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Over the Counter (OTC) bruxism splints available on the Internet

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Over the Counter (OTC) bruxism splints available on the Internet

Abstract

Some individuals may now be bypassing their dentists for treatment of bruxism. Self-diagnosed, self-adjusted and self-monitored consumers can access Over the Counter (OTC) bruxism splints via the Internet. This paper aims to raise awareness and categorize the types of splint available. Whilst some may regard this market as benefitting consumers there are potential pitfalls which need to be highlighted. These include unevidenced claims of efficacy. Safety information is notable for its paucity and is totally lacking on many internet sites. However, manufacturers are not obliged to display safety information on the internet, but it must be provided with the product. A search of the MAUDE database showed a number of potentially serious adverse events associated with these splints including choking hazards, tissue damage and occlusal changes. None of the splint designs assure full occlusal coverage. As with any partial coverage appliance, if worn for protracted periods there may be a risk of unwanted tooth movement. Dentists should report or assist patients with reporting suspected adverse events with OTC splints to the relevant Competent Authority. In the UK this is the Medicines and Healthcare Products Regulatory Agency (MHRA).

Introduction

Bruxism, as recently defined by an International expert group, is *“a repetitive jaw-muscle activity characterised by clenching or grinding of the teeth and/or by bracing or thrusting of the mandible. Bruxism has two distinct circadian manifestations: it can occur during sleep (indicated as sleep bruxism) or during wakefulness (indicated as awake bruxism)”*.¹ It is a common disorder affecting an estimated 16% of the adult population for sleep bruxism and 24% for awake bruxism.² Clearly some subjects will be affected by both types of bruxism. Bruxism is a persistent but fluctuating problem in many subjects³

Whilst patients can be counselled to help control awake bruxism other methods are needed to control sleep bruxism, particularly when patients develop associated symptoms of jaw or tooth pain, or where they wish to protect teeth or restorations from damaging occlusal forces. It should be emphasized that whilst the occlusion is at the receiving end of parafunctional activity it is not the cause of it and sleep bruxism is now regarded as a centrally-mediated, sleep-related disorder.⁴ Consequently, it is inappropriate for dentists to recommend invasive treatments to correct occlusal

discrepancies as a primary treatment for bruxism (although in order to improve predictability, it is sensible to avoid incorporating occlusal discrepancies in bruxists who require restorative treatment). Nowadays, non-invasive treatments for bruxism are recommended including occlusal splints of various designs supplemented by advice and occasional pharmacological intervention. Despite the lack of substantial scientific evidence supporting any particular splint design as being effective in reducing bruxism many authorities still recommend full coverage stabilization splints² to spread occlusal contact optimally⁵ and avoid unwanted occlusal changes.⁵⁻⁷ The full coverage stabilization splint which is also used extensively for the management of some temporomandibular disorders (TMD) is generally regarded as a safe option.^{8,9} Clinically when adjusted properly it works well for many sleep bruxism patients, but it is not a panacea with the response of patients being variable and unpredictable¹⁰. Whilst the stabilization splint does not efficiently treat bruxism in all patients it is often used over long periods to protect the teeth in patients who continue to brux.¹⁰ Contraindications to this type of splint are not absolute but include sleep apnoea^{11,12} and unstable disc displacements with reduction.¹³

Another type of full coverage splint is the soft splint - a popular choice with many dentists being quick and easy to fit. Clinically some patients are happy with this appliance, but others find their bruxism aggravated more than in patients wearing stabilization splints.¹⁴ Whether this effect results from the resilient nature of the material or the splint's unprescribed occlusion is not known.

There are also dentists who advocate partial coverage splints such as the NTI-TSS splint which in some patients may successfully reduce clenching⁶ or may be helpful as a short-term treatment for acute TMD. However to avoid unwanted occlusal changes, dentists fitting such appliances are advised to fit them only in those patients who are likely to be compliant with follow-up appointments.^{6,9}

Nowadays, the Internet has added a new dimension to dentistry. Not only are individuals increasingly aware and informed of health related conditions they can now obtain Over the Counter (OTC) appliances online as a possible alternative in an attempt to manage their bruxism (also for snoring and sleep apnoea) without the need for a dental or medical consultation. In the context of this paper an individual buying an oral device without advice or supervision of an appropriate Dental Healthcare Professional is termed a "consumer". A "patient" is defined as an individual under treatment by a Dental Healthcare Professional. An individual may be both a patient and a consumer if they omit to tell their dentist that they are using an OTC splint.

OTC splints originated in the USA but are increasingly available in the UK and other parts of Europe. Companies are distributing online and via other commercial outlets (e.g. pharmacies and supermarkets). There is also a trend for some dentists to sell OTC appliances directly to patients. OTC splints come in a variety of designs allowing them to be fitted to different jaw sizes.

The aim of this paper is to survey OTC bruxism splints available to individuals in the UK via the Internet, categorize their characteristics, and determine any web-based claims or safety warnings. Further, an online search was made for possible complications including unwanted occlusal change. Finally, advice is given regarding the UK regulation of these appliances and the need for appropriate reporting.

Materials and Method

An Internet search was made (10/03/2013) of OTC bruxism splints available in the UK and determine if these were also available in the USA. The search engines and phrases used are shown in table 1. With each search phrase ten search engine pages were searched for OTC bruxism splints. Sites were identified as UK sales points if prices quoted were in Pounds Sterling or US sites if in Dollars. For each OTC splint the name of the splint was used as a search term and pursued for ten search engine pages to determine the respective retail outlets.

The following information was recorded for each OTC splint: the name of the manufacturer, name of the device, its UK price and any claims and safety warnings made either on a major UK retail website or via other UK web retail outlets. In addition, a note was made of any web-based mention of “CE marking”, indicating compliance with the EC Medical Devices Directive’s requirements for safety, quality and performance. In the context of performance this does not need to be supported by clinical trial data to show efficacy and safety if a manufacturer or supplier submits a medical device as low-risk.

The manufacturer’s claims posted on the UK websites were tabulated and two of the authors (RWW and LV) categorised them into a number of common themes. A similar approach was made for any caution notice or safety advice existing on the relevant UK website.

A classification of OTC bruxism splints was devised by grouping the splints according to similarity in design. The classification considered the broad type of design and whether it potentially provided full coverage of all the teeth in one arch or was specifically partial coverage. The classification also took into account splint adjustability. In order to check appropriate classification a splint from each

manufacturer was ordered on line for physical inspection. In all 22 splints were ordered, including three OTC impression systems.

The Internet search was repeated (04/07/13) using the same protocol to corroborate the findings of the March survey. This July survey identified any further splints being marketed in the UK as well as any additional or changed claims and safety warnings. A note was made of any splints no longer being sold since the first survey and any identified checked online (15.07.13). The web pages were all copied via the “print screen” command and saved as Word files allowing the table contents to be cross-checked by a second investigator.

Online search for associated adverse events

To determine if OTC bruxism splints had been associated with any adverse events a generic search in the U.S. Food and Drug Administration’s (FDA) “Manufacturer and User Facility Device Experience Database” (MAUDE)¹⁵ was carried out. The following strategy was used: Go to Simple Search → Search term: Bruxism; Date Report Received by FDA: ALL YEARS (i.e. between 1992 and 2013). The results were hand searched to select OTC bruxism splints from other products. Subsequent search terms were used to generate additional hits. These included all the generic terms derived from the product names in table2 (“grinding guard” “grinding gard”, “night guard”, “nightguard”, night-guard, “bite guard”, “dental splint”, “dental guard” and “bruxo”) and the product names themselves. Reports of reactions to splint cleaning products were not included, neither were in-surgery devices customised by the dentist. By carrying out the search on the same computer all previously viewed database entries were highlighted allowing irrelevant products and those previously selected to be excluded. Each set of searches was saved as a Word File. Any duplicate entries were excluded and multiple reports for the same incident were collated into a single entry. For each entry the reporter (manufacturer, consumer or dentist), incident summary and date were identified. Common themes to describe the various incidents were agreed between three of the authors (RWW, FL & SD).

Results

The splints available from UK websites and their characteristics are summarised in table 2 with sub-tables explaining the codes used to summarise the manufacturers’ claims and the Internet based safety warnings. Table 2 shows in white those splints that were available in both the March and July surveys. The boxes shaded grey identify splints introduced after the March survey. Prices, manufacturer’s claims and Internet based safety warnings relate to the July survey. Where any significant change in claims or safety warnings had taken place between the two surveys these are mentioned within the text below.

In the March survey a total of 22 different splints supplied by 13 manufacturers/suppliers were identified with all but one of the manufacturers selling their products via a single major UK retail website. One of the splints is not shown in the table as it was no longer available in the July survey. This was a laboratory made splint made from a self-recorded impression. Eleven of the 22 splints available on UK websites were also available on USA websites. In the July survey the number of splints available in the UK had risen to 37 and the number of manufacturers/suppliers to 23. Twelve of the 37 splints were also available on USA websites.

Four generic designs were identified, three of them having the potential for full coverage whilst one design was intentionally partial coverage:

1. *The unretentive gutter* – a U shaped plastic device placed between the dental arches and adjusted by the individual with scissors
2. *Bite pads on posterior teeth* – the pads are connected bilaterally to buccal flanges in the molar/premolar regions. The buccal flanges are in turn connected by a thin plastic strap that sits in the lower buccal sulcus. The individual can adjust the pads using a number of different settings depending on lower arch size. As with the “unretentive gutter” there is no retention provided from the teeth with the inter-occlusal portion balanced between the upper and lower arches
3. *Boil and bite* – Fitted in the same way as a thermoplastic sports mouth guard and adjusted by the individual with scissors
4. *Self-impression kit* – The individual is sent an impression kit (tray and putty) and returns the self-made impression to a commercial laboratory. A soft, vacuum formed splint is custom made by the laboratory and returned to the individual.

As only one manufacturer mentioned CE certification online this information was not tabulated. The need for CE certification to accompany the product when delivered to the end-user will be raised in the Discussion.

OTC bruxism splints ranged in price from £0.01 to £61.00, but postage and packing could add as much as £17.00 to the price, particularly if the appliance was sent via a UK retail website but from a supplier outside the UK. Some appliances are sold in packs of two or four.

The types of manufacturers’ claims for their products can be seen in the Sub-table (i) of Table 2. Some of the claims were available on the main UK retail website whilst others were only available on the manufacture’s/supplier’s website. The most common claim (16 splints) was “Protects teeth/restorations from grinding /clenching/bruxism”. Other commonly made claims (four to six

splints) suggested that splints “Protects the TMJ” or “Cures/treats/reduces/helps/prevents bruxism” or reduces unspecified symptoms. Five products carried a claim of “Headaches/facial pain/jaw pain reduction whilst one claimed to improve sleep/reduce sleep disruption. Six products claimed to be similar to professionally made splints but less expensive. Some manufactures/suppliers made claims about splints in general but not necessarily about the product on sale.

There was a variety of Internet based safety warnings as seen in the Sub-table (ii) of Table 2. Again, some of this information was only available on the manufacture’s/supplier’s website. One splint was supported by a comprehensive list of 19 safety items, but 14 splints carried no safety information on their websites. Detailed safety notices comprising 15-16 items were provided for five splints in the March survey, but in the July survey these had all been removed by one manufacturer and reduced to two items by another. Strangely, one manufacturer in the March survey advised their Grinding Teeth Guard; Berry Flavour ‘Not to be used as a nightguard to prevent against bruxism’, however, in the July survey that solitary warning had been removed. There was an inconsistency in the minimum age with three manufactures each recommending 10, 14 and 16 years respectively. A further three manufacturers set the minimum age at 18. No minimum age was mentioned by the other 17 manufacturers.

Only two manufacturers provided a guide to how long each day the splint should be worn. One recommended no more than 12 hours in each 24 hour period for three months before consulting a dentist. The other endorsed wear of the splint throughout the day or the night to help relieve tooth grinding symptoms.

Online search for associated adverse events

The results of the MAUDE adverse events database are shown in table 3. In total 20 reports were identified relating to those found for the OTC bruxism splints. Only the generic terms “bruxism”, “grinding guard” and “nightguard” generated relevant entries; one further entry was discovered by sequentially entering all the product names. Summaries of the adverse events are shown in table 4 whilst the themes describing the types of event are shown in Table 5. Eleven adverse events were reported by manufacturers and 9 by consumers. No reports were made by dentists. All of the reports except three were made between 2008 and 2013.

Discussion

This Internet survey clearly indicates the variety of OTC bruxism splints currently available to individuals in the UK. From a customer’s perspective this market may appear attractive giving freedom of choice and being less expensive than a splint fitted and followed up by a dentist. It also

saves time waiting for a dental appointment. The manufacturers and suppliers of OTC bruxism splints can also claim directly (through online or printed information) or indirectly (through promotion and advertising) to have raised awareness of bruxism to consumers and to the dental profession. Indeed, there is some potentially helpful information available to consumers about awake bruxism (e.g. SleepRight provides information for consumers based on a 3 step self-help philosophy of Awareness, Accountability and Behaviour Modification). However, this rapidly emerging market in the UK throws up a number of important issues that the dental profession should be aware of.

Currently, UK dentists may be unaware that consumers can bypass some of their professional services by way of the Internet. Indeed, they may well have patients using OTC appliances who fail to volunteer this information. As with the prolonged wear of any intra-oral appliance individuals may be at greater risk of developing dental problems (e.g. unwanted occlusal changes, mucosal trauma and dental disease where the oral hygiene is inadequate).

OTC bruxism splints have been available in the USA for almost 20 years and are a thriving business. Indicative figures from one manufacturer suggest several hundred thousand splints sold annually in the USA and increasing sales in Europe. In our March survey over half of the companies selling OTC splints in the UK originate from the USA indicating an intention to grow the market this side of the Atlantic. However, our July survey showed only one further USA company entering the UK market which had increased in four months by 68% (in terms of number of different splints). Some of the companies most recently entering the UK market appear to be UK based, but it is difficult to determine from where many of them are trading and whether any are offering the same product, but under different names. Companies include some dental laboratories. These laboratories sell an OTC impression kit but supply a splint customised to fit an individual customer. By the time of the July survey one of these laboratories was no longer advertising. We will consider the UK regulation implications of both mass produced and custom made devices later in the discussion. However, the practice of laboratories supplying an OTC impression kit and a custom made appliance currently falls in a regulatory grey area. The Medicines and Healthcare products Regulatory Agency (MHRA) considers it to be a matter for the professional bodies which in the UK is the General Dental Council who have been made aware of the situation.

The proposed classification system provides a useful tool to differentiate between the growing numbers of OTC bruxism splints available. An interesting trend observed with the July survey is the marketing of several multi-purpose devices to be used not only for bruxism but also as anti-snoring appliances (one product) or bleach trays (five products). Readers should be aware that while “boil

and bite” OTC bruxism splints closely resemble sports mouth guards in appearance the former are classified by the MHRA as medical devices whilst the latter are not. Consequently, sports mouth guards which are used intermittently for short periods are not governed by the same regulatory framework. However, if an OTC sports mouth guard were marketed for the purpose of managing bruxism it would be regulated in the UK by the MHRA.

There are a number of significant pitfalls with consumers buying OTC splints and bypassing their dentist. Not least, it relies on the consumer self-diagnosing their condition which may be more complex than simply one of tooth grinding and clenching. For example, a consumer with facial pain may buy an OTC splint in the hope that it will solve the problem, but the pain may have little or nothing to do with bruxism and the opportunity for a professional diagnosis may be delayed or lost. Alternatively, a consumer may be diagnosed by their dentist, but buy an OTC splint because they find the one provided by their dentist too expensive or too onerous in terms of follow-up requirements. Whilst one manufacturer states in their Internet safety warning that consumers with jaw or tooth pain should ask their dentist before OTC splint use, there are 22 manufacturers in the July survey who make no such recommendation. Consumers may be further confused when they read on one site that an OTC splint may be used to treat jaw pain but other sites say that jaw pain is a contra-indication to use. It would be interesting to know how many consumers with jaw or tooth pain do consult their dentist after browsing an OTC website or, having bought the splint, after reading the accompanying instructions.

Consumers browsing with the intention of buying an OTC bruxism splint on line may find it difficult to gauge how safe these products are: Most web sites (including the major UK retail website and those of the suppliers/manufacturers) either have no safety warnings or only mention a lower age limit. Even then they fail to agree whether this should be age 10, 14, 16 or 18 years. Where safety information is given it is unknown to what extent consumers comprehend or comply with it. Moreover, manufacturers and suppliers may decide for whatever reason to remove safety notices from websites so that information regarding potentially deleterious effects of appliances is no longer available to potential customers. This action was observed with two manufacturers when we repeated our internet survey in July, but we understand that manufacturers and resellers are not legally obliged to give full information online. However, they are obliged to do so when the product is delivered to the end user. As well as providing information, the product needs to be marked with a “CE” mark indicating compliance with the Medical Devices Directive, considered later in the regulatory section of the article.

It is worth emphasising that the major UK retail website, where all but one of the products are sold, issues a legal disclaimer in relation to the web-based information for all their healthcare products. The disclaimer advises consumers not to rely on this information for self-diagnosis or self-treatment. In addition, consumers are advised to read the information and safety warnings that come with products. If the consumer purchases from a UK based seller, they are covered by the UK Distance Selling Regulations.¹⁶ This provides protection for consumers when they enter into a contract with an online supplier. The consumer has seven working days from the day after the receipt of the goods to examine the goods and determine if they are suitable (some manufacturers offer 14 days, but if no information on returns is provided the consumer has up to three months and seven days). If they are dissatisfied for any reason, they can return the goods for a full refund. Similar provisions apply to sellers based in the EU. Assuming the product arrives with the necessary cautions and instructions the consumer has in theory sufficient time to consult the manufacturer or their dentist if they require further clarification. In practice how many take the trouble to do so is unclear and may be worthy of further research.

Consumers will assume that the materials used to make these splints are safe. Clearly, some splints have the potential to leach substances intra-orally as illustrated by the berry and mint flavours of two products. To what extent other substances (e.g. phthalates) leach out is unknown. Under current regulatory arrangements (see below) manufacturers are not obliged to submit clinical trial data for their products showing both safety and efficacy. Neither are there specific ISO (International Standards Organisation) standards for the materials these products are made from as there are for polymeric materials used in dentistry (e.g. denture and orthodontic bases¹⁷). However we understand ISO is becoming aware of the need to consider this further.

As regards efficacy Table 2 shows a wide range of claims being made by manufacturers for their products, but it is difficult to know on what basis they are being made as there is no published research regarding OTC splints. Claims stating that a splint will cure bruxism, reduce headaches and facial pain or improve sleep quality need to be viewed with particular caution. Whilst some claims allude to splints in general, consumers may not unreasonably assume that these apply to the splint on sale without realising that it has no published trial results. In the UK the Advertising Standards Authority is responsible for enforcing codes relating to medical device advertising. These codes are written and maintained by the Committee of Advertising Practice.¹⁸ So far we are unaware of any manufacturer's claims made for OTC bruxism splints being scrutinised by the ASA.

Online search for associated adverse events

The search of the MAUDE database provided a qualitative analysis of the type of problem generically associated with OTC bruxism splints. Although derived from the American experience this information should be helpful to dentists and consumers in the UK. We made no attempt to identify specific manufacturers and splints, although boil and bite splints can be recognised from the scalding incident. No reports were made by dentists, but two consumers had been advised and supported by dentists where extensive remedial treatment was required. Some reported events are of concern, particularly the choking hazard caused by individuals swallowing or inhaling parts of a broken appliance or indeed occasions where the splint is swallowed whole. Patients may wrongly associate local and systemic symptoms with the wear of an OTC splint. Nevertheless, gross gingival trauma, development of Trismus (“TMJ lockjaw”) and changes to the occlusion are events that clearly should not be ignored. We will return to the issue of occlusal changes in the following section.

We acknowledge that this type of search will have shortcomings particularly in respect of under reporting recognized by the FDA.¹⁵ Furthermore, the reports are not evidence of proof of causation. Neither is there sufficient of them to show superiority of one product over another or to identify features of a product predisposing to particular adverse events. Reports of contaminated or potentially contaminated packaging relate to sales from shops rather than Internet trade.

OTC bruxism splints have been available for almost 20 years but MAUDE consumer reports have only really started in the past 5 years. Until recently reporting has not been easy for consumers. The FDA now recognises that the reporting form is “too technical” and has collaborated with consumer groups to produce a more user friendly version.¹⁹ Nevertheless, consumers and dentists need to know that regulatory reporting is expected of them; if not, under-reporting may well continue.

Despite the reports on the MAUDE database there are no published case reports. This may indicate that problems rarely occur with OTC bruxism splints. However, there are case reports and trial data showing occasional problems with professionally fitted appliances e.g. stabilisation splints¹³, soft splints⁷ and partial coverage appliances.⁶ The recurring theme with these reports is the possibility of unwanted tooth movement and occlusal change – particularly with partial coverage splints.

Unwanted tooth movement and partial coverage splints

All of the OTC splints surveyed in this study had the potential to be partial coverage, either by design or as a result of simply not fitting the full arch. This misfit between splint and arch may occur following adjustment of a “one size fits all splint” by an individual using scissors. Alternatively, individuals recording their own impressions prior to splint construction may not include all of the

teeth. They are after all not trained in recording impressions, and taking a good impression on yourself would represent a challenge - even for a dental professional.

The literature reports that partial coverage appliances 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.^{20, 21} The resulting tooth movements can either be planned, as part of some orthodontic or restorative treatment,^{21, 22} or unwanted.^{6, 7, 23} Indeed, recommendations have been made only to prescribe partial coverage splints where dentists are sure of patient compliance with follow-up.^{6, 9}

The potential for tooth movement will increase with prolonged wear of the partial coverage splint. For example, Dahl and Krogstad²⁴ showed that 6-14 months of partial coverage splint wear on the anterior teeth caused a combination of incisor intrusion and molar over-eruption. The incisors intruded by a mean of 1mm while the molars had over-erupted by 1.5mm. It is generally accepted that orthodontic tooth intrusion is not easily achieved but incisors have the potential to intrude more than molars (mean values of 1.5mm compared with 1mm).^{25, 26} Other studies have shown that following extraction unopposed teeth can erupt to varying extents in different patients ranging from 0.5mm to 5.4mm.²⁷

The Gelb appliance is a partial coverage splint which is a custom made appliance for TMD enjoying a period of popularity during the 1980s and 1990s. This appliance only covers the posterior teeth leaving the anterior teeth separated. We know from clinical observations and from study results that in some patients prolonged wear of the Gelb appliance results in posterior open bite, particularly when worn full-time.²⁸ Brown et al²⁸ reported a study of 64 patients wearing Gelb appliances for between 6 months and 4.8 years. A subgroup of 16 patients had complete radiographic records (lateral cephalographs) with the splint removed before and after treatment. All 16 of them had developed posterior open bites following treatment. Various significant tooth intrusions and extrusions were reported for the 64 patients using measurements recorded from the radiographs. However, the mandibular molars did not show significant intrusion. Such measurements may have been subject to inherent methodological limitations¹². Hence, we are uncertain whether the 16 posterior open bites resulted either from changes in tooth position or changes in mandibular posture or both. To what extent these posterior open bites resolved with time was not reported. Clearly, the full-time wear of a Gelb appliance incorporating indentations which hold the jaw forwards is an extreme form of splint therapy. We must emphasise that whilst some OTC bruxism splints superficially resemble the Gelb appliance, they do not have indentations and the instructions

recommend sleep use and not full-time wear. Consequently, any hazard of producing unwanted tooth movement should be much less, if used only for sleep and for limited periods.

In the UK dentists routinely create interocclusal space of 1-2mm for restorative purposes using the Dahl approach.²² This tooth movement is often achieved in only 3-4 months. Hence, many UK and other European dentists increasingly recognise the potential for unwanted occlusal change with prolonged wear of partial coverage appliances. This clinical experience in combination with the above studies illustrate the potential for unwanted tooth movement with any partial coverage splint, particularly in susceptible individuals when worn for protracted periods.

If a consumer buys an OTC bruxism splint without the knowledge and supervision of a dentist, then the potential for unwanted occlusal change is increased as the consumer may not be looking out for it. Furthermore, the insidious nature of occlusal change may allow a considerable change to occur before the consumer becomes aware of a problem. It is assumed that many patients will buy OTC bruxism splints for overnight wear to control the effects of sleep related bruxism. In this respect splint wear occurring during the hours of sleep may be considered “short-term” and an assumption, backed by some bodies of expert opinion, made of low risk. However, patients with both awake and sleep related bruxism may decide to wear their splints for longer periods, particularly if the instructions that come with the splint are unclear about the potential hazards of unwanted tooth movement and the need to limit the amount of splint wear. The low level of evidence based on expert opinion also needs to be born in mind.²⁹ Clearly, it would be helpful if the question of, “what constitutes a safe period of wear of a partial coverage splint?” could be answered with a properly conducted clinical trial. Sufficient numbers of patients would of course be needed to ensure the trial included those who were susceptible to unwanted tooth movement. The ethical considerations of undertaking such a trial would of course need careful consideration.

Given the potential for unwanted tooth movement it is surprising there are only two MAUDE database entries and no published case reports of this occurring with OTC bruxism splints. Perhaps one of the reasons is not being 100% sure about proof of causation. Individuals buying OTC splints will rarely have comprehensive records for comparison. In the vignette (see Text Box 1) the only evidence that the teeth had moved was based on retrospective information: the patient history, the occlusal analysis and the two DPT radiographs. Other factors such as the unerupted wisdom teeth, differences in x-ray machines, TMD symptoms and masseteric hypertrophy complicate the presentation in this case. Nevertheless, where dentists have a strong suspicion of causation they have an ethical obligation to assist their patients in reporting safety issues to the relevant regulatory agency. Moreover, if the dentist has prescribed the OTC splint he or she has a professional obligation

to do so – much in the same way as UK doctors do with the “Yellow Card” system used for reporting suspected side effects with drugs. This obligation, previously implicit in General Dental Council’s Standards for Dental Professionals³⁰, has become explicit in the new Standards published September 2013.³¹ Indeed, both the General Medical Council³² and the Royal College of Surgeons³³ are now also keen to emphasise the responsibility of health care professionals in reporting problems with medical devices.

European Regulation and reporting problems with OTC bruxism splints

UK Dentists will be aware of the MHRA in relation to prescribing custom made appliances. The MHRA is also the Competent Authority in the UK in relation to OTC bruxism splints. Other countries in the EU have their own Competent Authorities which have similar arrangements to the MHRA.

Manufacturers self-certify the risk level of their products and, on the basis that bruxism splints should just be worn overnight, the EC Medical Devices Directive agrees with them being categorised as Class 1 Medical Device or “low risk”. As the market for medical devices, including OTC bruxism splints, is international the evidence presented by manufacturers may include certification or approval from other authorities (e.g. the FDA in the USA).

Responsible manufacturers need to comply with the requirements operating in the country where they wish to sell their products. Within the UK and most other European countries manufacturers of OTC bruxism splints must deliver appropriate literature (indications, instructions and cautions) to the end user and mark their OTC products with a “CE mark”. The CE mark indicates compliance with the EC Medical Devices Directive’s requirements for safety, quality and performance. For Class I appliances manufacturers have to self-declare compliance by submitting a dossier but, as mentioned previously, do not need to submit trial data for their product showing efficacy and safety. In addition, manufacturers must register with the Competent Authority where they or their authorised European representative is based. In the UK the MHRA also has a market surveillance and enforcement role. Under these arrangements manufacturers are expected to monitor any reports received from healthcare professionals, patients or consumers involving their products. There are generic guidelines which apply to all classes of medical device which inform manufacturers when to notify the MHRA regarding significant events.³⁴ A significant event would be one that *“led, or might have led, to death or to a serious deterioration in state of health”*. With such a high threshold it would be unlikely that the MHRA would receive many reports from manufacturers of OTC bruxism splints. However, we can see from Table 4 there are several associated hazards (e.g. scalding, choking, tissue damage, occlusal changes and onset of TMD significantly impacting on patient’s quality of life) that the MHRA would expect manufacturers to report.

Recognising the need to identify any emerging safety issues the MHRA encourages healthcare professionals, patients and consumers to report issues with medical devices using their online reporting tool. In this way they can update their adverse incident database. The MHRA advise that some apparently minor incidents may have greater significance when aggregated with other similar reports. So, it is better to report a suspected adverse incident than ignore it.

A summary of advice on reporting to the MHRA and at the same time to manufacturers can be found in Text Box 2.

If a patient has had a problem requiring specialist referral we recommend the specialist assist with the task of reporting. Whoever makes the report should bear in mind that this may be a *suspected adverse reaction*. In other words absolute proof of causation is not expected by the MHRA.

On receipt of a report the MHRA will also correspond with the manufacturer and if necessary investigate and resolve any potential breaches of the regulations which implement the EC Medical Directive into UK law. This may involve checking that the technical documents the manufacturer is required to hold demonstrate conformity with the requirements of the Directive. The MHRA therefore need to know about products being sold without a CE marking.

For readers in other European countries who come across problems with OTC splints details of the relevant Competent Authorities may be found at:

http://ec.europa.eu/health/medical-devices/files/list-of-contact-points-within-the-national_en.pdf

Advice on monitoring partial coverage splints

If a dentist is aware that a patient is wearing a partial coverage splint (either custom made or OTC) it is crucial that he or she monitors for unwanted occlusal change. The simplest way of doing this is to record an occlusal examination before a patient embarks on treatment. In this way any changes in shim stock contacts³⁵ can be detected at future appointments. Another excellent method of recording an archive of occlusal contacts is to use the Occlusal Sketch technique.^{36,37} In addition, impressions can be made and casts poured as a three-dimensional baseline record so that any subsequent changes can be detected visually. We advise prospective monitoring as it allows changes to be picked up before they become irreversible and both difficult and expensive to treat. Where early changes are detected patients can be advised either to discontinue use or try a custom made full-coverage design.

Unless a dentist prescribes an OTC splint, or is aware that their patient has started to wear a self-prescribed splint, it is hard to see how baseline records could have been taken of the occlusal

condition before splint treatment started. Therefore, if problems occur a retrospective assessment will be needed. For this purpose we advise study casts, photographs and radiographs where clinically justifiable. The photographs should highlight changes that appear associated with the splint wear. It is also worth recording an occlusal examination or occlusal sketch as mentioned previously. If previous records exist these should of course be retrieved for comparison.

Conclusion

This paper considers the possibility that individuals may be bypassing their dentists by buying OTC bruxism splints on the Internet. Dentists need to keep this market in mind when reviewing patients to check if they are using such appliances, particularly if there are unexplained occlusal changes or other problems.

Where problems occur it is good practice to inform the appropriate Competent Authority which in the UK is the MHRA.

Bruxism is often a long term problem and because tooth movements are not considered desirable in its management, the use of custom made full coverage splints is still recommended, unless there are specific contra-indications. With any type of bruxism appliance the importance of regular review is critical.

Acknowledgements

We are grateful to the MHRA for their advice regarding the EU regulatory aspects of this article.

Tables

<p><u>Search Strategy</u></p> <p>Search Engines Used www.google.co.uk www.google.com Amazon.co.uk Amazon.com</p> <p>Search Phrases Used "Bruxism protection" "Bruxism guard" "Bruxism mouth guard" "Bruxism appliance" "Night guard" "Occlusal splint" "Occlusal bite guard" "Bite plate"</p>
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Table 1: Search engines and phrases used to locate OTC splints available the UK and determine if also available in the USA.

Splint Design	Adjustability	Manufacturer/ Supplier	Device Name	Price	Manufacturer Claims	Safety Warnings
Unretentive gutter ("Full coverage")	1 size fits all Trimmed with scissors	TotalGard	Physiogard Nightguard	£13.99	B, D*	3*
			Physiogard Nightguard Stressgard II Biteguard	£26.99		
		OnceAll	OnceAll Dual Layers Dental Teeth Boxing Mouth Guard Stop Night Teeth Grinding	£15.49	C	-
Bite Pads on posterior teeth ("Partial coverage")	1 size fits all Self-adjustable pads; with 4 settings	SleepRight	Dental Guard Dura- Comfort	£30.00	D*, F*, J*,	6*, 21*
			Dental Guard Secure-Comfort	£28.00		
			Dental Guard Slim-Comfort	£29.95		
	1 size fits all Self-adjustable pads; with 5 settings	Dentek	Comfort Fit Dental Guard	£31.00	D*	-
Boil & bite ("Full coverage")	1 size fits all Trimmed with scissors	2PLUS2	Pair of Night Guards Mouth Guards for Bruxism	£29.97	B	2, 15, 16, 17, 18, 19, 20
		BruXPerformance **	BruXoGard	£24.34	A*, D*, F*, H*, J*	6*, 14* 24*, 25*, 26*
			PowrGard 4Braces	£24.34		
		Dentek	Custom Comfort Dental Guard (twin pack)	£17.27	-	-
			Maximum Protection Dental Guard	£29.98	D, F, G	2*, 6*, 10*, 12*, 13*, 16*, 17*, 27*, 28*, 29*, 30*, 31*, 32*, 33*, 34*, 35*, 36*, 37*, 38*
		Dr Brux	Dr Brux Mouthpiece (generally unavailable except via Italian supplier trading in pound sterling)	£61.00	C, H	-
		Icebrite	Pair of Night Guard Mouth Guards to Prevent Teeth Grinding	£3.95	A, C, D	-
		Mammoth Supplements	Grinding Teeth Guard (Bruxism); Berry Flavour	£5.49	D	-
		Sleep Solutions (Myofunctional Research Co)	Sleep Solutions BruXogard Soft Mouth Guard	£24.43	B*, D, E	-
			Sleep Solutions BruXogard Hard Mouth Guard	£35.27	B*	8
		2PLUS2	Thermoforming Mouth Trays for Teeth Grinding/ Bleaching/ Whitening	£1.25	-	1
		AllThingsLovelyJubbly	Stop Snoring Anti Snoring Device Sleep and Mouth Piece Guard Teeth Grinding Cure	£10.99	C	6, 15, 22, 23
		Archtek	Grinding Guard – Relieves Symptoms Associated with Teeth Grinding	£10.70	A*, B*, D	-
		Doctors	Med Tech Products Doctors Nightguard Advanced Comfort	£23.65	C*, D*	-
		MAKS	2pcs Replacement Thermoforming Mouth Trays/ Guards for Teeth Whitening/ Bleaching or Teeth Grinding	£1.99	-	-
		Mammoth XT	Bruxism Grinding Teeth Mouth Guard- Sleep Gum Shield / Night NightGuard / Boil n Bite - Spearmint	£5.99	A, D	-
			Mammoth XT Pair of Teeth Grinding Mouth Night Guard - Bruxism	£19.99	A, D	-
		Smile 4 You	Replacement Thermoforming Mouth Trays/ Guards for Teeth Whitening/ Bleaching or Teeth Grinding	£2.48	-	9
		Start Here	4x Replacement Thermoforming Mouth Trays/ Guards for Teeth Whitening/ Bleaching or Teeth Grinding	£0.01	-	-
		Top Choice	Replacement Thermoforming Mouth Trays/ Guards for Whitening/ Bleaching or Teeth Grinding	£2.35	-	9
Self-impression kit ("Full coverage")	Splint made by dental laboratory	Nightguard Direct Ltd	Professional Custom Made 2mm Night Guard	£55.00	D, F, H*	-
			Professional Custom Made 3mm Night Guard	£55.00	D, F, H*	-
			Professional Custom Made Dual Laminate Night Guard	£55.00	D, F, H*	7*
		Smiles 4 Less	Dental Teeth Grinding Night Guard – Custom Fit (3mm moderate grinding) Lower Teeth	£44.99	H	4
			Dual Laminate Teeth Grinding Night Guard – Custom Fit (2mm heavy grinding) Lower Teeth	£54.99		
			Dental Teeth Grinding Night Guard – Custom Fit (2mm minimal grinding) Upper Teeth	£39.99		
			Dual Laminate Teeth Grinding Night Guard – Custom Fit (3mm severe grinding) Lower Teeth	£59.99		
		ProWhite Direct	Night Guard for Teeth- Grinding/ Bruxism - Dental -Professional - Custom Made - 2mm	£29.99	H	5
			Night Guard for Severe Teeth Grinding/ Bruxism, 2mm Dual Laminate - Dental - Professional - Custom made	£44.99		
Night Guard for Severe Teeth Grinding/ Bruxism, 3mm Dual Laminate - Dental - Professional - Custom made	£49.99					

Grey shading indicates splints appearing on market since the March Survey

Also available in the USA

**Only available direct from supplier (not on main UK retail website)

* Information available only on manufacture's/supplier's website (not on main UK retail website)

Table 2: Master table showing four categories of splint design available in the UK with prices, coded claims and safety warnings. Survey data for July 2013.

Code	Manufacturer Claims
-	No claims
A	Headaches/facial pain/jaw pain reduction
B	Unspecified symptom reduction
C	Cures/treats/reduces/helps/prevents bruxism
D	Protects teeth/restorations from grinding/clenching/bruxism
E	Protects TMJ from grinding/clenching/bruxism
F	Claims similar but less expensive than professionally made splint
G	Improves sleep/reduces sleep disruption
H	Generic claims about splints not specific to product on sale
J	Other (e.g. most durable, years of success, re-establishes space between upper and lower teeth)

Table 2 (i) Codings for manufacturers' claims in main table

Code	Caution Notice on the Internet
-	None
1	Not to be worn to prevent against bruxism
2	Not to be worn as a sports guard
3	Not for persons <10 years old
4	Not for persons <14 years old
5	Not for persons <16 years old
6	Not for persons <18 years old
7	Only for use when recommended by a dentist
8	For night time use only
9	For mild grinders only
	Do not use:
10	For more than 3 months without consulting your dentist
11	For more than 6 months without consulting your dentist
12	If your dentist has told you that you have TMJ pain or clicking
13	If you have tooth pain from grinding or any other tooth or jaw pain
14	If you have jaw problems
15	If you have tooth or gum problems
16	With dentures, braces or other dental appliances e.g. implants
17	With loose teeth, loose fillings or loose crowns
18	A bridge
19	Advanced periodontal disease
20	Several missing teeth
21	For >12 hours in a 24 hour period
22	If you suffer from sleep apnoea
23	If you suffer from epilepsy
	Consult a dentist before use if you:
24	Have tooth or gum problems
25	Wear a denture or brace
26	Are under 14 years of age
27	Have major health problems or serious breathing problems
28	Oral sores, bleeding gums or any gum disease
29	Cavities with no fillings
30	Difficulty chewing
31	Pain of the jaw, teeth or face
32	Two or more missing teeth
	Stop using the splint and ask a dentist if:
33	Soreness, bleeding gums, teeth loosen or reaction occurs in mouth
34	Pain develops e.g. jaw, teeth or ear pain or headache
35	The splint causes gagging, discomfort or falls out of the mouth easily
36	A change in the bite is noticed
37	Neck stiffness or joint clicking develops
38	The same symptoms persist after 1 month of use

Table 2 (ii) Codings for manufacturers' claims in main table

Search term	OTC bruxism splints	Total hits	Previous hits	Irrelevant products
Bruxism	12*	118	0	106
Grinding guard	4	14	4	6
Nightguard	4	18	8	6
Specific products**	1	16	8	7
Total number of incidents	20			

* One event appeared to generate two reports

**Products shown in bold from Table 2.

Table 3 Search results from the FDA's MAUDE database for adverse events associated with OTC bruxism splints.

Reporter C, D, M	Incident summary	Incident code
C	Scalding of consumer's hand and face caused by microwave heated water contained in a drinking glass. On immersing the splint the water "exploded" boiling up steam and superheated water over consumer's skin.	1
M	Uncomfortable splint which consumer considered was causing severe gum irritation and loss of a filling.	2, 6
M	Gingival recession around lower molars requiring surgical intervention – possibly caused by splint. Claim supported by manufacturer's insurance in view of dentist's contention that appliance may have been causative.	3
M	Open sore developed in gums after wearing splint for 3 days. Plastic material (possibly from splint) impacted into gum requiring surgical removal resulting in bone and gingival tissue loss. Device available for evaluation but packaging not kept so lot number unknown.	3
C	Painful blisters inside mouth after wearing splint for one night. Splint no longer worn and blisters resolved	4
M	Tooth pain after one night of wearing splint. Patient reports dentist diagnosed a cracked lower molar on each side of her mouth.	5
M	Splint broke apart and tooth damage. Consumer considered damage caused by the way her teeth grind on splint. Manufacture requested product from consumer to investigate, but had no response.	7, 5
C	Splint broke during sleep. Consumer (occupation risk manager) perceived a choking hazard.	7
M	Consumer woke with pieces of the splint stuck in her throat after only two nights of wearing the device. Concern over possibility of aspiration.	7
M	Appliance partly swallowed during sleep. Wife woke husband because of his choking noises and retrieved appliance using her fingers. Emergency room treatment required, possibly due to pharyngeal injury during removal.	8
M	Appliance partly swallowed during sleep causing gagging. Patient able to self-retrieve.	8
M	Appliance partly swallowed during sleep causing gagging. Patient able to self-retrieve.	8
M	Appliance completely swallowed during sleep two weeks prior to contacting manufacturer to demand refund.	8
C	"Lock jaw tmj" after wearing splint for only 7 hours. Told by dentist condition could last for years. Patient aggrieved as splint bought only to treat bruxism. No mention of TMD history.	9
M	Progressive occlusal change after one year of wearing splint every night. Dentist advised patient to discontinue splint wear but teeth continued to move over following year resulting in "teeth not closing", development of a 5mm anterior open-bite, chewing difficulties and development of a lisp. Dentist supporting patient in upgrading case to serious. Remedial orthodontic treatment recommended.	10
C	Bite has changed and jaw pain after using splint for one month. Splint no longer used but symptoms persist.	10
C	Gave consumer "bad gas" during 5 months of wear. Event abated after use stopped.	11
C	"Brown stuff" in mouth followed by general malaise for 3 days. Consumer suspects contamination or chemical leaching from splint.	11
C	Consumer concerned product needed a safety seal packaging as it appeared that other products on the shelf had been opened and handled.	12
C	"Dried blood" noticed on splint being sold at drug store suggesting it had already been used.	12

Table 4 (previous page): MAUDE adverse event summaries (n=20) from all specified search terms showing who made the report (consumer C, dentist D or manufacturer M) coding the type of problem according to table 5. (MAUDE database updated 30.11.2013).

Type of adverse event	Code
Scalding	1
Gingival irritation and discomfort	2
Gingival damage or recession	3
Mucosal reaction	4
Cracked, damaged or painful tooth	5
Lost or damaged restoration	6
Splint broken in use (+/- choking)	7
Splint swallowed/part swallowed during sleep (+/- choking)	8
TMD (diagnosis part-confirmed by dentist)	9
Occlusal change	10
Systemic reaction	11
Product contamination	12

Table 5: MAUDE adverse event categories and codings based on reports in table 4.

Occlusal change suspected to be associated with an OTC splint

A 22-year-old male patient was referred to Newcastle Dental Hospital with a 6 year history of bruxism and more recently disturbance in his occlusion. The patient explained that his teeth met prematurely at the back of his mouth and was increasingly aware of sliding his lower jaw and teeth to improve the number of teeth meeting. In addition, he had a dull pain over the insertion of left masseter and left masseteric hypertrophy.

Previous treatment by his dentist had included the provision of lower soft splints to address his bruxism whilst his left sided masseteric hypertrophy was managed by the Maxillofacial Surgeons with Botox injections. He repeatedly perforated the lower soft splints around the canine regions, so in January 2011, unbeknown to his dentist, he purchased an OTC bruxism splint over the Internet. He continued to wear the self-prescribed appliance each night for eight months, even replacing it when it became too worn. However, towards the end of this period he began to notice an increasing problem with his bite when he removed appliance.

On examination the patient had a large slide between the retruded contact position and intercuspal position. The slide had a 3mm lateral component to the left. The retruded contact was between teeth 27 and 37. Clinically both of these teeth appeared over-erupted, as did teeth 17 and 47. When the appliance was placed in the patient's mouth it extended only to the distal aspects of 46 and 36 leaving all the second molars uncovered. By contrast, the soft splint supplied by the patient's dentist covered all the lower teeth. A dental pantomograph (DPT) revealed a distinct step between the first and second molars (Figure 1). A previous DPT which predated the use of the appliance is shown in Figure 2.

Diagnoses were made of occlusal disruption associated with overeruption of the second molars and prolonged wear of an OTC splint leaving these teeth uncovered, sleep related bruxism, left sided masseteric hypertrophy and mild left sided myofascial pain. At this point the patient was instructed to stop wearing the OTC splint immediately and use only the soft splint provided by his dentist. He was also counselled on the importance of biting together on his second molars whilst swallowing but otherwise to avoid clenching his teeth. In addition, remedial jaw exercises were prescribed to be carried out 2-3 times a day for his TMD symptoms. Following occlusal analysis with mounted study casts, arrangements were made for the unerupted 18 and 28 to be extracted and after initial settling of the occlusion he was successfully fitted with a stabilization splint. Treatment extended over 8 appointments. The occlusion re-interdigitated successfully without occlusal adjustment and his TMD symptoms were well controlled. We recommended the patient continue to wear his stabilization splint whilst the sleep bruxism was active. The masseteric hypertrophy will continue to be reviewed by the Maxillofacial Surgeons. The occlusion will continue to be reviewed by the Restorative Dentists.

Text Box 1: Case Vignette .

Where a dentist, a patient or a consumer experiences problems associated with an OTC bruxism splint:

- Report the problem both to the MHRA and to the manufacturer
- Dental care professionals should assist their patients with reporting
- There are separate forms for DCPs and for patients/consumers to report issues:
<http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Devices/index.htm>
- The OTC splint should be kept by the dentist or the consumer. The MHRA may require the splint to be examined and tested. If so they will request for the splint to be sent to the manufacturer who will report directly to the MHRA.

Text Box 2: Advice on reporting issues with OTC bruxism splints.

Figures

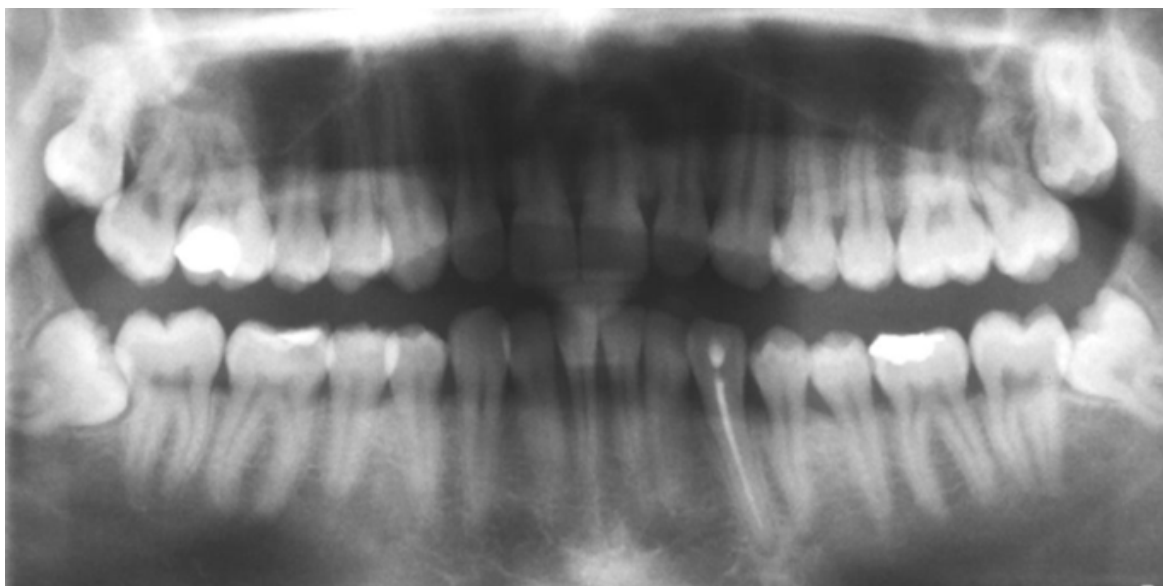


Figure 1 – DPT recorded on presentation, highlighting a distinct step between the distal aspects of all four first molars and the adjacent mesial aspects of the second molars.



Figure 2 – DPT recorded 3.5 years before presentation – no step in the occlusal plane is evident.

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