

A new prefabricated element for relaxing the musculature in patients with bruxism.

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Abstract

Bruxism is a pathology that affects numerous patients, complicating particularly in cases of strong musculature (brachyfacial, with intense overbite). It can be quantified using devices such as the Bite-strip. In this task we evaluate the "MFS" antibruxism device finding an improvement both at a subjective level and in the number of bruxist events measured with the Bite-strip.

Keywords: "MFS" antibruxism device. Bite-strip. Bruxism.

Summary

Bruxism is a pathology that affects numerous patients, complicating particularly in the cases of powerful musculature (brachyfacial, with intense overbite). In this task we evaluate the "MFS" antibruxist device finding an improvement both at a subjective level and in the number of bruxist events measured with the Bite-strip.

Key words: "MFS" antibruxist device. Bite-strip. Bruxism.

Introduction

Orthodontic treatment of patients with a brachyfacial pattern¹ often involves an element that should be taken into account at diagnosis^{2,3} and follow-up: bruxism and its complications.

Bruxism is particularly interesting because of the conditions under which this pathology develops. In order to better understand patients with bruxism, diagnosing this pathology and its treatment, we are going to answer the following questions.

What is bruxism?^{4,5}

Bruxism is a pathology that occurs in "clenching" patients, who have a strong masticatory pattern and a horizontal mandibular growth that involves a short face (brachyfacial pattern)^{6,7}. Bruxism, commonly associated with nocturnal "teeth grinding" that some patients experience, is the result of intense muscle activity, which results in wasting of the grinding surfaces of the teeth. Tooth abrasion occurs progressively until the point that the patient becomes aware of the problem in its advanced stages of dental waste. It is a subconscious process and the patient is not aware of their habit.

Stress is considered to be the most important trigger of bruxism, accompanied by feelings of anxiety, malaise and pain. Some sleep disorders are associated with bruxism, as is alcohol use and some medications (antidepressants). Some compulsive or aggressive personalities have a high incidence of bruxism. Malocclusions also act as a trigger for bruxism. Therefore, the real cause is unknown and the majority of experts consider the onset of bruxism to be a response to increases in psychological stress.

Are patients with bruxism aware of their problem?

According to already published literature, a low percentage of patients with bruxism are aware of their problem. They usually discover bruxism because of their partner's complaints of intense "night-time noises". There is a high prevalence that decreases with age. The number of subjects who suffer from it is estimated to vary from 50 to 95% of the adult population. Approximately 15% of all children also suffer from bruxism.

What are the current treatments for bruxism?

The current treatments for bruxism are few: muscle relaxants and relaxation techniques, such as yoga or sleep therapy. Other therapies that are used include repositioning splints, which relieve the patient from their normal intercuspation and raise the bite, resulting in relaxation of the masticatory musculature.

How is an early diagnosis of bruxism made?

Early diagnosis of bruxism is made by identifying typical signs and symptoms that accompany the patient's intense masticatory pattern, which may vary from moderate irritation to an intense medical problem and, depending on the severity of the bruxism, may include:

- Short, brachyfacial face.

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- Well developed mandible with marked mandibular angles and a horizontal inferior border of the body of the mandible.
 - Tooth abrasions
 - Overbite in the anterior sector of the occlusion
 - Short clinical crowns in the lateral sectors of the occlusion (premolars and molars).
 - Facial or mandibular pain. -
- Morning fatigue.
- Headache without an apparent etiology.
 - Night-time noises ("teeth grinding") indicated by another person, close to the patient.
 - Tooth mobility.
 - Periodontal alterations.
 - Tooth sensitivity.
 - TMJ problems.

Starting with identifying patients in the "risk group" for being a possible candidate for bruxism, there is currently a specific test for early diagnosis:

What is the "Bite-Strip"?

The "Bite-Strip"^{6,9} (Figure 1) is a prefabricated single-use/disposable device for the diagnosis of bruxism that allows the level of the patient's bruxism to be established on a scale from zero to three.

The "Bite-Strip" is a miniature single-channel electromyograph equipped with a miniature lithium battery, a microprocessor, a mini-electrode and an electrochemical numeric marker, all in a reduced format that is capable of being applied to the skin of the patient's face (over the masseter muscle) at night.

The patient uses this apparatus at night, attached over the masseter. The next day, a numeric value is read (from zero to three) that is permanently printed on an electrochemical numeric marker.

Values of zero to one are normal, while values of two and three indicate the presence of moderate or intense bruxism, respectively.

The "Bite-Strip" evaluation scale goes from zero to three. These values correspond to the following number of nocturnal bruxism events by the patient: Zero: a. less than 40 bruxism events; b. One: between 41 and 74 bruxism events; c. Two: between 75 and 124 bruxism events; d. Three: more than 125 bruxism events.

Prefabricated element developed to relax the facial musculature (masseters)

We have developed a prefabricated element to induce relaxation of the masticatory musculature in the patient. This is an elastic element available in different

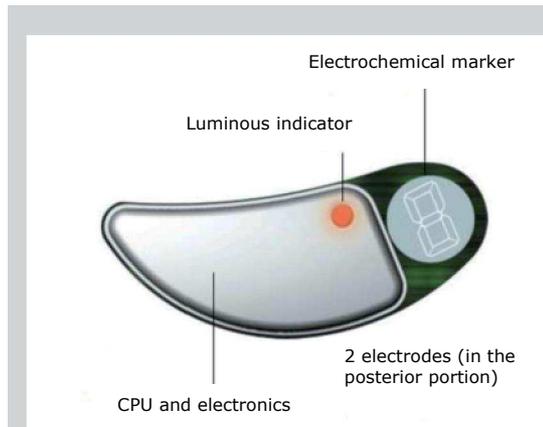


Figure 1. Bite-strip

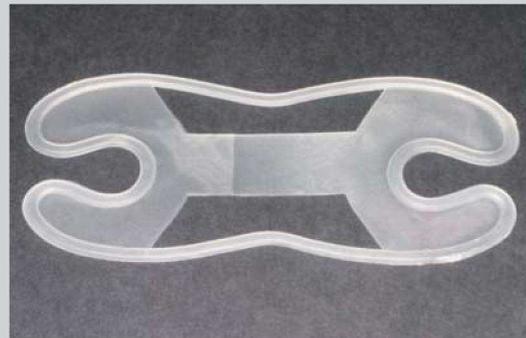


Figure 2. Muscle relaxant

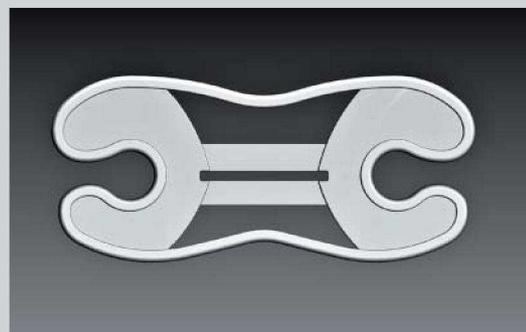


Figure 3. Muscle relaxant device with rectangular space to allow for the passage of air

sizes, which we have christened with the names "facial muscle relaxer" or "anti-bruxing". This device has been designed with an elongated "eight" shape with two disc-shaped ends and an intermediate portion that connects them together, which promotes relaxation of the orbicular muscles. Within its design, a rectangular strip impedes oral respiration (Figure 2), though it also has a rectangular perforation (Figure 3) for when the patient needs to breathe through the mouth. It has been

Figure 4.
Different sized muscle relaxants

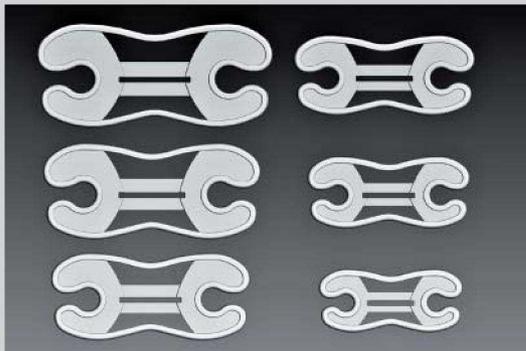


Figure 5.
New design for anti-bruxism device.

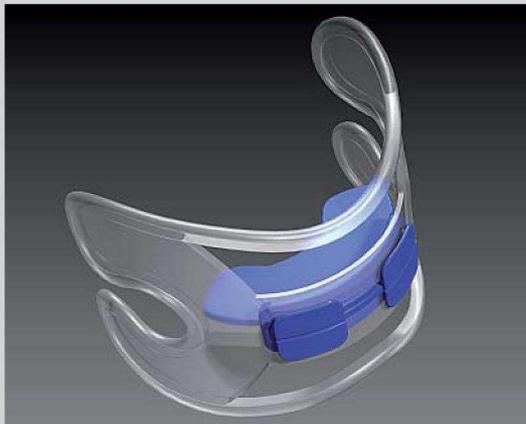


Figure 6.
New design for anti-bruxism device.

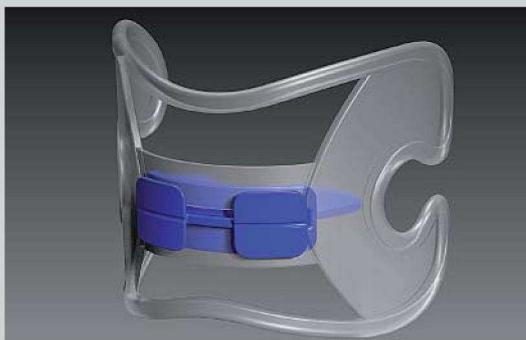
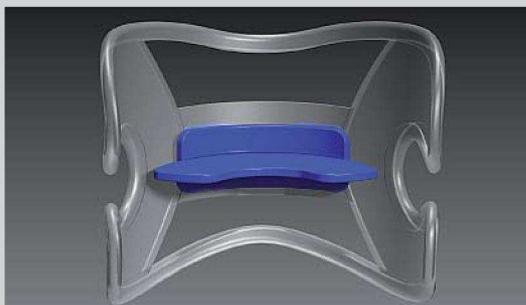


Figure 7.
New design for anti-bruxism device.



developed in different sizes (Figure 4) to allow for adjustment of the necessary size in each clinical case.

The patient uses it at night and places it at vestibule level. The immediate clinical effects are the following:

- Maintains the mouth in a position with the mandible open.
- Absence of contact between the posterior teeth.
- Relaxation of the orbicular muscles.
- Relaxation of the masticatory muscles.

When used, patients with bruxism will immediately feel a sensation of "occlusal incompetence", i.e., the subjective feeling of an absence of contact between the posterior teeth of the occlusion.

Although this device is manufactured with an elastic material that allows for closure of the mouth (and contact between the posterior teeth), when the patient forces their muscle potential to close the mandible, the posterior action will return to the open mandibular position as it will be uncomfortable for the patient to keep the mouth closed with the teeth in occlusion.

Once this study was completed, a new design was developed for the MFS "muscle relaxant" device, which incorporated an anterior bite plate (Figures 5-7) for the purpose of generated (in the patient) anterior occlusal contacts that impede contact between the molars. In addition, this element, incorporated in the design of the device, would act as a "C-plate", promoting extrusion of the posterior teeth of the occlusion with posterior rotation of the mandible, thereby correcting the patient's anterior overbite.

This new variant in the design of the "muscle relaxant" device converts it into an "anti-bruxism" device that also acts as a corrective orthodontic device for the overbite in the same way as all devices that lift the bite in the anterior section.

This double design, depending on whether or not there is an anterior bite plate, leads us to contemplate two variants of the same underlying apparatus:

- The MFS "muscle relaxant", indicated for patients with a brachyfacial pattern with strong musculature.
- The "anti-bruxism" and/or overbite corrector, indicated for bruxism patients and/or patients with an overbite.

Intense muscle pattern and overbite

Patients with an intense muscle pattern have a strong anterior rotation of the mandible with an overbite at the level of the occlusion. Early correction of the existing dental and skeletal problem must go hand in hand with improvement of their muscle pattern. From there, the clinical action of the "muscle relaxant" (inhibiting nocturnal activity of the grinding masticatory muscles) will be empowered by incorporating the anterior bite plate in the design. This will act on the dental occlusion (overbite) and

develop and reposition the mandible (posterior rotation), with the resulting functional improvement in the growth pattern through action generated by stretching the masticatory muscles.

The new MFS "anti-bruxism", therefore, provides the clinical benefits of "muscle relaxation" and, in addition, the results expected with the use of an anterior bite plate or elevation plane, used in both the removable apparatus as well as the fixed apparatus ("turbo-bite, BACO).

Indications for the MFS "muscle relaxant" devices and the new "anti-bruxism" device

While the "muscle relaxant" aims at inhibiting muscle activity, the "anti-bruxism" device also acts at the level of the occlusion through a double action:

- Introducing incisive contact (bite plane), avoiding posterior occlusal contact that is strengthened by bruxism.
- Acting on tooth eruption, promoting extrusion of the posterior tooth sectors, correcting overbite at the incisors.

Aims of this study

This study was developed in accordance with the following aims:

- To determine the subjective score for clinical symptoms rated by patients with bruxism (evaluated in three levels: good, normal and poor) after using the "anti-bruxism" device.

To determine the number of nocturnal bruxism events with the use of the "anti-bruxism" device, measured with the "Bite-Strip", in comparison with their initial score.

Materials and methods

For this study, sixty (60) patients with bruxism, 30 men and 30 women, were selected. These patients had achieved a double score with the "Bite-Strip", a maximum intensity level of which was three (3), for two consecutive nights, and had partners who had reported "night-time noises" (teeth grinding).

They were invited to use the "anti-bruxism" device each night for one week. At the end of this period, they once again took their score using the "Bite-Strip", over two consecutive nights, and the results were recorded.

At the end of the test, each subject was told to describe their improvement in relation to the following symptoms:

Morning facial fatigue. - Morning facial pain.

- Headaches.
- Night-time noises or teeth grinding (as indicated by the partner).

The patient had to note: "poor" (P) if there were no apparent changes; "normal" (N) if there was some improvement; and "good" (G) if improvement was considered complete.

The statistical score was then scored after the data was collected.

Results obtained

After evaluating the changes recorded using the use of the "Bite-Strip", the results were the following:

Descriptive statistics of the 4 variables studied were drawn up, using the minimum, maximum, arithmetic mean and standard deviation (Tables 1-5).

| | N | Minimum | Maximum | Mean | Stand. dev. |
|--------|----|---------|---------|------|-------------|
| Onset1 | 60 | 3 | 3 | 3.00 | 0.000 |
| Onset2 | 60 | 3 | 3 | 3.00 | 0.000 |
| Final1 | 60 | 0 | 3 | 0.77 | 0.909 |

Table 1. Descriptive statistics

Table 2. Onset1

| | Frequency | Percentage |
|--------|-----------|------------|
| Final2 | 60 | 0 |
| | | 3 |
| | | 0.70 |
| | | 0.869 |

Table 3. Final1

| | Frequency | Percentage |
|---|-----------|------------|
| 3 | 60 | 100.0 |

Table 4. Onset2

| | Frequency | Percentage |
|---|-----------|------------|
| 3 | 60 | 100.0 |

Table 5. Final2

| | | |
|---|----|------|
| 0 | 29 | 48.3 |
| 1 | 20 | 33.3 |
| 2 | 7 | 11.7 |
| 3 | 4 | 6.7 |

| | | |
|-------|----|-------|
| Total | 60 | 100.0 |
| 0 | 31 | 51.7 |
| 1 | 19 | 31.7 |
| 2 | 7 | 11.7 |
| 3 | 3 | 5.0 |
| Total | 60 | 100.0 |

Once the frequency tables were drawn up for the final scores 1 and 2, we found that, in both cases, 50% of the values were 0 and only 6.7% and 5%, respectively, continued to have a score of 3.

Table 6.

| Initial 1 -Final 1 | | | | |
|--------------------|---------------------|--------|------|----------|
| Mean | Standard deviation. | t | d.f. | Sig. |
| 2.23 | 0.909 | 19.035 | 59 | P<0.0001 |

Table 7.

| Initial 2 -Final 2 | | | | |
|--------------------|---------------------|-------|------|----------|
| Mean | Standard deviation. | t | d.f. | Sig. |
| 2.30 | 0.869 | 20.49 | 59 | P<0.0001 |

Table 8.

| Initial 1 -Final 1 | | | | |
|--------------------|---------------------|---|-------------|--|
| Mean | Standard deviation. | 95% Confidence Interval of the difference | | |
| | | Lower limit | Upper limit | |
| 2.23 | 0.909 | 2.0 | 2.46 | |

Table 9.

| Initial 2 -Final 2 | | | | |
|--------------------|---------------------|---|-------------|--|
| Mean | Standard deviation. | 95% Confidence Interval of the difference | | |
| | | Lower limit | Upper limit | |
| 2.30 | 0.869 | 2.07 | 2.52 | |

Table 10.
Wilcoxon test for paired data

| N | | Mean range | Sum of ranges | z | Sig. |
|-----------------|-----------------|------------|---------------|------|--------|
| Final1 - onset1 | Negative ranges | 56(a) | 28.50 | 6.66 | 0.0001 |
| | Positive ranges | 0(b) | 0.00 | | |
| | Ties | 4(c) | | | |
| | Total | 60 | | | |

a: Final1 < Onset1; b: Final1 > Onset1; c: Final1 = Onset1

Table 11.
Wilcoxon test for paired data

| N | | Mean range | Sum of ranges | z | Sig. |
|-----------------|-----------------|------------|---------------|------|--------|
| Final2 - onset2 | Negative ranges | 57(a) | 29.00 | 6.73 | 0.0001 |
| | Positive ranges | 0(b) | 0.0 | | |
| | Ties | 3(c) | | | |
| | Total | 60 | | | |

a: Final2 < Onset2; b: Final2 > Onset2; c: Final2 = Onset2

When calculating the differences between an initial score of 3, with the final score on the two evaluations, the mean differences were 2.23 and 2.3, respectively. The 95% confidence intervals were calculated in order to quantify the decreases (Tables 6-9). The means between the initial and final values (2.23 and 2.3 coding units for the "Bite-Strip") indicate the large level of improvement in the number of bruxism events, in the patient sample, following night-time use of the MFS "muscle relaxant" element.

When applying Student's t test for paired data in both scores, we found significant differences between the initial and final scores, with t=19 and t=20.5, with very small probabilities of error when reaching this conclusion.

If we consider the evaluation by individuals with four scores 0, 1, 2 and 3 as a measure on an ordinal scale, it would be logical to apply the nonparametric Wilcoxon test for paired data between the initial and final situation. In the two tests, we found significant differences between the initial and final situations, with very low levels of significance (Tables 10 and 11).

The final scores were studied using descriptive statistics and by calculating the difference between the two measurements (Tables 12-14).

We can see that the mean difference is 0.067, a value near 0. In other words, no difference between the observations. On 80% of occasions, the value is 0, on 7% it is -1 and on 13% the difference is 1.

No statistically significant differences were found between these two scores when applying Student's t test or the Wilcoxon test (Tables 15-18).

Finally, we calculated the Kappa concordance index in the score, which gave a value of 0.681,

A level of significance less than 0.0001, which allows us to confirm that there is conformity between the two observations (Table 19).

With regard to the subjective score, Figure 8 shows the description of the results, with a score of 1 (good), 2 (normal) or 3 (poor) answered by the patients. We can confirm that the majority of subjects indicated an improvement in bruxism and their symptoms.

Discussion

With the results obtained from the entirety of the sample, we can confirm that we have a double score indicating improvement in bruxism after using the MFS "muscle relaxant" device.

- An objective score, from the "Bite-Strip" used as a single-channel electromyographic diagnostic method, which allows us to reliably determine the number of nocturnal bruxism events by the patient before and during the use of the muscle relaxant or MFS anti-bruxism device.
- A subjective score obtained from data provided by the partner, who will indicate the changes by measuring the improvement in the level of tooth grinding the patients experience when asleep, even when they themselves are not aware of it.

The precision and reliability of the "Bite-Strip" as a device for monitoring bruxism during sleep is relevant.

Conclusions

The following conclusions were made at the end of this study:

- From evaluating their clinical symptoms, the subjective changes in patients with bruxism (scored as good, normal or poor) who used the "anti-bruxism" device indicates that the subjects noted a clear improvement, in both men and women.
- The level of night-time bruxism events scored by patients who used, the "anti-bruxism" device, measured with the "Bite-Strip" has decreased significantly, from an initial mean of 3 prior to using the anti-bruxism device, to a final mean of 0.73 after using the anti-bruxism device.

| | Measurement | N | Standard deviation. |
|--------|-------------|----|---------------------|
| Final1 | 0.77 | 60 | 0.909 |
| Final2 | 0.70 | 60 | 0.869 |

Table 12. Related sample statistics

| | Frequency | Percentage |
|-------|-----------|------------|
| -1.00 | 4 | 6.7 |
| 0.00 | 48 | 80.0 |
| 1.00 | 8 | 13.3 |
| Total | 60 | 100.0 |

Table 13. Final1- Final2

| | N | Minimum | Maximum | Measurement | Standard deviation |
|--------------------|----|---------|---------|-------------|--------------------|
| Ended 1 – Ended: 2 | 60 | -1.0 | -1.0 | 0.067 | 0.446 |

Table 14. Descriptive statistics for difference in final scores.

| Measurement | Final 1 – final 2 | | | |
|-------------|---------------------|------|------|-------|
| | Standard deviation. | t | d.f. | Sig. |
| 0.067 | 0.446 | 1.16 | 59 | 0.252 |

Table 15. Comparison of means for final scores

| Measurement | Standard deviation. | Final 1 – final 2 | |
|-------------|---------------------|-------------------|-------------|
| | | Lower limit | Upper limit |
| 0.067 | 0.446 | 0.05 | 0.18 |

Table 16. 95% Confidence Interval of the difference between scores

| | Final 2 | | | | |
|--------|---------|----|----|---|-------|
| | 0 | 1 | 2 | 3 | Total |
| Final1 | 0 | 25 | 4 | | 29 |
| | 1 | 6 | 14 | | 20 |
| | 2 | | 1 | 6 | 7 |
| | 3 | | | 1 | 3 |
| Total | 31 | 19 | 7 | 3 | 60 |

Table 17. Table of Final1 * Final2 contingency

| | | Mean range | Sum of ranges | z | Sig. |
|-----------------|-----------------|------------|---------------|------|-------|
| Final2 - Final1 | Negative ranges | 8(a) | 6.50 | 1.15 | 0.248 |
| | Positive ranges | 4(b) | 26.00 | | |
| | Ties | 48(c) | | | |
| | Total | 60 | | | |

Table 18. Ranges

a: Final2 < final1; b: Final2 > final1; c: Final2 = final1

| | N | Value | Standard deviation. | Approximate sig. |
|-----------------|----|-------|---------------------|------------------|
| Kappa agreement | 60 | 0.681 | 0.084 | 0.0001 |

Table 19.
Symmetric measures

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