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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Occlusal appliances – an alternative in pain treatment of temporomandibular disorders

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SUMMARY

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

The objective 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 standard Research Diagnostic Criteria for Temporomandibular Disorders diagnostic protocol proposed by Dworkin and LeResche, a group of 44 patients with painful TMD was included. The 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, therapy with non-steroidal anti-inflammatory drug ibuprofen (Brufen, Mylan, Canonsburg, PA, USA) or a combination therapy of ibuprofen and diazepam, a medication from the benzodiazepine family (Diazepam, Hemofarm, Vršac, Serbia) was carried out over a period of three weeks. In order to assess the effects of the therapy with stabilizing occlusal splint and the drug therapy, before and after the therapy, pain intensity measurements were performed with visual analogue scale and digital pressure algometer.

Results A significant reduction in the intensity of painful symptoms was 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 the therapy with stabilization occlusal splint is a valid procedure in the reduction of pain in patients with TMD.

Keywords: temporomandibular dysfunction; occlusal splint; pharmacotherapy

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 (TMD) is the reduction of the intensity of pain and the relaxation of the mastication muscles [1, 2].

In the treatment of patients with signs and symptoms of painful 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 objective of the study was to examine in parallel the analgesic effect of the 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 TMD, proposed by Dworkin and LeResche [6], was used for diagnosing and numerically expressing pain intensity. Respondents were divided into three treatment groups formed by random selection based on the Research Diagnostic Criteria for Temporomandibular Disorders protocol. 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, Canonsburg, PA, USA) or a combination therapy of ibuprofen and diazepam, a medicine from the benzodiazepine family (Diazepam®, Hemofarm, Vršac, Serbia). All three groups were of equal age structure in the range of 25–45 years. The respondents were thoroughly informed about the protocol of the study and gave voluntary consent to participate in the study, which was

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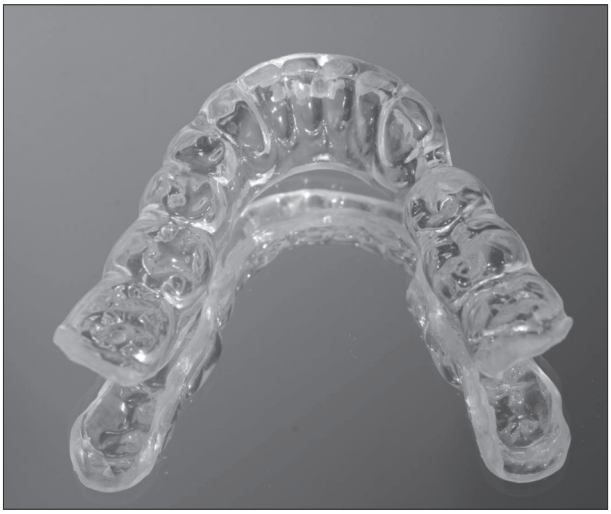

Figure 1. Stabilization splint made of thermoplastic poly-carbonate

approved by the Ethics Commission of the Faculty of Dentistry, University of Belgrade. The chosen methodology was applied to each patient individually.

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*, on 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, 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 5-minute pauses between the measurements. The measured force is displayed on the machine's display in newtons (N). 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 the pain was measured in the same time and space conditions.

In order to minimize the error in algometer measuring, the respondents were asked to avoid consuming alcohol, nicotine, and caffeine on the day of the measurement. The same procedure after the therapy had been administered was applied in all therapeutic groups. A digital algometer (FORSE ONETM FDIX, Wagner Instruments, Greenwich, CT, USA) was used in the research; it has a National Institute of Standards and Technology of the US Department of Commerce certificate, and is registered at the US Patent Office under the number 5,471,885.

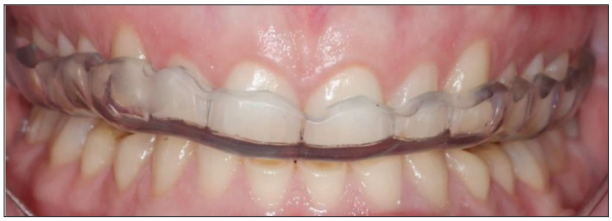

Figure 2. Stabilization occlusal splint as a therapeutic option for pain reduction in patients with temporomandibular disorders

Respondents in the control group were treated with combined therapy of ibuprofen (Brufen, Mylan, 400 mg, twice daily during a 12-hour period, after meals) and diazepam (Diazepam, Hemofarm, 5 mg, one hour before bedtime) over a period of three weeks, or with ibuprofen alone (400 mg, twice daily during a 12-hour period, after meals) during the same time frame. 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 the recurrence of the disorder symptoms. Applied medicines have the ISO certificate and registration certificate at the Agency for Medicines and Medical Devices of Serbia.

PASW Statistics, Version 18.0 (SPSS Inc., Chicago, IL, USA) software was used for all statistical analysis. 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 the incidence of TMD was observed between different sexes. All subjects in the pharmaceutically treated group were female, while in the group treated with the stabilization splint there were 35% men and 65% women (Table 1).

Table 1. Number and demographic characteristics of respondents

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

*Statistically significant difference;
[a]single-factor analysis of variance;
[b]χ^2 test

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 analgesics and sedatives (62.5%), as well as in the group treated with the 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).

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%)	

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, nor after it. 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).

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

A statistically significant correlation in the intensity of pain measured by the VAS scale and 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, great subjective pain influence and evaluation on the VAS scale in respondents (Table 4).

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

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).

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

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

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

In the measurement of VAS pain by scaling, a univariate regression analysis found that 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 the 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, which is more disturbed as the pain is stronger.

When assessing post-treatment pain measured with the DA, the univariate regression analysis as statistically significant included sex, strength of the pain measured by the DA before treatment, and the pain level after treatment measured on the VAS scale. Multivariant regression analysis, the severity of pain measured by the DA 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).

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

Observed risk parameters	Univariate		Multivariate R2	
	#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

DISCUSSION

Pain is not only a signal of tissue damage, but also a difficulty in most dental procedures, 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 aforementioned facts indicate that it is imperative to have effective analgesia with minimal side effects. Pain, as a symptom of TMDs and associated dysfunction of the mastication muscles and TM joints, is a significant entity 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 TMDs 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 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 TMD, 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 with an occlusal stabilization splint exclusively. In the therapeutic group treated with a 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 splints are 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 electromyographic activity of the masseter and temporal muscles [16].

Lazić et al. [17] 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 polycarbonate (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. Fifteen respondents (34.1%) showed symptoms of articular dysfunction regardless of the possibility of condyle reduction or of the degree of mouth opening, and seven respondents (15.1%) showed symptoms and signs of muscular dysfunction regardless of the degree of mouth opening. 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, 19, 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 six times higher in females than in males. Of the 44 subjects who were included in the study, 15.9% of the 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 [20, 21].

The available methods vary significantly among researchers, which does not allow for a comparison of different studies. The most common problems in comparing the results of other studies lie in different time frames given to respondents 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 previous 24 hours. This is one of the reasons for the existence of variability of the results [22, 23].

A statistically significant correlation was observed in the measured intensity of 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 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 [24].

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 the intensity of pain is necessary.

In any case, one should be cautious in interpreting the results for at least three reasons. The first one is that patients with chronic pain have normal adjustment to the existing conditions, whether or not therapy is performed, and symptom regression occurs. Another reason for symptom regression is the consequence of the 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 [25].

The third reason lies in the fact that the pain regression is also influenced by psychosocial factors, primarily the quality of life, social and cultural status, and previous painful experiences [26].

CONCLUISION

The study found that the intensity of the pain is not a predictor of the dysfunction of the orofacial system. Considering the objectives of the study, the analysis of the obtained results suggests that therapy with an occlusal stabilization splint can significantly reduce the pain intensity and confirmes 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 the intensity of pain measured before treatment is irrelevant. Significant deviation in respondents' assessments of the same pain intensity experience, depending on the type of the measuring instrument, was also found.

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Conflict of interest: None declared.

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Оклузални сплинт – алтернатива у терапији болесника са темпоромандибуларним дисфункцијама

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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 Коришћењем стандардног дијагностичког протокола (*RDC*/ТМД) предложеног од стране Дворкина и Лерешеа, издвојена је група од 44 болесника са болним темпоромандибуларним дисфункцијама. Болесници су подељени у три терапијске групе случајним избором. Прва група је подвргнута терапији стабилизационим оклузалним сплинтом у 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 визуелном аналогном скалом и дигиталним притисним алгометром.

Резултати У све три терапијске групе постигнуто је значајно смањење интензитета болних симптома. Нису забележене значајне разлике у успешности смањења бола између предложених терапијских модалитета.

Закључак Добијени резултати потврђују да је терапија стабилизационим оклузалним сплинтом валидна процедура у смањењу бола код болесника са ТМД.

Кључне речи: темпоромандибуларне дисфункције; оклузални сплинт; фармакотерапија