

Freely available or over-the-counter occlusal splints obtainable in commercial outlets: a reality dentists should know.

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Abstract: Aim and objective: Bruxism is defined by The American Sleep Disorders association as “tooth grinding during sleep plus tooth wear, sounds or jaw muscle discomfort in absence of medical disorder. People are obtaining over the counter splints (OTC) as a possible alternative to manage bruxism without the need for dental assessment. The aim of this study is survey OTC bruxism splints available in Chile through the internet or other commercial outlets, categorize their characteristics, claims, safety warnings and contrast it with scientific evidence. Materials and Methods: An internet search was made for OTC bruxism splints available in Chile. Only Chilean domains were evaluated. Information recorded was manufacture, name of the device, splint design, material, adjustability, price, claims and safety warnings. Results: five devices were found in our search. Only one is from a Chilean laboratory, being the most accessible. All devices have a full coverage splint design. the material made of is only described in one and their prices in the market are very dissimilar. The most usual advertising was “Eliminate Bruxism. Stop Night-Time Grinding & Clenching”. Two manufactures suggest that the device will help to sleep better. No manufacture provided a guide for how long each day the splint must be worn. Conclusion: Dentists should be aware to keep this market in mind when reviewing patients if there have been unexplained occlusal changes or other problems. Bruxism is often a long-term problem and with any type of bruxism appliance the importance of regular review by a professional is critical.

Keywords: Occlusal splint; bruxism; temporomandibular joint.

INTRODUCTION.

With the boom of the Internet and social media networks, it is common to see self-medication and self-treatment. Self-medication has traditionally been defined as “the taking of drugs, herbs or home remedies on one's own initiative, or on the advice of another person, without consulting a doctor”.¹

Families, friends, neighbors, the pharmacist, previously prescribed medications or suggestions from newspapers, popular magazines and commercial advertisements are common sources of ideas about self-medication and self-treatment.² Dentists should be aware of this, so that we can evaluate, educate and guide our patients in the best possible way when asked about these issues.

Not only are people increasingly aware and informed about health-related conditions, but they can now obtain over-the-counter occlusal splints at commercial outlets as an alternative, in an attempt to manage

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their bruxism without the need for a dental or medical consultation.³ Bruxism is defined by The American Sleep Disorders association as “tooth grinding or clenching during sleep plus one of the following: Tooth wear, sounds or jaw muscle discomfort in the absence of medical disorder”.⁴ Even if the occlusion is affected by this activity, it is not its cause, and sleep bruxism is now considered a centrally mediated sleep-related disorder.⁵

Bruxism can occur during sleep (SB) or during wakefulness (AB), both may be classified into Primary, when not related to any other medical condition; or Secondary, when associated with neurological disorders or as a result of an adverse effect of drugs.^{6,7}

AB is usually seen as a habit of tightening the jaw that appears in response to states of stress or anxiety,⁸ whereas sleep bruxism represents a sleep related rhythmic masticatory activity generally associated with arousals from sleep.^{9,10}

Treatments for primary awake bruxism is challenging. As increased levels of anxiety and somatization symptoms have been reported in these patients, interventions such as counseling regarding triggers, habit modification, relaxation therapy, or biofeedback have been suggested as appropriate managing techniques.¹¹ As such treatment cannot be limited to occlusal splints only.

While it is true that Occlusal splints have been considered as the first-line strategy for preventing dental grinding noise and tooth wear in primary sleep bruxism, it should be also supplemented by advice and occasional pharmacological intervention.¹²

People and patients are not aware of the factors that are considered when a specialist in the area indicates and prepares an occlusal splint. Critical aspects such as design, coverage, material and the extension of the occlusal contacts play a fundamental role in its preparation and in the purpose of the splint. In addition, and although rare, occlusal splints can make breathing worse during sleep in patients with obstructive sleep apnea (OSA) and, thus, special care should be taken when treating sleep bruxism in this population.¹³

Free trade or over the counter occlusal splints are for sale in supermarkets, pharmacies and websites. Unfortunately, they are not yet regulated by the Public Health Institute of Chile and come in a variety of

designs allowing them to be fitted to different jaw sizes. The most striking topic about these devices is that many claim to eliminate bruxism.³

As with prolonged use of any intraoral device, individuals may be at risk of developing dental problems such as undesired occlusal changes, mucosal trauma, and dental disease.¹⁴ Even while using a professional occlusal splint (PS) undesired occlusal changes may occur,¹⁴⁻¹⁶ which is why follow-up sessions are so important.

This information may not be known by the individuals who purchases these devices over-the-counter (OTC) and there appears to be no liability on the part of the manufacturer or the laboratories in case the patients or clients develop adverse side effects when using these OTC splints.³ The aim of this study is to analyzed freely available or over-the-counter occlusal splints obtainable in commercial outlets for individuals in Chile, without the supervision of a professional, in stores or via the Internet, categorize their characteristics, claims and safety warnings, contrast it with scientific evidence and ethics.

MATERIALS AND METHODS.

This descriptive, cross-sectional and exploratory study was based on a global Internet search conducted in March 2018 for OTC or freely-available bruxism splints, as a pilot study to evaluate the validity and reliability of the proforma, study design, and calibration of the examiners. The data regarding freely available or OTC splint were recorded through observation and collected in Microsoft Excel (2017).

A second internet search was conducted in April 2018 for OTC bruxism splints available in Chile. Only Chilean domains were evaluated. The inclusion criteria were the OTC occlusal splints or free trade that are sold in authorized sales points. The exclusion criteria were OTC splints for sale by unauthorized persons, on the black market, and second-hand OTC splints.

The search engines used were the following:

- www.google.cl
- www.mercadolibre.cl
- www.yapo.cl

The search phrases used were: Bruxism protection “Protección para bruxismo”; Bruxism guard “guardia

para bruxismo”; Bruxism splint “Placa para bruxismo”; Dental Night guard “Protector dental nocturno”.

With each search phrase, five pages of search results were searched for OTC bruxism or free trade tablets and for each over-the-counter splint the name of the splint was used as a search term and five pages of search engine results were perused in order to determine the respective commercial outputs.

Information recorded for each OTC splint included: Name of the manufacturer; Name of the device; Splint Design; Material; Adjustability; Price in US Dollars; Claims; Safety warnings.

The data collection for OTC occlusal splints was performed by two investigators previously calibrated in the pilot study. The database was recorded and analyzed with Microsoft Excel (2017).

Table 1. Summary of splint characteristics.

Origin	Manufacture	Name	Splint design	Material	Adjustability	Price USD
Chile	La Prepie Laboratories	Drimwell	Full coverage	---	One size fits all	32.9
USA	The Doctor’s	Night guard advanced comfort	Full coverage	---	One size fits all	16.5
USA	Dentalmed	Mounth guard	Full coverage	---	One size fits all	11.9
Taiwan	---	Stop snoring solution	Full coverage	EVA	One size fits all	12.5
USA	Dental Care labs	Mounth guards	Full coverage	---	Self-adjustable pads with four settings	88.0

Table 2. Claims made by the manufacturers for the splints.

Manufacturer claims	Drimwell	Night guard advanced comfort	Mouth guard Dentalmed	Stop snoring solution	Mouth guards Dental Care labs
NO CLAIMS					
Eliminate Bruxism. Stop Night-Time Grinding and Clenching	x	x	x	x	x
Helps prevent damage from teeth grinding	x	x		x	x
Helps you sleep more comfortably	x				x
Inexpensive device to reduce life stress	x				x
Better recovery while sleeping	x				x
Wake up with no pain	x				x
Similar to the dental protectors prescribed by many dentists for nighttime teeth grinding		x			
Made of high quality silicone material BPA and latex free		x			
Moldable to all different mouth shapes alignments and teeth sizes for custom fit		x	x		
Can be used as an athletic mouth guard			x		
Can be used as a teeth whitening tray			x		
Dental protector should last approximatedly six months		x			
Stop snoring			x		
Relax jaw muscles					x
Alleviates facial muscle pain, spasms, neck and joint pain, shoulder pain and headaches					x

Table 3. Splints safety warnings.

Safety warnings	Drimwell	Night guard advanced comfort	Mouth guard Dentalmed	Stop snoring solution	Mouth guards Dental Care labs
None			x		x
Do not use if					
If you are under eighteen years old	x	x		x	
If you wear braces, dentures, or other dental product	x	x			
if you can wiggle any of your teeth	x	x			
If your dentist has told you that you have TMJ	x	x			
If you have any tooth or jaw pain or pain with bruxing or tooth grinding	x	x		x	
As an athletic mouth guard. Product does not absorb shock	x	x			
For more than three months without consulting you dentist	x	x			
Ask a dentist before use if you have					
Loose fillings, loose caps or cavities with no filling	x	x			
Clicking of your jaw	x	x			
Jaw pain, teeth pain, face pain or have difficulty chewing	x	x		x	
Mouth sores	x	x			
Gum disease or bleeding gums	x	x		x	
Serious breathing, respiratory or other health problems	x	x			

Table 3. Splints safety warnings.

Safety warnings	Drimwell	Night Guard advanced comfort	Mouth guard Dentalmed	Stop snoring solution	Mouth Guards Dental Care labs
WHEN USING THIS PRODUCT					
See your dentist every six months	x	x			
STOP USE AND ASK A DENTIST IF					
The symptoms persist					
after several weeks of use	x	x			
The product easily falls out of your mouth.					
The product causes you to gag or feels uncomfortable.	x	x			
You have bleeding gums, soreness, or other reactions inside your mouth	x	x			
You notice new symptoms (jaw pain, teeth pain, ear pain, headache ,neck stiffness, or joint clicking) because of the product	x	x			
You have loose teeth or a change in your bite that lasts more than a few minutes after removing the product	x	x			
Stop using if you have sleep apnea				x	
Stop using if you have epilepsy				x	

RESULTS.

The splints available on Chilean websites and their characteristics are summarized in Table 1. We found five devices that met the inclusion criteria. Only one is from a Chilean laboratory (Drimwell), being the most accessible and readily available in commercial positions, sold in all pharmacies throughout the country. Three are from the USA, and one is from Taiwan without an associated manufacturer (Stop-Snoring).

All devices have a full coverage splint design, the material they are made of is described only for the Stop-Snoring splint, which is ethylene-vinyl acetate (EVA). EVA has proven to be a suitable material for the manufacture of sports mouth guards. In addition, it has shown good results in force dissipation and demonstrated shock-absorbing abilities and a great potential for protection.¹⁷

The market prices are very different, ranging from 11.90 to 88.00 US (Table 1).

The adjustment capacity is the same for four of five devices, since all are “one size fits all”. Only Mouth Guard from the USA comes with self-adjusting pads, with four configurations: there are four sizes pads (2 upper and 2 lower) that the buyer should choose according to comfort level. All the splints had the same following adjustment instructions: Boil and bite; mounted as thermoplastic sport mouth guard and adjusted by the individual with scissors. (Table 1)

The types of manufacture’s claims for their devices are tabulated in Table 2. The most usual advertising was “Eliminate Bruxism, Stop Night-Time Grinding & Clenching”, follow for “Helps prevent damage from teeth grinding”. Two manufactures suggest that the device will help to sleep better, reduce life stress and a better recovery while sleeping. Meanwhile one splint claims to help “Stop snoring” and another to “Alleviates facial muscle pain, spasms, neck and joint pain, shoulder pain and headache” as to “Prevents temporomandibular joint disorder”.

Table 3 describes the safety warnings associated with the splints. Two devices do not have safety warnings, both from the USA; two splints have a very detailed 20-item safety warning list intended to avoid any damage to the person using it. One device comes with only six

warnings. Three manufacturers set a minimum age of 18 years to use the device.

No manufacturer provided a guide on how long the splint should be worn per day. Only one splint, Stop-snoring, comes with the warning to stop its use if the client has sleep apnea or epilepsy. (Table 3)

DISCUSSION.

The search for OTC or freely available occlusal splints shows a wide and readily accessible source of occlusal devices available to customer, with accompanying claims of home treatment for bruxism and pain related to fatigue. It is also notable that advertising is carried out in authorized commercial outlets, such as pharmacies, supermarkets and retail stores.

There are many varieties of over-the-counter or OTC occlusal splints available in Chile for any client who wants to buy one. As such, from the patient's point of view, these devices may seem attractive, less expensive and an alternative to a professional splint (PS). Time is another factor to consider, as a PS takes time for its preparation, taking into account the sessions of diagnosis, evaluation and monitoring, while an over-the-counter splint seems to have no need for a dental specialist. Many of these over-the-counter splints come with claims in their advertising to be like those that dentists prepare, or worse, claim they were designed by dental professionals.

Chilean policy is clear with respect to the preparation and commercialization of health devices. These over-the-counter splints are included in the concept of a health device established by article 2 of the Chilean sanitary code,¹⁸ since they state in their advertising that the purpose of the device is the treatment or relief of a disease, which is regulated by the aforementioned article 2. For this sole reason, these freely available occlusal splints should have a health certification or authorization issued by the Public Health Institute of Chile, as established in Article 3,¹⁸ and which they do not currently have. PS are design by dentists and manufactured by a dental laboratory technician, regulated by Chilean norms,¹⁹ which means that only when indicated by means of a dental prescription issued by a professional, may a splint device be manufactured. It is striking, to say the least that commercial outlets are allowed to sell these OTC occlusal

splints without a dental prescription.

The potential bypass of a dental professional that these OTC devices can encourage in patients is worrisome. No suggestion was found about consulting a dentist before using this product, and what is worse, the products provide information and warnings that promote self-diagnosis and self-treatment.³ Nonetheless, there are some recommendations to consult a dentist if some adverse effects or health problems persist while using the devices, and also that the use of these OTC occlusal splints may delay a timely diagnosis. Headaches and facial pain may be associated with different causes and are not always related to bruxism.²⁰

Another problem that arises is that a patient to whom a specialist has prescribed a PS to complement their treatment for bruxism, may decide to buy an OTC occlusal splint as an economic alternative because it was already diagnosed by a dentist.³

OTC bruxism splints have been available in the USA for almost 20 years and they are a prosperous business with growing sales in Europe. This market not only sells prefabricated occlusal splints, as is the case in Chile, but devices with a printing kit with instructions, which are then sent to the manufacturer and a personalized occlusal device is delivered to the customer's address without any control.³

Dentists may be unaware that their patients can circumvent some of their professional services through the Internet. In fact, they may have patients who use freely available or over-the-counter devices and who do not provide this information. As with the prolonged use of any intraoral device, people may have an increased risk of developing dental problems,²¹ so it is critical that the dentist take this market more seriously. A study conducted in the United Kingdom, looked for the associated adverse effects of the OTC splints in the USA database of MAUDE (Manufacturer and User Facility Device Experience). The recorded events included scalding, gingival irritation, gingival damage or recession, mucosal reaction, damaged or painful tooth, damages to restorations, splint broken during use, splint swallowed, occlusal change, product contamination, and systemic reaction.³

An important aspect that we analyze is the design of the splint. In our search, all the OTC splints were of full coverage, but with a standard size that did not necessarily

include the entire dental arch in its fullness. Therefore, no device can guarantee full coverage if there is no professional supervision.

In the case of a professional occlusal splint, many specialists recommend full coverage stabilization splints to spread occlusal contact optimally and avoid unwanted occlusal changes.²¹⁻²³ Several studies have shown that partial splints can generate disorders like condylar fibrocartilage degeneration²⁴ and may have the potential to cause tooth movement via dento-alveolar intrusion of the teeth covered by the appliance, and extrusion or over-eruption of those not covered.²⁵ Partial splints are recommended only in patients that are compromised by dental care and are under professional guidance,¹⁶ which is not the case for OTC occlusal splints.

The freely available or OTC occlusal splints are made from ethylene-vinyl acetate (EVA), a material that may be fitted with heat, and accordingly categorized as soft. Scientific evidence has shown that soft polyvinyl PS are less durable than hard acrylic PS. Soft PS have been found to increase masseter and temporalis muscle activity and may lead to increased muscle pain or discomfort in some patients.²⁶ On the other hand, soft PS could aggravate bruxism, due to premature posterior contacts as these splints cannot be balanced.²⁷ More studies are necessary to investigate if the same occurs for soft OTC splints.

Another study mentions that in a systematic review and meta-analysis of randomized controlled trials, it was found that well-adjusted hard stabilization appliances are more effective in treating joint and muscle pain compared with no use of appliances, and with use of soft stabilization appliances, anterior bite appliances and non-occluding appliances.^{20,25} Therefore, the usage of soft splints, as the case of OTC splints, to treat muscle pain should be ruled out. Moreover, hard PS are suggested to be more effective in reducing bruxism than soft professional splints.³⁰

Professional occlusal splints have been considered as the first-line strategy for preventing dental grinding noise and tooth wear in primary sleep bruxism.²² This device works well for many sleep bruxism patients and even if does not efficiently treat bruxism in all patients it is often used over long periods to protect the teeth in patients who continue to grind.²¹ This information differs from the claims made by freely available or OTC occlusal splints

that these devices eliminate bruxism and teeth grinding, without scientific support.

In our search, some manufacturers claim that their OTC splints eliminate bruxism and stop night-time grinding and clenching. This is not true, it does not eliminate the disorder, only reduces its effects on the teeth.²⁹ On the other hand, bruxism is a multifactorial disorder, and single specific treatments are not available.³⁰ A study of professional occlusal splints used for this purpose concluded that there is not enough evidence to state that the occlusal splint is effective for treating sleep bruxism.³¹ Most papers describe that PS only reduce bruxism activity, but they do not eliminate the disorder.^{29,31}

Manufacturers of OTC occlusal splints claim that freely available splints generate a relaxation of jaw muscles leading to awakening with no pain. As the vertical dimension increases from the occlusal contact on the insertion of the occlusal splint, muscular effort decreases resulting in the relaxing of the muscles.³² A transient effect of reduction in electromyographic activity of the masticatory muscles has been demonstrated, which did not last more than two weeks;³³ this can give the customer a false sensation of relief and correct functioning of the device. However, no OTC occlusal splint indicates how long each device must be worn, some suggest using it for 6 months.

Other claim is that splints alleviates facial muscle pain, spasms, neck and joint pain, shoulder pain and headache. The same review³³ refutes this last even in PS and point out that the occlusal splints are mainly recommended to prevent dentition damage from tooth grinding.

Temporomandibular disorder (TMD) pain management requires various methods of treatment that conform to the origin of the dysfunction including counselling, exercises, occlusal splint therapy, massage, and manual therapy.³⁴

A recent review³³ indicates that is not clear whether the use of a stabilization splint can be beneficial for reducing

pain in TMD, given its therapeutic effect remains controversial; however, it appears to have an undeniable placebo effect for pain management.³⁴

One OTC device claims to help prevent snoring, which is a matter of concern, as albeit rarely, occlusal splints may worsen respiration during sleep in patients with obstructive sleep apnea (OSA) and special care should be taken when treating sleep bruxism in this population.¹³

Even though OTC occlusal splints come with safety warnings, manufacturers don't take responsibility for the adverse side effects that these devices may produce. The dental professional community is also unaware if patients who buy them are following OTC splints instructions. There are no studies that indicate if consumers who have used these devices have had a dental appointment for occlusal changes or dental records regarding the use of OTC occlusal splints.

CONCLUSION.

Many occlusal splints are available through the Internet and at commercial outlets. People without professional knowledge can buy them to solve their bruxism while avoiding the supervision of a dentist. These OTC devices come with many inaccurate claims of a solution to bruxism and general pain. When OTC occlusal splints have safety warnings, they are not enough, and these devices can confuse the client or promote self-diagnosis and self-treatment. The market for OTC occlusal splints and their operation is disturbing due to advertisements, commercialization and use. We strongly recommend to the dental community report to the appropriate authorities such as the Public Health Institute of Chile and the Dental College problems associated with the use of OTC or freely available occlusal splints. Health Dental authority should be aware and remain alert as this market is thriving in developed countries and we expect Chile to be no exception.

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