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Orthokinetic splint as treatment of trigeminal neuralgia associated with temporomandibular dysfunction

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Abstract

Introduction: *Trigeminal neuralgia (TN) is a disorder characterized by recurrent unilateral brief electric shock-like pains, abrupt in onset and termination, limited to the distribution of one or more divisions of the trigeminal nerve, and triggered by innocuous stimuli. The worldwide prevalence of TN is estimated to be 0.3%. The prevalence of temporomandibular dysfunction (TMD) is assumed to be > 5% of the population. The study of the association of TN and TMD and their management with a repositioning splint is not enough, perhaps not studied yet.* **Objectives:** *The purpose of this study is to clinically observe the effectiveness of repositioning a splint in managing TN associated with TMD.* **Materials and methods:** *Thirty-three subjects fulfilled the selection criteria and were taken into consideration until a 4-month follow-up. The original sample enrolled 16 patients, but five declined the informed consent. Finally, 11 subjects were followed up until 4 months of clinical trial.* **Results:** *The use of splint had statistical differences and improved the visual analog scale scores and falling recurrent spasmodic attacks. In addition, the splint increases between 1.2 and 2.4 mm of the distance between the mandibular condyle and mandibular fossa.* **Conclusion:** *It can be concluded that the splint could be an option in managing TN associated with TMD.*

Keywords: *Trigeminal neuralgia. TMD. Splint.*

Introduction

The International Classification of Headache Disorders 3 of beta version defines Trigeminal Neuralgia (TN) as "a disorder characterized by recurrent unilateral brief electric shock-like pains, abrupt in onset and termination, limited to the distribution of one or more divisions of trigeminal nerve and triggered by innocuous stimuli" also named as "tic douloureux"[1].

There is not enough statistical data on TN in Mexico. However, the worldwide prevalence of TN is estimated to be 0.3%[2]. TN is directly proportional to increasing age with an annual incidence of 17.5/100,000 in individuals aged from 60 to 69 years and 25.6/100, 000 in those older than 70 years[3]. The prevalence is 155 cases per million in the United States[4]. The approximate prevalence rate in the general population is expected to be between 0.1 and 0.3% and among the primary care settings that it is estimated at 12%/100,000 persons with a female-to-male ratio of 2:1[5].

TN can be treated by pharmacological, surgical, and neuromodulation methods like peripheral nerve stimulation[4-7]. Carbamazepine stands as the first-line therapy of TN. However, the failure of pharmacological treatment leads to surgical interventions, which are effective

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for pain relief at 80-90% with possible side-effects and recurrence rates in the span of 5-7 years[8,9]. Temporomandibular dysfunction (TMD) is a group of musculoskeletal and neuromuscular conditions that involve the temporomandibular joint (TMJ), the masticatory muscles, and all associated tissues and structures[10].

The prevalence of TMD is assumed to be greater than 5% of the population[11]. The ratio of female-to-male prevalence is generally found to be 2:1[12]. The etiology of TMD is unknown but is expected to be both multifactorial and biopsychosocial consisting of initiating, predisposing, and perpetuating factors such as macro-trauma or micro-trauma attributed to failed healing due to psychosocial profile of patient, failed treatment, or genotype[13,14]. One factor could be the partially edentulous and edentulous prosthetic or toothed for long period would promote a shift in the vertical and transverse mandibular positions; as a result, the position of the condyles in the mandibular fossae may also change[15]. Change of the rest position due to the reduction of vertical dimension of occlusion is also considered to be one of the predisposing factors[15].

Different management and treatment options exist for TMD. In 2014, Mansur Dogan mentioned the effective outcome of bio-oxidative ozone therapy in reducing the visual analog scale (VAS) scores, at an 87.8%, associated with TMD[16]. However, splint therapy is more frequent and may be defined as "the art and science" of establishing neuromuscular harmony in the masticatory system and creating a mechanical advantage for parafunctional forces with removable appliances[17]. Bite plane splint, Hydrostatic splint, Mandibular Orthopedic Repositioning Appliance, Pivot Splint, Soft Splint, Stabilization Splint, and Repositioning Splint are different kinds of available devices[18]. All of them are included in the category of occlusal splint.

The frequency of association of TN and TMD is unknown and the publication about that combination is not enough. In 2014, Speciali and Dach mentioned that TMD and headache share the same nociceptive system of trigeminus, and the first and second branches of trigeminus are affected in TMD[19]. This permits the transfer of nociceptive information toward the caudal nucleus of trigeminus which shares a specific central pathway, leading to a pain modulation[19]. Both conditions lead to craniofacial allodynia during painful exacerbations, a symptom associated with peripheral and central sensitization[19]. The Pain Clinic and Palliative Care of General Hospital of Mexico "Dr. Eduardo Liceaga" attends approximately 150 patients with TN at year. Non-published personal observation allows us to estimate this association around 10% in the department. The treatment of subjects with this association is challenging.

The aim of this study is to evaluate in a sample of patients the effect of the repositioning splint in the management of TN associated with TMD.

Materials and methods

The target population consisted of patients diagnosed with TN associated with TMD in the Pain Clinic and Palliative Care of General Hospital of Mexico "Dr. Eduardo Liceaga" who authorized under informed consent to participate in this study and met the following selection criteria. Patients were male or female, were aged over 18 years, diagnosed with TN in any branch associated with TMD, who could read and write, who were on pharmacological treatment with carbamazepine at least once for 6 months in the painful period, with or without the history nerve block with phenol or radiofrequency, and who were partially edentulous and edentulous prosthetic or toothed. The patients excluded were who presented hypersensitivity to polymers with a history of head injury, other brain diseases, those who suffered collagenopathies with a history of maxillary or mandibular surgery, neuralgia of herpetic origin, or uncontrolled psychiatric disorder. Patients who withdrew their informed consent and patients who did not complete at least one follow-up were eliminated.

To evaluate changes in pain intensity, VAS was applied, introduced by Scout Huskinson in 1976. It is a line of 10 cm without millimetric registration where one end represents no pain with a numeric value of "0" and the other end represents the maximum possible pain with a numeric value "10." The patient crosses a vertical line where he considers that the pain is best registered[20]. The score of VAS was performed by means of the technique proposed by Downie in 1978[20], which involves the transfer of original VAS record to a sheet of acetate that has a line of same length as previous scale but of millimeter division so that the data recorded by the patient could be converted to millimeters and quantified.

Pain was evaluated in six trigger points (trigger point was considered as the one that produced "Tic Douloureux"); the emergence of the supraorbital nerve (V1), the emergence of infraorbital nerve (V2), the emergence of the mental nerve (V3), temporalis muscle, external TMJ, and masseter muscle. The "Tic Douloureux" was produced by exerting a pressure of 3.0 kg/cm^2, using a digital algometer (Wagner Inc.). This constant was obtained after quantifying subjective threshold of pain in 20 healthy subjects, not paired by age or sex and family members of patients.

All study subjects were evaluated by means of a digital panoramic radiography for Tatis analysis with no turns or tilts, 1:1 relation, where somatometric references portion, orbit, and menton were observed in maximum intercuspation[21,22]. These data were analyzed by the Orthoeditor and Orthokinetor Plus software 2[23].

The objective was to adequately analyze the position of the condyle in relation to the glenoid cavity, to develop the repositioning splint with acrylic (polymethyl methacrylate) according to the technique proposed by Dr. Tatis[24,25]. The splint maintained a space in the glenoid cavity between 4 and 6 mm[24,25]. Patients were indicated the employment and removal of the repositioning splint and its use for 24 h except during aliments.

Each subject underwent seven evaluations of pain by digital algometer at every trigger point according to the following plan: Baseline in the first interview (BL); immediately before placement of stabilizing splint (BS); and immediately after placing stabilizing splint (AS), 1 month (1M), 2 months (2M), 3 months (3M), and 4 months (4M) after placement of the repositioning splint.

Side effects were recorded on a list that included: nausea, dry mouth, sialorrea, and mucous membranes.

This pilot study was submitted to the Committee of Ethics and Research of General Hospital of Mexico "Dr. Eduardo Liceaga" and was approved with the registration number DI/13/203/04/079. The rights of research subjects according to the Declaration of Helsinki were respected and complied. The study was completed on December 9, 2015.

Results

In this study, the total target population was 150 subjects for 2015 year and 31 subjects fulfilled the selection criteria; the study was taken into consideration until a 4-month follow-up. The original sample enrolled 16 patients but five declined the consent informed. Finally, 11 subjects were followed up until 4 months of clinical trial (Fig. 1).

Subjects were categorized by their age, sex, weight in kilograms, height in centimeters, anesthetic block, and comorbidities, side of TN, and the branch involved. The mean age group of this study was 57.36 years SD ± 12.89, with a median of 63 years. TN had a female preponderance in accord to the subjects studied in this trial. In this study, we observed that although both the trigeminal branches V2 and V3 of the left side were involved, the right-side V2 branch was more commonly affected, leading to the highest number of anesthetic blocks (3 times) to manage the pain. Average of carbamazepine doses administrated was of 238.63mg SD ± 175.84 (Table 1).

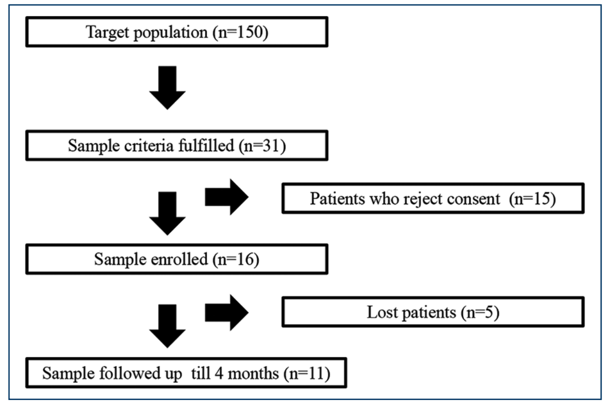

Figure 1. This diagram shows the distribution of patients from the target population until 4 months of follow-up. Eleven patients were followed-up for during this clinical trial.

The mean VAS score at BL (2 weeks before splint application) was 6.32 SD ± 0.857 and 5.76 SD ± 0.538 in BS. There was a significant decrease in pain after the application of splint among the 11 enrolled subjects at 4-month follow-up in all the trigger points with a mean VAS score of 0.79 SD ± 0.249 at M3 and 0.69 SD ± 0.162 at M4 (Fig. 2). The changes of VAS score obtained by the Freidman test ($p = 0.0001$) demonstrated substantial evidence indicating the success of repositioning splint use in managing TN in this trial.

The effect of repositioning splint is shown by differences between distance before and after the treatment. Fig. 3 shows the rest in millimeters (delta) observed between condyles and the mandibular fossae. Distance increase at least 1.2 mm in anterior-posterior projection and at least 2.2 mm in lateral projection.

Discussion

The results of this study showed that this therapeutic procedure improved VAS scores more than 80%, compared to two previous measurements (BL and BS). There was a significant decrease of more than five points at 4-month follow-up according to VAS indicating an alleviation of pain. With these preliminary data, we believe that the splint may be an alternative

Table 1. Demographic table shows that the mean age of the patients was 57.36 (SD ± 12.89) years and the median age was 63 years

Id	Sex	Age (years)	Weight (Kg)	Height (cm)	A-B	Doses (CBZ)	Com	Side	Branch
1	0	36	98	163	0	600	0	R	V3
2	0	63	54	150	2	100	0	R	V2
3	1	68	73	174	3	0	1	R	V2
4	0	49	87	160	2	300	2	R	V2
5	0	65	56	154	0	0	2	L	V3
6	0	53	69	167	1	200	0	R	V2
7	0	69	68	155	0	200	0	R	V3
8	0	34	69	157	0	200	0	R	V3
9	0	59	68	156	0	300	2	R	V2, V3
10	0	71	87	146	0	400	3	L	V2, V3
11	0	64	65	158	0	325	0	R	V3
Median/frequency	10F/1M	57.36	72.18	158.18	7N/4Y	238.64	6N/5Y	9R/2L	6V2/7V3

Female patients have more predominance than male patients with a ratio of 10:1. The frequency of anesthetic blocks (A-B) given is indicated in the table. The maxillary trigeminal branch (V2) is lightly less affected than mandibular trigeminal branch (V3) and had a frequent history of anesthetic blocks. We can also note that the most common side affected was right-side. All the patients are on carbamazepine with the mean doses of 238.63 mg (SD ± 175.84) per day (CBZ/d). 0: female; 1: male; Com: comorbidity (number of associated illnesses); R: right; L: left; V1: ophthalmic branch; V2: maxillary branch; V3: mandibular branch. 0: none; 1: diabetes mellitus; 2: HAS; 3: DM and HAS. Patients 3 and 5 were treated with carbamazepine before splint but side effects of medication caused dropout of carbamazepine.

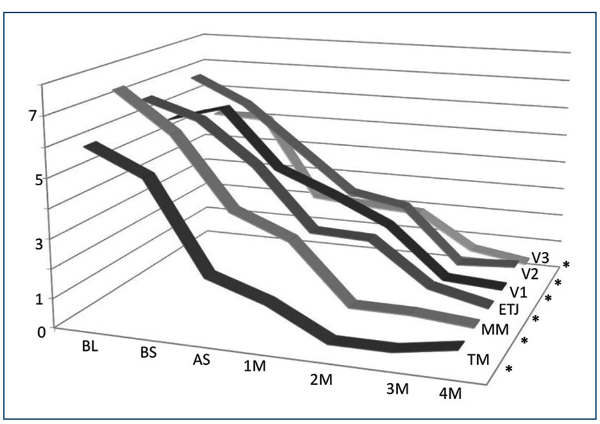

Figure 2. The graph shows the visual analog scale (VAS) score 2 times before the treatment (BL and BS).
A follow-up after splint included immediately after splint (AS) and 1, 2, 3, and 4 months before splint (1M, 2M, 3M, and 4M). The mean of VAS was explored in the trigger points in each time. We can note that after the application of splint, there was a significant decline of VAS values at every trigger point TM, MM, ETJ, V1, V2, and V3 indicating a therapeutic success of splint with a mean VAS of 0.79 at 3rd month and 0.69 at 4th month.
Base line: 2 weeks before splint; before splint: immediately before splint; After Splint: immediately after splint use; TM: temporal muscle; MM: masseter muscle; ETJ: external temporomandibular joint; V1 (ophthalmic branch); V2 (maxillary branch); V3 (mandibular branch); 1M: 1st month; 2M: 2nd month; 3M: 3rd month; and 4M: 4th month; p = 0.0001 is *(by Friedman test).

treatment for patients with TN associated with dysfunction of the TMJ.

We hypothesize than the repositioning splint could work by repositioning the mandibular joint. Hence, the splint could restore vertical, anterior-posterior, and medial-lateral position achieving the decompression of auriculotemporal nerve. The auriculotemporal nerve is derived from the mandibular branch of the trigeminus,[26] and we think that it suffers compression during its trajectory in the glenoid cavity in patients who suffer from the TMD. The splint would restore sensory and/or motor function by decreasing the trigeminal pain that is triggered when the auriculotemporal nerve is compressed[27,28].

This clinical trial has some limitations that include the small group of patients and just by a 4-month follow-up. Mainly, it was not a randomized and blinded clinical trial. It is a very heterogeneous group with anesthetic blocking and non-blocking, different doses of carbamazepine, different branches, and different age. Consequently, this is a pilot study, and its results are preliminary and could serve to design a new project. The splint has been associated with improving the myofascial pain (Table 2). However, the role of splint in the association of TN and TMD is not yet explained. The frequency of association between TN and TMD is a

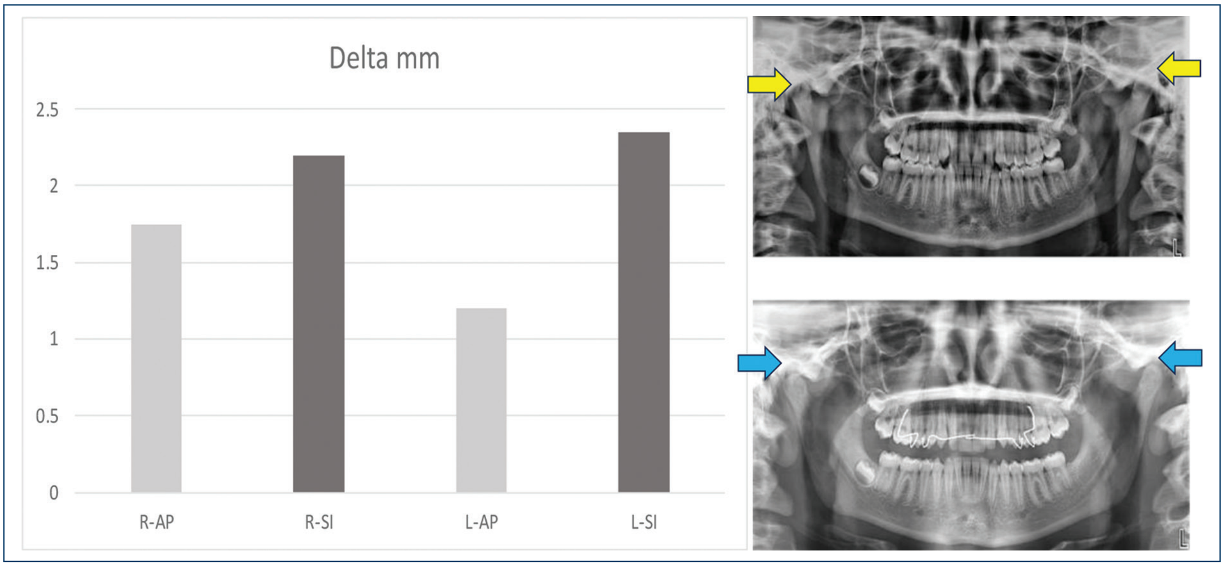

Figure 3. On the left, the graph represents the distance achieved between the mandibular condyle and mandibular fossa on either side (Left and Right) after the colocation of the repositioning splint. Delta (differences between before and after splint); R-AP: Right Anteroposterior; R-SI: Right Superoinferior; L-AP: Left-Anteroposterior; and L-SI: Left Superoinferior. On the right superior image, it shows the absence of space in condyle and mandibular fossa (yellow arrows). On the right inferior image, the space into this joint has been recovered (blue arrows).

Table 2. This table shows the mean of VAS score in different times of study

Pain trigger	BL	BS	AS	1M	2M	3M	4M	p-value
TM	5.98	5.11	2.08	1.43	0.39	0.39	0.73	0.0001
MM	7.45	6.09	3.69	2.9	0.91	0.9	0.73	0.0001
ETJ	6.77	6.17	4.73	2.65	2.57	1.15	0.7	0.0001
V1	5.69	6.2	4.19	3.4	2.5	0.82	0.7	0.0001
V2	6.88	5.99	4.5	3.01	2.65	0.77	0.9	0.0001
V3	5.15	5.05	2.19	2.027	1.92	0.71	0.4	0.0001
mean	6.32	5.77	3.56	2.57	1.82	0.79	0.69	0.0001

BL: 2 weeks before the splint application; BS: immediately before splint use; AS: immediately after splint use; 1M: 1st Month; 2M: 2nd Month; 3M: 3rd month; 4M: 4th Month; p: value of significance by Friedman test.

relatively common medical phenomenon at the Pain Clinic of Hospital General de México “Dr. Eduardo Liceaga.”

Moreover, the study of the effect of splint in reducing the pain in this association does not exit. Probably, this is the first study attending the association between TN and TMD and its management.

Conclusion

Repositioning splint could serve as an option in the management of TN associated with TMD noting minimum side effects.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

Use of artificial intelligence for generating text. The authors declare that they have not used any type of generative artificial intelligence for the writing of this manuscript nor for the creation of images, graphics, tables, or their corresponding captions.

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