflammatory drug Ibuprofen (Brufen®, Mylan) or Ibuprofen and medicine from benzodiazepine family Diazepam (Diazepam®, Hemofarm) for a period of three weeks. In order to assess the effects of therapy with stabilizing occlusal splint and drug therapy, before and after the therapy, pain intensity measurements were performed with visual analogue scale (VAS) and digital pressure algometer.

Results A significant reduction in the intensity of painful symptoms has been achieved in all three therapeutic groups. No significant differences in the effectiveness of pain reduction between the proposed therapeutic modalities were noted.

Conclusion The obtained results confirm that therapy with stabilization occlusal splint is a valid procedure in the reduction of pain in patients with TMD.

Keywords: temporomandibular dysfunctions; occlusal splint; pharmacotherapy

САЖЕТАК

Увод/Циљ Бол порекла мишићно-скелетних структура мастикаторног система представља један од симптома који припадају категорији темпоромандибуларних поремећаја или темпоромандибуларних дисфункција (ТМД).

Циљ истраживања је био да се процени ефекат терапије стабилизационим оклузалним сплинтом у контроли болних симптома ТМД у поређењу са ефектом терапије лековима.

Методе Користећи стандардни дијагностички протокол (*RDC*/ТМД) предложен од стране Дворкина и Лереша издвојена је група од 44 пацијента са болним темпоромандибуларним дисфункцијама. Пацијенти су подељени у три терапијске групе случајним избором. Прва група је подвргнута терапији стабилизационим оклузалним сплинтом у временском периоду од месец дана. У две контролне групе је спроведена терапија нестероидним антиинфламаторним леком ибупрофеном (Бруфен, *Mylan*) или комбинацијом Ибупрофена и лека из групе бензодиазепина – диазепама (Диазепам, Хемофарм) у периоду од три недеље. У циљу процене ефеката терапије стабилизационим оклузалним сплинтом и терапије лековима, пре и после спроведене терапије изведена су мерења интензитета бола, визуалном аналогном скалом (ВАС) и дигиталним притисним алгометром.

Резултати У све три терапијске групе постигнута је значајна редукција интензитета болних симптома. Нису забележене значајне разлике у успешности редукције бола између предложених терапијских модалитета.

Закључак Добијени резултати потврђују да је терапија стабилизационим оклузалним сплинтом валидна процедура у редукцији бола у пацијената са ТМД.

Кључне речи: темпоромандибуларне дисфункције, оклузални сплинт, фармакотерапија

INTRODUCTION

Pain in the orofacial region is a signal of tissue damage and complicates most dental procedures. The presence of pain endangers the psycho-physical health and indirectly, social

and working abilities of patients. For the mentioned reasons, the first step in the treatment of various forms of temporomandibular dysfunction is the reduction of intensity of pain and the relaxation of the mastication muscles [1, 2].

In the treatment of patients with signs and symptoms of painful temporomandibular dysfunctions (TMD), different therapeutic modalities are used, which should not give negative side effects, nor cause irreversible structural changes in tissue [3]. The concept of therapy with occlusal stabilization splint is based on several therapeutic mechanisms, indirectly taking part in the control of painful symptoms and reducing the intensity of pain [4, 5].

The aim of the study was to examine in parallel the analgesic effect of occlusal stabilization splint in relation to the effect of drug therapy in the reduction of painful symptoms in individuals with clinically confirmed signs of TMD.

METHODS

The research was conducted as a prospective study involving 44 subjects divided into three treatment groups heterogeneous by sex and age, who came to the Clinic for Prosthodontics, University of Belgrade, with TMD symptoms. A standardized protocol for temporomandibular dysfunctions, proposed by Dworkin and LeResche (1992), was used for diagnosing and numerical expression of pain intensity [6]. Respondents were divided into three treatment groups formed by random selection based on the Research Diagnostic Criteria for Temporomandibular Disorders protocol (RDC / TMD). The first group consisted of 20 patients who received therapy with a stabilization splint (Figures 1 and 2.). The remaining 24 respondents were divided into two control groups that had therapy with non-steroidal anti-inflammatory drug Ibuprofen (Brufen®, Mylan) or combination therapy Ibuprofen and medicine from benzodiazepine family Diazepam (Diazepam®, Hemofarm). All three groups were of equal age structure in the range of 25 to 45 years. Respondents were thoroughly informed about the protocol of the study and gave voluntary consent to participate in the study. The chosen methodology was applied to each patient individually, and also the study was approved by the Ethics Commission of the Faculty of Dentistry, University of Belgrade.

Algometric measurement was performed in parallel with visual analogue scale (VAS) and digital algorithm. The pain threshold was measured by a digital algometer in the region of m. masseter and m. temporalis, both sides. Measuring sites corresponded to palpable painful sites observed during the clinical examination. Painful places were previously marked with an ink pencil.

In order to measure the pressure threshold of the pain, the rubber tip of the algometer-probe was attached to the facial skin in the projection of the painful site which was applied by a suitable procedure.

Measurement implied a gradual increase in mechanical pressure to a painful place in the interval of 0.5 N / sec. The respondent was instructed to verbally report the moment of pain. The measurement was repeated three times, with pauses between the measurements for 5 minutes. The measured force is displayed on the machine's display in N units. The pain threshold was defined as the moment in which the patient's sense of pressure turned into a painful sensation. The pain threshold was calculated as the mean of the two last measurements, of three consecutive measurements.
The pressure measurement was performed at bilaterally symmetrical points. The respondent was informed that the same pressure force was applied on both sides. The intensity of pain was measured in the same time and space conditions.
In order to minimize the mistake in measuring the algometer, the respondents were asked to avoid consuming alcohol, nicotine and caffeine on the day of the measurement. The same procedure was applied after the therapy was carried out in all therapeutic groups. In the research was used digital algometer (FORSE ONETM FDIX, Wagner Instruments, Greenwich CT, 2007, USA).

The algometer has a NIST certificate (* NIST - National Institute of Standards and Technology of the US Department of Commerce) and is registered at the US Patent Office under the number 5,471,885.

Respondents in the control group were combined with administered Ibuprofen (Brufen, Mylan®, 400mg, 2 times a day for 12 hours, after meals) and Diazepam (Diazepam®, Hemofarm, 5mg, one hour before bedtime) for a period of three weeks, i.e. Ibuprofen alone (400mg, 2 times daily for 12 hours after meal) at the same time interval. Since benzodiazepines are administered in smaller doses, the hypnotic effect of these drugs was

avoided. Diazepam doses were gradually reduced before completion of therapy in order to avoid symptoms of disorder recurrence. Applied medicines have ISO certificate and registration certificate at the Agency for Medicines and Medical Devices of Serbia.

SPSS 18.0 statistical software was used for all statistical analysis (IBM, USA). The level of statistical significance was set at $p < 0.05$.

RESULTS

The age of subjects with different orofacial pain treatment did not statistically significantly differ among subjects of different therapeutic groups. A statistically significant difference in incidence of TMD was observed between different sexes. All subjects in the treated treatment group were female, while in the group treated with the stabilization splint there were 35% men and 65% women (Table 1).

Between the analyzed groups treated with different therapeutic approaches, there was no statistically significant difference in the cause of the existing pain. In the treatment group treated with analgetics and sedatives (62.5%), as well as in the group treated with stabilization splint (55%), the majority of subjects had musculoskeletal dysfunction, while in the group treated only with analgetics the frequency of subjects with joint and musculoskeletal dysfunction was the same (37.5%) (Table 2).

Between the analyzed groups treated with different therapeutic approaches, a statistically significant difference in the values of subjective intensity of pain (VAS) was not noticed before the therapy as well as after the therapy. Between the analyzed therapeutic groups there was no statistically significant difference in pain intensity with an objectively registered digital algometer (DA), before and after the performed therapy. A statistically significant difference in pain intensity was observed in all treatment groups before and after the therapy, regardless of the chosen treatment method (Table 3).

A statistically significant correlation in the intensity of pain measured by the VAS scale and algometer (DA) was observed. The correlation coefficient values obtained before and after therapy indicate the existence of a statistically significant association, but the absolute values of the coefficients in both cases were less than 0.5, indicating the existence of

significant deviations between the methods, that is, the great influence of the subjective pain and evaluation on the VAS scale in respondents (Table 4).

By a correlation analysis of the current intensity value of the pain shown by the numerical scale and the score of pain in the VAS scale, a statistically significant correlation was noted in the assessment of the pain measured by these instruments. Despite similar criteria of pain assessment with these methods, the absolute value of the coefficient of correlation points to significant deviations in the assessment of the respondents for the same pain intensity experience (Table 5).

In order to evaluate the efficiency of different therapeutic modalities for pain reduction, a multivariate regression model was used, where the severity of the pain after treatment was assessed by the VAS and DA method. In this regression model, the effect of all observed risk factors, pretreatment factors, applied therapies, and other outcomes (depression, psychosocial status) was evaluated, on the evaluation of pain VAS and DA method after the therapy.

In the measurement of VAS pain by scaling, a univariate regression analysis found that the pain after the applied therapy was associated with the pain described before the start of treatment, the assessment of working ability, social life, everyday activities, chronic pain, reduction of orofacial functions and depression (Table 6). The intensity of pain measured prior to the therapy by VAS and the assessment of social life were singled out, as the predictors of post-therapeutic intensity of pain. Respondents who complained of severe pain before initiating therapy had a higher intensity of pain after the applied treatment. In all subjects with pain in the orofacial region, regardless of pain reduction after therapy, one can always expect the influence of pain on their social life that is more disturbed as the pain is stronger.

When assessing post-treatment pain measured with algometer, the univariate regression analysis as statistically significant included: sex, strength of the pain measured by the algometer before treatment and the pain level after treatment measured on the VAS scale. Multivariant regression analysis, the severity of pain measured by the algometer before therapy and the measurement of VAS after therapy, have been singled out as factors with an independent impact on the severity of pain, measured by the same method after therapy (Table 7).

DISCUSSION

Pain is not only a signal of tissue damage, but also a difficulty in most dental procedures by delaying the rehabilitation of functions and reducing the chances of a patient returning. Pain control is often inadequate, either due to insufficient analgesia or due to unacceptable side effects of drug therapy. In addition, inadequate analgesia can contribute to the onset of hyperalgesia during the recovery period. The above facts indicate that it is imperative to have effective analgesia with minimal side effects. Pain, as a symptom of temporomandibular disorders and associated dysfunction of the mastication muscles and TM joints, are significant entities of TMD. A simple and reliable determination of the origin of pain is detrimental for the choice of therapeutic modality. Multifactorial etiology and overlapping of symptoms and signs of various temporomandibular disorders complicate this requirement [7]. An additional problem in the choice of therapeutic approach lies in the fact that pain, as the most prominent symptom, can occur secondary as a result of disorders of adjacent structures. Since the causes of TMD and the interaction between different entities of TMD are very complex, initial therapy should be non-invasive and reversible. In this respect, occlusal splint represents the therapy of choice, since it temporarily improves the functional relationship of the structures of the orofacial (OF) system. The occlusal splint, acting on the cause of the disorder influences on symptoms, and also plays a role as a diagnostic agent. This fact is particularly important in cases when there is a suspicion of the dominant influence of occlusal factors in the development of TMD. Detailed mechanisms by which occlusal splints achieve these results are still the subject of discussion [8]. Stabilization splint is sometimes referred to as the relaxation splint due to its primary application in the reduction of muscle pain [9].

The results of this study indicate a positive effect of the stabilization splint in the reduction of painful symptoms regardless of the temporomandibular dysfunction, as there is a statistically significant difference in the measured intensity of pain in all treatment groups before and after the applied therapy ($p \leq 0.05$). All subjects of the clinical population who were male (15.9%) were treated physically exclusively with occlusal stabilization splint. In the therapeutic group treated with stabilization splint (55%), the majority of subjects had a diagnosed musculoskeletal dysfunction. The majority of respondents with moderate depression were in the treatment group treated with occlusal splint (45%), as well as subjects without defined depression (45%). Positive effects of stabilization pain therapy in pain

reduction were observed in many studies [10-14]. Stabilization splints, as splints of flat surfaces, are conventionally made of solid material. Such a splint is resistant to the long-lasting effect of occlusal forces of varying intensity and satisfies the requirements of physiologically optimal and stable occlusion [15]. Solid-type splints reduce the EMG activity of the masster and temporal muscles [16].

Lazić et al. carried out a comparative analysis of the mechanical and chemical properties, structure, surface of PMMA breaks and thermoplastic polymers. The results of the tests indicate that thermoplastic poly-carbonate (TPK) materials are more suitable for making occlusal splints, since the beginning of the deformation is elastic, and they also have a potency of flow and characteristics of viscoelastic polymers. Mechanical properties and appearance of faulty surfaces imposes the use of TPK materials for making occlusal splints [17].

The choice of splint as a therapeutic agent in the treatment of painful TMDs requires caution and a properly diagnosed dysfunction. Also, limited therapeutic capacity should be taken into account as well as possible complications during the wearing of such compensation (caries of the tooth below the splint, gingivitis due to poor oral hygiene, difficult speech and breathing functions, and eventual psychosomatic reactions to foreign bodies). These facts imply the obligation to conduct regular and frequent check-ups after giving splint to the patient.

Given that the studied population consisted of patients who sought help regarding treatment of TMD, we can say that respondents belong to the clinical population. Of the 44 patients in the clinical population who exposed the signs and symptoms of TMD, 22 subjects (50%) had a combined musculoskeletal dysfunction. 15 respondents (34.1%) showed symptoms of articular dysfunction regardless of the possibility of condyle reduction or degree of mouth opening, and 7 respondents (15.1%) of symptoms and signs of muscular dysfunction, regardless of the degree of opening of the mouth. In this regard, the results of the study on the distribution of various subgroups of TMD are similar to the results of many studies [18 - 20].

Differences in the frequency and distribution of TMD subgroups are due to different criteria of homogenization of the examined population and various diagnostic methods. In

addition, there is a difference in the type of population surveyed (clinical or general), as well as in the age of the population group.

By analyzing the distribution of TMD among the sexes in the clinical population, the results show that the incidence of symptoms and signs of TMD is 6 times higher in females than in males. Of the 44 subjects who were included in the study, 15.9% of respondents were male. The high incidence of TMD in women is considered to be the consequence of greater responsibility of women towards their own health and more frequent visits to the doctor, and that women are more affected by stress [21, 22].

The available methods vary significantly among researchers, which does not allow comparison of different studies. The most common problems in comparing the results of other studies lie in the different times that have been given to the respondent to evaluate the pain.

While some researchers require information on the current intensity of pain, others require that respondents rank the pain level over the past 24 hours. This is one of the reasons for the existence of variability of the results [23, 24].

A statistically significant correlation was observed in the measured intensity of the pain with the VAS scale and the DA method, which also indicates the existence of significant discrepancies between the measurement methods, i.e. the great influence of the subjective pain experience and the assessment on the VAS scale. In addition, some studies point to the unreliability of the digital algorithm method by pressing force in successive measurements [25].

The inconsistency of the results of the multivariate regression analysis for pain measured by the VAS scale and the algometric method after the applied treatment is another confirmation of the quality of VAS as an instrument for subjective assessment of the pain experience. Given that the experience of pain is an individual category involved in the psychosocial life of an individual, despite the bias that the VAS scale implies in the assessment of pain, a comparative application of the VAS scale with other instruments for measuring intensity of pain is necessary.

In any case, one should be cautious in interpreting the results from at least three reasons. The first is that patients with chronic pain, have a normal adjustment to the existing

condition, whether or not therapy is performed, and symptom regression occurs. Another reason for symptom regression is the consequence of a doctor-patient interaction. Patient encouragement and information on the causative agent and benign character of the disease leave a positive effect on the patient and his presentation of the symptoms of pain [26].

Finally, the third reason lies in the fact that the pain regression is also influenced by psychosocial factors, primarily quality of life, social and cultural status, and previous painful experiences [27].

CONCLUISION

The study found that the intensity of the pain is not a predictor of the dysfunction of the OF system. Considering the objectives of the study, the analysis of the obtained results suggests that therapy with occlusal stabilization splint can significantly reduce the pain intensity and confirmed the positive analgesic effect of occlusal stabilization splint in TMD patients. All therapeutic modalities applied in this study have proved to be equally effective in reducing painful symptoms so that the prognostic significance of intensity of pain measured before treatment is irrelevant. Significant deviation in respondents' assessments of the same pain intensity experience, depending on the type of measuring instrument, was also found.

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Conflict of Interest: None declared.

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Table 1. Number and demographic characteristics of respondents

Observed parameters		Therapy			p
		Ibuprofen + Diazepam	Occlusal splint	Ibuprofen	
Number of respondents (n)		8	20	16	
Age (X ± SD)		44.63 ± 12.56	35.6 ± 10.7	38.5 ± 9.5 4	[a]0.136
Gender n (%)	Man	0(0%)	7(35%)	0(%)	[b]0.007*
	Women	8(100%)	13(65%)	16(100%)	

*statistically significant difference;

[a]single-factor analysis of variance;

[b]χ^2-test

Table 2. Distribution of respondents according to diagnosis in relation to therapy

Diagnosis (disfunction)		Therapy			p
		Ibuprofen + Diazepam	Occlusal splint	Ibuprofen	
n (%)	Muscular	1 (12.5%)	2 (10%)	4 (25%)	0.657
	Articular	2 (25%)	7 (35%)	6 (37.5%)	
	Musculo-skeletal	5 (62.5%)	11 (55%)	6 (37.5%)	

*statistically significant difference

Table 3. Subjective and objectively assessed intensity of pain before and after the therapy

Pain intensity (X ± SD)	Therapy			p
	Ibuprofen + Diazepam	Occlusal splint	Ibuprofen	
VAS'	57.00 ± 21.29	59.05 ± 20.60	59.13 ± 15.61	0.962
VAS''	34.00 ± 18.99	28.55 ± 17.79	34.75 ± 17.73	0.553
VAS' *vs.* VAS''	p = 0.001*	p = 0.000*	p = 0.000*	
DA'	10.86 ± 1.81	11.27 ± 3.60	10.53 ± 2.25	0.751
DA''	15.42 ± 2.08	14.55 ± 3.76	15.14 ± 2.59	0.755
DA' *vs.* DA''	p = 0.001*	p = 0.000*	p = 0.000*	

VAS' – pain intensity assessed by visual analog scale before the therapy; VAS'' – pain intensity assessed by visual analog scale after the therapy; DA' – pain intensity assessed by digital algometer before the therapy; DA'' – pain intensity assessed by digital algometer after the therapy;

*statistically significant difference

Table 4. Correlation between different methods of measuring intensity of pain

Correlation	VAS'	VAS''	p
DA'	R = -0.473		0.001*
DA''		R = -0.472	0.001*

DA' – digital algometer before the therapy; DA'' – digital algometer after the therapy; VAS' – visual analogue scale before the therapy; VAS'' – visual analogue scale after the therapy;

*statistically significant correlation

Table 5. Correlation of pain levels assessed in different ways

Correlation	VAS'	DA'	p
NS	R = 0.510		0.000*
		R = -0.293	0.053

VAS' – visual analogue scale before the therapy; DA' – digital algometer before the therapy; NS – current pain;

*statistically significant correlation

Table 6. Uni- and multivariate regression analysis related to VAS''

Observed risk parameters	Univariate		Multivariate R^2 = 0.528	
	#B (95%CI)	p	B (95%CI)	p
Sex	6.529 (-8.326 – 21.384)	0.380	/	/
Age	0.179 (-0.327 – 0.686)	0.479	/	/
VAS'	0.608 (0.378–0.838)	**0.000***	0.426 (0.115–0.737)	**0.009***
DA'	-2.658 (-4.418–-0.899)	**0.004***	-0.931 (-2.655–0.794)	0.281
Therapy	1.315 (-6.336–8.965)	0.731	/	/
Diagnosis	-1.546 (-8.974–5.881)	0.677	/	/
Working Ability	3.211 (0.818–5.604)	**0.010***	-3.024 (-7.327–1.279)	0.162
Social life	4.088 (1.732–6.444)	**0.001***	4.517 (0.516–8.517)	**0.028***
Everyday activity	2.600 (0.287–4.912)	**0.029***	0.186 (-2.314–2.687)	0.881
Level of chronic pain	12.643 (1.944–23.342)	**0.022***	-2.776 (-13.366–7.814)	0.598
Reduction of function	5.182 (1.159–9.205)	**0.013***	3.334 (-0.231–6.900)	0.066
Depression	9.082 (1.696–16.467)	**0.017***	1.164 (-6.141–8.468)	0.748

VAS'' – visual analogue scale after the therapy; VAS' – visual analogue scale before the therapy;

DA' – digital algometer before the therapy;

*statistically significant;

#non-standardized coefficient B

Table 7. Uni- i multivariate regression analysis related to digital algorithm measurement (DA'')

Observed risk parameters	Univariate		Multivariate R^2	
	#B (95%CI)	p	B (95%CI)	p
Sex	-2.868 (-5.294–-0.442)	**0.022***	-0.690 (-2.638–1.258)	0.478
Age	-0.024 (-0.112–0.063)	0.577	/	/
VAS'	-0.040 (-0.090–0.010)	0.115	/	/
DA'	0.766 (0.530–1.001)	**0.000***	0.634 (0.358–0.911)	**0.000***
Therapy	-0.022 (-1.343–1.299)	0.973	/	/
VAS''	-0.081 (-0.129–0.034)	**0.001***	-0.036 (-0.129–0.034)	**0.005***
Diagnosis	-0.430 (-1.706–0.847)	0.501	/	/
Working ability	0.023 (-0.424–0.470)	0.919	/	/
Social life	-0.257 (-0.712–0.197)	0.260	/	/
Everyday activity	0.147 (-0.273–0.567)	0.483	/	/
Level of chronic pain	-1.337 (-3.258–0.584)	0.167	/	/
Reduction of function	-0.423 (-1.158–0.313)	0.253	/	/
Depression	-0.323 (-1.683–1.036)	0.634	/	/

DA' – digital algometer before the therapy; DA'' – digital algometer after the therapy; VAS' – visual analogue scale before the therapy; VAS'' – visual analogue scale after the therapy;

*statistically significant;

#non-standardized coefficient B

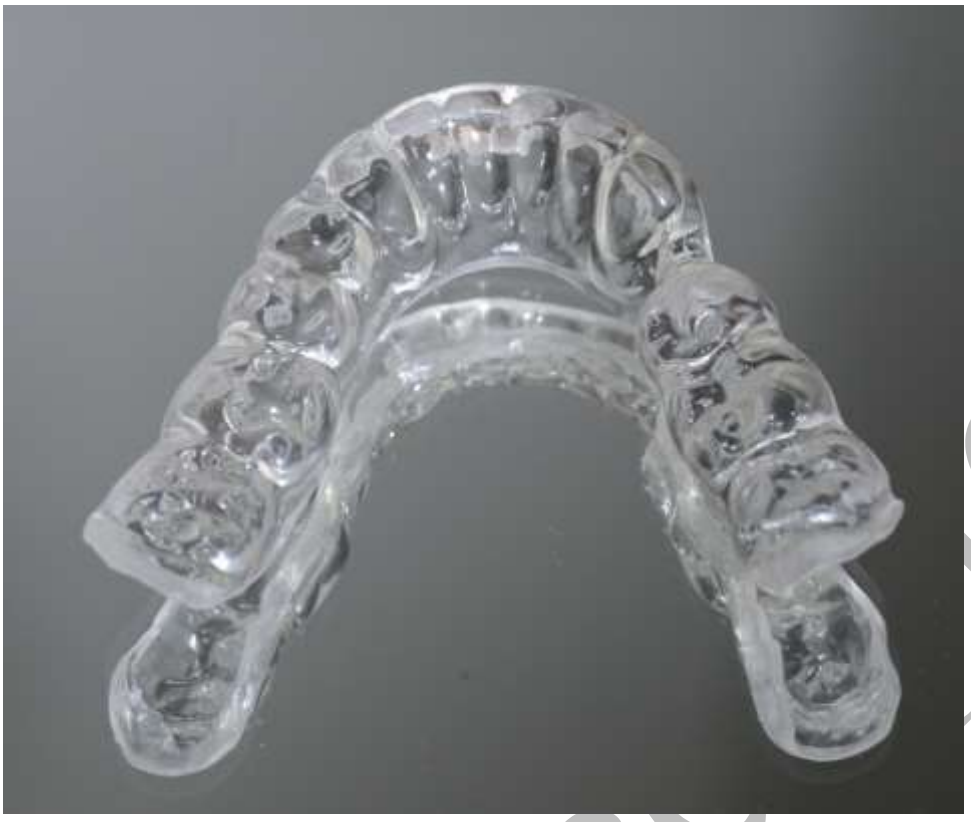

Figure 1. Stabilization splint made of thermoplastic poly-carbonate

Figure 2. Stabilization occlusal splint as a therapeutic option for pain reduction in patients with temporomandibular disorders

