Measuring Patient Compliance with Occlusal Device Wear in the Management of Bruxism

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Declaration

I hereby declare that this thesis has not been submitted for a degree or examination board at any other university and is my own work with the exception of assistance listed in the acknowledgments and where specifically referenced in the text.

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Mohammad Alqhtani

27th February 2020

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Abstract

Background: Sleep Bruxism (SB) is a complex oral condition that is characterised by repetitive jaw-muscle activity, by clenching or grinding of the teeth and/or by the bracing or thrusting of the mandible. Sleep bruxism has been associated with a multitude of clinical problems such as temporomandibular joint and muscle pain, tooth wear and is a major cause of dental prosthesis failure or fracture. The wearing of protective occlusal devices is an essential component of the management of tooth grinding (bruxism). In the absence of definitive treatment for sleep bruxism, occlusal devices are the most commonly prescribed method for its management in dentistry, acting to reduce bruxism activity or prevent its deleterious effects on the teeth, restorations and the masticatory system.

Compliance with occlusal device wear is essential to prevent further tooth wear and protect any restorations that have been placed. To obtain the maximum preventive and therapeutic effects of occlusal devices, patients should demonstrate acceptable levels of compliance with occlusal device wear. To date, there has been no objective data available concerning compliance for patients using occlusal devices for the management of sleep bruxism. The aim of this study was to measure occlusal device wear time using an inbuilt microsensor objectively

Materials and Methods: This study was a longitudinal prospective clinical cohort trial of two groups of possible sleep bruxer participants who were either using the maxillary occlusal hard device for the first time (new wearers) or participants who worn the device for at least three months following prosthodontic treatment (experienced wearers).

Possible sleep bruxism patients were identified and recruited based upon their bruxism questionnaire responses, which acted as inclusion criteria. If the current appliances were deemed suitable for experienced wearers, microsensors were retrofitted into existing appliances. For new wearer participants who were to have their first occlusal devices fabricated, and experienced wearers who presented with unsatisfactory devices the microsensors were incorporated at the time of device fabrication. Recall appointments were timed for one week, four weeks and 12 weeks post-placement. The recorded wear times were documented graphically using dedicated TheraMon® Software. The readout data was then demonstrated, and the daily wear times were determined as wear-time graphs.

Results: Out of the 46 recruited participants, only 23 wore the occlusal device for the 90 night period of the study. Fourteen participants (12 new users and 2 experienced users) were excluded from the study as they were not compliant with device wear instructions. A further 9 patients (5 new users and 4 experienced users) withdrew for reasons including being lost to follow up due to relocation, delays to device manufacture as they were undertaking additional dental treatment, losing the device, or having a defective senor which they did not want replaced.

The overall 90 night median occlusal appliance wear time for all participants was 5.50 h/night. There was a small, statistically insignificant, drop in compliance over time across the three 30-day periods. For the overall study period, there was a significant difference in median occlusal appliance wear time between new patients (N=10; 4.04 h/night) and

experienced patients (N=13; 6.79 h/night) with approximately 2.5 hours difference. No significant differences in wear time were found with respect to age and gender.

Conclusions: This study exhibited the effectiveness of using a thermo-sensitive microsensor in monitoring sleep bruxism patient compliance and, for the first time, reported the objective wear times of occlusal devices for bruxer patients. Only half of the participants wore the appliances for the duration of the study period.

The overall 90 nights median occlusal appliance wear time for all participants (N=23) was 5.50 h/night. Significant differences in median occlusal appliance wear time between new and experienced users were identified. Gender and age had no influence on occlusal device wear patterns.

Chapter 1. Introduction

1.1 General Background

1.1.1 Definitions of Bruxism

Bruxism has been described and investigated since early times. Teeth gnashing and clenching have been in existence as long as humankind; both the Old and New Testament make reference to gnashing. Bruxism is derived from the Greek term "brychein", which refers to teeth grinding. Marie & Pietkiewicz first introduced the term "la bruxomanie" in 1907 to describe teeth grinding and gnashing without a functional purpose (Marie & Pietkiewicz 1907), and this was later adopted as "bruxism". Several researchers have described this activity using different terms. For instance, Black referred to bruxism as a non-functional activity associated with abnormal teeth wear (Burton 1983), while Karoly referred to the state as "neuralgia traumatica" (Basic & Mehulic 2004). Nocturnal and diurnal bruxism were first distinguished in the scientific literature by Miller in 1936, when he referred to habitual diurnal grinding as "gnashing" and nocturnal grinding as "bruxomania" (Miller 1936). It is clear from the dental literature that there was little consensus regarding a definition of bruxism.

According to the International Classification of Sleep Disorders (ICSD-1) bruxism was defined as a "parasomnia" (Thorpy, 1990). The American Academy of Sleep Medicine (AASM) revised the definition in 2005 (ICSD-2), reclassifying bruxism as a sleep-related movement disorder (AASM, 2005). The International Classification of Sleep Disorders-2 (ICSD-2) redefined bruxism as "an oral activity characterised by grinding or clenching of the teeth during sleep, usually associated with sleep arousals" (AASM, 2005). Awake bruxism

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was omitted from this definition and classified as a separate disorder distinct from sleep bruxism (AASM, 2005). According to the American Academy of Sleep Disorders (AASD), sleep and awake bruxism are entirely different entities with different aetiologies and predisposing risk factors (Medicine 2005). As a result of insufficient evidence portraying bruxism as an abnormal function, caution has been advised when labelling bruxism as a disorder (Lobbezoo *et al.* 2013). Teeth clenching is forceful biting during either static or dynamic occlusion; however, teeth grinding is only a forceful movement during dynamic occlusion (De Laat and Macaluso, 2002). Clinicians and researchers from a range of backgrounds, including dentistry, neurology and sleep medicine, have repeatedly redefined bruxism. Bruxism has also been defined in the Glossary of Prosthodontic Terms as "the parafunctional grinding of teeth" and as "an oral habit consisting of involuntary rhythmic or spasmodic non-functional gnashing, grinding or clenching of the teeth, in other than chewing movements of the mandible, which may lead to occlusal trauma" (Ferro *et al.,* 2017). According to this definition, there was no differentiation between awake and sleep bruxism, and it also implied that the presence of teeth was required.

The American Academy of Orofacial Pain (OFPG-4) defined bruxism as 'diurnal or nocturnal parafunctional activity, which included clenching, gnashing, gritting and grinding of teeth (De Leeuw and Klasser, 2008). It can be clinically diagnosed based on the presence of excessive tooth wear (facets), which could not have been caused by normal masticatory function. However, contemporary bruxism can only be investigated in detail using sleep laboratory recordings (De Leeuw & Klasser, 2008). Furthermore, several authors have

avoided using diurnal and nocturnal bruxism as the terms may be inaccurate, preferring unbiased terms such as sleep and awake bruxism (Melo *et al.* 2019).

According to an International Expert Consensus, bruxism was redefined as "a repetitive jaw-muscle activity characterised by the clenching or grinding of the teeth and/or by the bracing or thrusting of the mandible. Bruxism has two distinct circadian manifestations: awake or sleep bruxism" (Lobbezoo *et al.* 2013). This definition appeared to overcome limitations in previous definitions and is commonly referenced in the contemporary dental and medical literature when defining bruxism.

1.1.2 Classification of bruxism

Masticatory muscle activities have been classified into functional activities, which include normal chewing and speaking, and parafunctional activities, which include teeth grinding and clenching. Apparently, parafunctional activities are controlled by an entirely different mechanism. Bruxism is described as a parafunctional activity, which involves the masticatory muscles. In 1996, sleep bruxism was classified based on the results of controlled polysomnography (PSG) studies (Lavigne *et al.* 1996). Based on electromyography (EMG) recordings, the authors classified sleep bruxism episodes as tonic or phasic. A phasic event was defined as an episode that occurred for between 0.25 and two seconds, while a tonic event constituted an episode lasting more than two seconds. The severity of sleep bruxism was classified based on the number of episodes occurring per hour. Sleep bruxism was classified as moderate to severe when four or more episodes were recorded per hour. If

between two and four episodes per hour were recorded, sleep bruxism was classified as mild.

Sleep bruxism was further classified as primary or secondary (Lavigne *et al.,* 2003). If sleep bruxism occurred without a clear cause, it was classified as primary (idiopathic). However, if sleep bruxism was associated with sleep disorders, neurological diseases and the use of specific medications, it was classified as secondary (iatrogenic).

In 2005, the ICSD-2 re-classified sleep bruxism within sleep-related movements as "an oral activity characterised by grinding or clenching of the teeth during sleep, usually associated with sleep arousals" (Medicine 2005). With regard to severity, the ICSD-2 classified sleep bruxism as mild, moderate or severe. If bruxism frequency was less than nightly, and was not associated with tooth damage or psychosocial impairment, then it was classified as mild bruxism. When sleep bruxism was observed nightly and caused mild impairment of psychosocial functioning, it was classified as moderate. Finally, sleep bruxism occurring on a nightly basis was defined as severe if it was associated with extensive tooth damage, temporomandibular joint disorders and severe psychosocial impairment. Psychosocial impairment assessment was performed using the Minnesota Multiphasic Personality Inventory (MMPI) (Rollman and Gillespie, 2000). Patients with TMD that demonstrated clinical-scale changes comprising the neurotic triad (hypochondriasis, depression, hysteria) of the MMPI were associated with "perceptions of severe pain, affective disturbances, and maladaptive patterns of psychosocial functioning".

Sleep or awake bruxism were classified based on the diagnostic tools used to assess potential subjects with sleep bruxism (Guaita & Högl 2016). An International Consensus in 2012 suggested new sleep or awake bruxism classifications of "possible", "probable" and "definite" bruxism (Lobbezoo *et al.* 2013). When only positive self-reporting was used, e.g. questionnaires and/or anamnestic examination, then this was classified as "possible" sleep or awake bruxism. If self-reporting was combined with a positive clinical examination, then this was classified as "probable" sleep or awake bruxism. Finally, if self-reporting, clinical examination and polysomnographic analysis with audio-visual recordings were used to assess for bruxism and found to be positive, then this was described as "definite" sleep or awake bruxism (Lobbezoo *et al.* 2013). For simplicity, the proposed grading systems for bruxism have been summarised in Table 1.1.

Significant differences have been reported between awake and sleep bruxism. Phenomenologically, awake bruxism is a semi-voluntary activity associated with stress and anxiety (Lavigne *et al.* 2003). Prevalence has been reported as approximately 22% (Jensen *et al*., 1993b). However, it is extremely difficult to investigate the true prevalence of awake bruxism due to the limitations of studies published in the dental literature. However, sleep bruxism is stereotypically a movement disorder and considered a form of parasomnia (Manfredini *et al.* 2013). There are no definitive diagnostic criteria for awake bruxism, unlike sleep bruxism, which has established diagnostic criteria (Lavigne, 2003)(Table 1.2).

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Author(s)	Proposed Grading System
International Consensus on the assessment of bruxism: Report of a work in progress (Lobbezoo *et al.* 2018)	Sleep/awake bruxism: 1. "Possible" is based on a positive self-report only. 2. "Probable" is based on a positive clinical inspection, with or without a positive self-report. 3. "Definite" is based on a positive instrumental assessment, with or without a positive self-report and/or a positive clinical inspection.
Bruxism defined and graded: an international consensus (Lobbezoo *et al.* 2013).	Self-report, clinical inspection, and instrumental assessment "possible", "probable" and "definite".
Lavigne and co-workers (Lavigne *et al.* 2001b)	Primary (idiopathic) and secondary (iatrogenic) bruxism.
International Classification of Sleep Disorders 2nd version (Medicine 2005)	Mild, moderate and severe bruxism.
Lavigne and co-workers (Lavigne *et al*. 1996)	Tonic, phasic and mixed bruxism episodes. Moderate and severe bruxism.

Table 1.1. Summary of proposed bruxism grading systems (Lobbezoo *et al*. 2018).

	Awake Bruxism	**Sleep Bruxism**
Methods	Interview, questionnaire, Ambulatory devices: (EMG recording).	Interview, questionnaire. PSG Sleep laboratory: EEG, EMG (masticatory and leg), ECG, respiration and electro-occulogram. Ambulatory devices. EMG recording with heart rate. Occlusal device with force sensor.
Diagnosis	Not always reliable (interview, questionnaire). Not validated (EMG recording).	More than 10% of MVC*confirmed with audio-video recording in a Sleep Laboratory. More than 10% of MVC last more than 3 seconds with more than 5 seconds interval and 5% increase in heart rate (EMG recording).
Advantages & limitations of diagnostic methods	*Limitations:* difficult to differentiate from other oromotor activity. *Advantages (Ambulatory systems):* Relatively easy to perform with reduced cost. *Limitations (Ambulatory system):* Few physiological parameters (audio-video).	*Advantages (sleep laboratory):* Highly controlled, detailed physiological records and ability to differentiate between sleep disorders. *Limitations (sleep laboratory):* Cost, manpower and unfamiliar environment. *Advantages (Ambulatory systems):* Relatively easy to perform with reduced cost. *Limitations (Ambulatory system):* Few physiological parameters (audio-video). *Limitations (splints with sensor):* May alter the bruxism activity.

Table 1.2. Diagnostic methods to recognise awake and sleep bruxism (Lavigne, 2003).
* * MVC refers to maximum voluntary contraction for the masseter muscle.

Several chairside diagnostic tools have been proposed to differentiate awake and sleep bruxism (Table 1.3).

	Validity	Limitations
Self-reporting: **Sleep grinding sounds**	Family or partner's complaint.	Not reliable if sleeping alone, confounded with TMD clicking, snoring and grunting.
Clenching during wakefulness	Both AB and SB.	Subject variability.
Muscle discomfort and fatigue (No Pain)	If present on waking associated with SB.	Concomitant with muscle and TMJ Pain/discomfort and headache.
Teeth sensitivity	Both AB and SB.	Confounded with local factors (caries, diet, ill-fitting restorations).
Clinical Examinations: **Tooth wear**	Positive in SB, not clear for AB.	Severe SB can occasionally demonstrate mild tooth wear, also associated with other oral habits, aging process, diet, saliva secretion, etc.
Masseter hypertrophy	Both SB and AB.	Confounded by dietary habits, Bilateral parotid swelling, etc.
Tooth indentation	Not specific.	Confounded by oral habits.
Miscellaneous features (occlusal trauma, pulpitis, metallic taste, cortical thickness and condylar shape changes and tooth fracture	Not specific.	Several intra-oral conditions that could overlap.
Oral Devices	Used for SB management	Not correlated with masseter muscle activity, as it may decrease or increase SB.

Table 1.3. Chairside diagnostic methods to differentiate between awake and sleep bruxism (Lavigne, 2003).

1.1.3 Epidemiology of bruxism and oral health effects

The prevalence of bruxism has been investigated in several studies with varying results. Two large self-reported sleep bruxism studies (2,019 and 13,057 respondents respectively) reported a prevalence of approximately 8% in the adult general population (Lavigne and Montplaisir, 1994, Ohayon *et al.* 2001a). No gender difference was observed; however, there was an apparent age-associated decrease in bruxism from 14% in childhood to 3% in the elderly (Ng *et al.* 2005). In contrast, a female predilection was observed by Manfredini and co-workers who reported significant differences in the prevalence of bruxism between female (57.8%) and male (25.5%) patients in a neuroscience clinic (Manfredini *et al.* 2004). Similarly, this female and male prevalence difference was also observed in an earlier study of clinical and/or self-reported-based diagnosis of bruxism (Jensen *et al.* 1993a). There is general agreement in the literature that bruxism decreases with increased age, with prevalence for children, adolescents and adults reported as 20%, 15% and 8%, respectively (Lavigne and Montplaisir, 1994; Widmalm *et al.* 1995; Carra *et al.* 2011). Lavigne *et al.* reported that almost 20% of the adult population reported day-time clenching *(Lavigne et al.* 2008a). The absolute prevalence of awake and sleep bruxism is difficult to estimate due to methodical limitations reported in the dental and medical literature. For example, bias in participant selection has been identified in some study designs, and therefore those cohorts may not be representative of the general population. Furthermore, a large number of studies were based on self-reported data provided by participants or their bed partners, with the inherent problems of low response rates, inaccurate recollection and subjective interpretation. Many studies reporting prevalence were carried out on participants with

cofounding comorbidities, including orofacial pain, psychological and neurological conditions. Due to the lack of accurate and reliable diagnostic and sampling methods, caution should be used when interpreting the published epidemiological data available.

The reported sequelae of sleep bruxism include temporomandibular joint (TMJ) and muscle pain or jaw locking, tooth destruction, temporal headaches and cheek-biting (Bader and Lavigne, 2000). Interestingly, studies based on self-reporting reported an estimated odds ratio (OR) between 4.2 and 8.4 for temporomandibular disorders or chronic myofascial pain when grinding and/or clenching are concomitant (Huang *et al.* 2002, Velly *et al.* 2003). Furthermore, Bader *et al.* studied 24 bruxers (23–67 years old) and found that 65% of the participants reported frequent headaches, mainly in the temporal area, especially in the morning (Bader et al., 1997). Such reported findings may have been associated with either stress or respiratory disturbances (Okeson *et al.* 1990 ; Camparis and Siqueira, 2006). Teeth grinding noise can also significantly disturb the sleep of room partners. Sleep bruxism may be exacerbated in the presence of some conditions. The following are the major risk factors that have been identified to date:

(i)   Smoking, caffeine and heavy alcohol consumption (Lavigne *et al.*, 1997)

(ii)   Type A personality-anxiety (Pierce *et al.*, 1995)

(iii)   Sleep disorders, snoring, sleep apnoea with odd ratios of 1.4 and 1.8, respectively (Sjöholm *et al.* 2000).

Bruxism is considered a significant clinical issue with damaging effects on teeth, dental restorations, periodontal and musculoskeletal tissues. Reduced restoration longevity due to bruxism is a common concern in dental practice. Studies focusing on the longevity of dental implants in bruxers were reviewed by Lobbezoo *et al.* and included nine studies with different evidence base levels (expert opinions, case reports, prospective case study and reviews) (Lobbezoo *et al.* 2006). The consensus from these studies was that the association between high rates of dental implant complications and bruxism lacked a solid evidence base. However, authors recommended the nocturnal use of hard acrylic occlusal devices (splints) following implant treatment for patients who demonstrated significant bruxism. In addition, a retrospective analysis was carried out to investigative porcelain fracture rates for metal ceramic fixed restorations and implant supported restorations (Kinsel and Lin, 2009). Data were collected from 152 patients with a total of 998 dental units. Porcelain fractures were significantly associated with bruxism and not wearing an occlusal device. Participants exhibiting bruxism or not wearing an occlusal device had approximately 7 times higher odds (OR = 7.23), and two times higher odds (OR = 1.92) of porcelain fracture when compared to patients not exhibiting bruxism and patients wearing an occlusal device.

In a recent retrospective comparative study of ninety-eight bruxers and controls investigating implant failure rates and mechanical and technical complications of implant-supported restorations, the authors reported that the odds ratio for implant failure in bruxers was 2.71 times that of non-bruxers (Chrcanovic *et al.* 2017). Furthermore, they found a high prevalence of mechanical complications for the bruxer group in comparison to

the non-bruxer group. The study suggested that bruxism significantly increased the rate of implant failure (18.4% for bruxers, compared with 3.3% for non-bruxers) for implants of regular length (11–13 mm). In addition, the authors reported a higher failure rate (25.7%), when short implants (7–10 mm) were used for bruxers, compared to 2.8% for non-bruxers. Furthermore, a higher failure rate of 32.9% was reported for turned-surface implants for bruxers compared with 5.3% for non-bruxers. The failure rate decreased when roughened-surface implants were used for bruxers and non-bruxers (11% and 1.5%, respectively). The study suggested that bruxism significantly increased the rate of implant failure, and mechanical and technical complications for implant-supported restorations (Table 1.4).

Complication	Bruxers	Non-bruxers	Odds Ratio
At least one implant failed	25	11	2.71
Acrylic teeth fractured or lost	154	44	12.091
Ceramic fracture	50	4	12.342
Prosthesis loosened	73	15	7.862
Screw fractured	96	3	40.991
Screw loosened	54	11	575

Table 1.4. Comparison of implant failure and mechanical complication rates for implant-supported prosthetic restorations. Rates for bruxers versus non-bruxers are shown (Chrcanovic *et al.* 2017).

1.2 Aetiology of Bruxism

1.2.1 General Introduction

The exact mechanism and pathophysiology of bruxism are still unclear and probably multifactorial in nature. Historically, it was proposed that peripheral (morphological) factors including malocclusion and occlusal interferences were at least aggravating factors for sleep bruxism (Ramfjord, 1961). Authors reported an increase in EMG activity associated with inter-occlusal interferences (Ramfjord, 1961). This was supported by other animal and human studies, which focused on resting EMGs recorded during the daytime for a short period of time in an experimental environment (Schaerer *et al.* 1967), (De Boever, 1969). The effects of experimental occlusal interferences on sleep bruxism were evaluated in one randomised control trial (Magnusson and Enbom, 1984). The authors reported similar prevalence in sleep bruxism for participants with or without occlusal interferences. Several human studies investigated occlusal interferences on cumulative masseter EMG activity at night. The authors concluded that sleep bruxism was not elicited by placing or elimination of experimental deflective occlusal interferences, even in patients with a prior history of bruxism (Rugh et al., 1984). Several authors who reported similar findings concluded that, for most individuals, the masticatory adaptive capacity is sufficient to cope with occlusal disharmony (Karlsson *et al.* 1992).

An occlusal-analysis study evaluating mediotrusive and laterotrusive interferences, deep-bite, open-bite and cross-bites was completed for 85 patients. The authors reported poor evidence of correlation between occlusal disharmony and bruxism (Manfredini *et al.* 2004).

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Lobbezoo *et al.* (Lobbezoo *et al.* 2001a) evaluated orofacial morphological differences (dental arch form, skeletal relationship, and occlusal relationship) between sleep bruxism subjects (confirmed using polysomnography) and non-bruxers. Twenty subjects were recruited and occlusal measurements recorded intra-orally and from dental casts. Skeletal measures were recorded using standardised cephalometric radiographs and the neurochemical outcome of oromotor activities was recorded using striatal D2 receptor expression. The authors found no correlation between orofacial morphology factors and sleep bruxism. Furthermore, the asymmetry in striatal D2 receptor expression that was reported in a previous study in association with sleep bruxism, was not correlated with morphological factors (Lobbezoo *et al*. 1996).

There are conflicting theories among researchers regarding bruxism-causing factors in both awake and sleep bruxism. The putative mechanisms for sleep bruxism genesis include exogenous factors and comorbidities, Sleep-Related Movement Disorders, sleep arousal, autonomic sympathetic-cardiac activation, genetic factors, neurochemicals and psychosocial factors, which will be covered in the following sections.

1.2.2 Role of Exogenous Factors and Comorbidities

Several risk factors and medical conditions have been associated with either sleep bruxism or bruxism-like masticatory activities while either awake or asleep. The exogenous factors for sleep bruxism include alcohol intake, cigarette smoking, caffeine intake, medication such as selective serotonin reuptake inhibitors, and drug addiction (e.g., addiction to

ecstasy)(Ohayon *et al*., 2001). Sleep bruxism may also be observed in combination with mental disorders, such as attention deficit/hyperactivity disorder (ADHD) (Silvestri *et al.,* 2009), movement disorders such as Huntington's disease and Parkinson's disease (Srivastava *et al.* 2002, Tan *et al.* 2000), dementia (Stewart *et al.* 1993; Kwak *et al.* 2009), Nocturnal Frontal Lobe Epilepsy (NFLE) (Bisulli *et al.,* 2010) and gastroesophageal reflux (Miyawaki *et al.* 2003b). Sleep disorder breathing (SDB) (obstructive sleep apnoea, central sleep apnoea, upper airway resistance) has frequently been associated with sleep bruxism; however, a possible cause and effect has not been elucidated (Sheldon, 2010, Grechi *et al.* 2008). Indirect evidence for an association came from one study, which reported a decrease in sleep bruxism activities following different sleep-disorder breathing treatments such as continuous positive airway pressure (CPAP) and adenotonsillectomy (Oksenberg and Arons, 2002, Eftekharian *et al.* 2008). These findings suggested that rhythmic masticatory muscle activity (RMMA) may be considered an oromotor response to maintain airway patency following nocturnal respiratory obstruction events (Khoury *et al.* 2008). The role of RMMA in sleep bruxism pathophysiology will be discussed in a later section. Furthermore, an alternative hypothesis regarding the role of RMMA suggested it was required as a physiological activity to lubricate the oropharyngeal pathway in response to the normal reductions in swallowing rate and salivary flow during sleep (Miyawaki *et al*., 2003a). Other sleep disorders, such as parasomnias, sleep talking, sleep walking, rapid eye movement (REM) sleep behaviour disorders, periodic limb movements, Restless Leg Syndrome (RLS) and enuresis may exacerbate sleep bruxism activity (Reutens and Sachdev, 2005). A large cross-sectional epidemiological study comprising 13,057 subjects, carried out by telephone

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survey, failed to demonstrate a longitudinal cause-and-effect relationship, despite several authors suggesting an association between some parameters and sleep bruxism (Ohayon *et al.* 2001). Therefore, these parameters may be interpreted as risk indicators rather than risk factors. The authors identified a range of risk indicators that were associated with sleep bruxism, as shown in Table 1.5.

Risk Indicator	Odds Ratio
High stress	2.2
Alcohol consumption (1 or 2 glasses/day)	1.5
Alcohol consumption (3 glasses or more/day)	1.8
Caffeine intake (6 cups or more/day)	2
Cigarette smoking (20 or more/day	1.6
Snoring	1.4
Loud Snoring	1.9
Obstructive Sleep Apnoea (OSA)	1.8
Nocturnal awakenings	1.4
Anxiety disorder (DSM IV criteria)	1.3

Table 1.5. Risk indicators for sleep bruxism (Ohayon *et al*. 2001).

1.2.3 Sleep-Related Movement Disorders Pathophysiology

Research has focused on the association between masticatory muscle activity and the sleep cycle in sleep bruxism pathogenesis. As sleep bruxism is associated with a series of rhythmic jaw movements generated during sleep, the association between sleep physiology and jaw movement is important, since the interaction between them may manifest as bruxism.

1.2.3.1 Physiology of Rhythmic Jaw Movements

A complex interaction between the peripheral nervous system, the brainstem movement centre and the cerebral cortex controls mandibular movement. It has been suggested that bruxism originates in the brainstem, governed predominately by the masticatory central pattern generator (CPG), controlling rhythmic opening and closing movements (Nakamura and Katakura, 1995). The CPG of rhythmical jaw movements can be classified into three processes: generation of the masticatory rhythm, regulation of muscle activity patterns of the jaw, tongue and facial muscles, and coordination of the activities of these muscles. The masticatory rhythm CPG is subdivided into two neuronal groups according to their function (Smith and Feldman, 1987):

1. Generation of the masticatory rhythm (rhythm generator) controlling the normal antagonistic sequence for rhythmical alternation of jaw closing and opening (Central Rhythm Generator, CRG)

2. Generation of the spatial pattern of activities of the jaw, facial muscles and tongue burst generator in response to sensory and neurological stimuli.

Although both groups are thought to be involved in sleep bruxism, the precise mechanisms are not clearly understood. Similarly, while several theories have been proposed for the neurological signal changes in sleep bruxism (Lund, 1991, Nakamura and Katakura, 1995)> It is still unclear how neurological and other stimulation mechanisms influence generation and modulation of bruxism.

1.2.3.2 Rhythmic Masticatory Muscle Activity (RMMA)

According to Lavigne *et al.*, approximately 60% of the population demonstrated occasional bursts of RMMA (Lavigne *et al.* 2001b). However, lower RMMA levels have been reported for normal individuals compared with bruxers. Sleep bruxism is represented as a severe manifestation of RMMA (Lavigne *et al.* 2007), when either trigger factors are potent, or the host response threshold is low (Bader and Lavigne, 2000) (Figure 1.1).
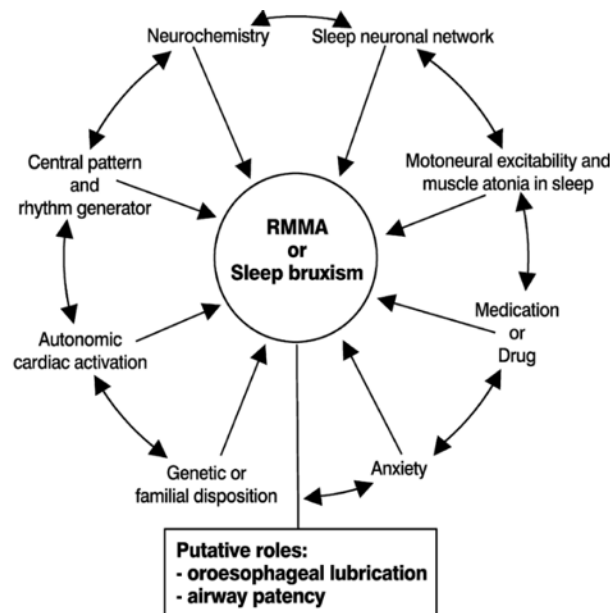
Figure 1.1. Integration of various influences associated with rhythmic masticatory muscle movement (RMMA) and sleep bruxism. (Lavigne *et al.* 2003a).

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Three patterns of RMMA have been proposed (Carra *et al*. 2012):

1. Phasic: brief, repetitive jaw contractions, with ≥ 3 consecutive EMG bursts lasting 0.35-2 seconds each,

2. Tonic: sustained muscle contraction lasting > 2 seconds,

3. Mixed: both phasic and tonic in the same episode.

Phasic and mixed patterns represented 90% of RMMA (56% and 34%), respectively (Miguel *et al.* 1992). While there were similarities in the grinding episode patterns between bruxers and controls, they occurred more frequently and forcefully in bruxers (Rompre *et al.*, 2007). A further two subgroups have been proposed by Lavigne *et al.* for young, otherwise healthy, bruxism patients based on rhythmic masticatory muscle activity (RMMA)(Lavigne *et al.* 2009):

1. Low frequency: ≥ 2 and < 4 episodes/hr

2. High Frequency: > 4 episodes/hr

Considerably higher EMG signalling (> 25 bursts of EMG activity per RMMA episode) and amplitude were associated with RMMA in 20 bruxers versus controls using polygraphic sleep recordings (Khoury *et al.* 2008). This increased signalling contributed to jaw opener muscle (suprahyoid muscle) and opening the airway to allow increase airflow amplitude.

1.2.3.3 Non-Rhythmic Jaw Movements

There are several normal physiological movements commonly observed during sleep, including swallowing, grimacing, talking, sighing, and coughing. The most frequently

reported orofacial movement during sleep was swallowing, which was reported to occur six times per hour, compared to sixty times per hour during daytime and wakefulness (Lichter and Muir, 1975). Lavigne *et al.* reported an association between swallowing and sleep arousal shifts during sleep (Lavigne *et al.* 2008b). The authors reported a decreased frequency of swallowing for bruxers compared to controls; however, increased swallowing activities were observed at the end of bruxism episodes. Grimacing commonly occurs in response to emotional conditions while dreaming, and usually occurs without full wakefulness (Sumitsuji *et al.* 1980). Sleep talking has been reported for up to 61% of the adult population, and it usually occurs during stages 2 and 3 of non-rapid eye movement sleep (Partinen, 2011).

Sleep sighing occurs between 1-25 times per night, and is commonly associated with stage 1 of non-rapid eye movement sleep, but can occur in any sleep stage (Perez-Padilla et al., 1983). Furthermore, the authors reported an association between sighs (64%) and sleep arousals, typically followed by respiratory disturbance such as central apnoea and hypoventilation.

1.2.3.4 Basic Sleep Cycle Physiology

The sleep cycle is an oscillation between non-rapid eye movement (non-REM) and rapid eye movement (REM) stages of sleep. It is also called the REM-NREM cycle, ultradian sleep cycle or sleep-dream cycle. A complete sleep cycle takes on average 90-110 minutes, resulting in 3-5 sleep cycles per 6-8 hours of night sleep. Each cycle consists of periods of non-REM and

REM sleep (Rechtschaffen, 1968). Non-REM is also called quiescent sleep. According to the American Academy of Sleep Medicine (AASM), non-REM sleep can be further subdivided into 3 stages (stages 1-2: light sleep and stage 3: deep sleep) (Schulz, 2008). Nearly 80% of sleep bruxism has been recorded in sleep stages 1 and 2, 10% during sleep stages 3 and 10% during REM sleep (Lavigne *et al.* 2003).

The transitions between deep sleep and light sleep are associated with abrupt changes in the pattern of brain wave activity, with activity of greater than 10-15 seconds being called 'sleep arousals' (Lavigne *et al.* 2002). Sleep arousal is represented by elevations in both EEG activity and muscle tone, and occurs frequently throughout sleep (Halász *et al.* 2004). Short periods of arousal have also been observed during switching from deep sleep to an aroused state. These arousals are called microarousals, and are characterised by abrupt shifts in EEG activity lasting 3–15 seconds, accompanied by an elevation in heart rate and muscle tone. Microarousals occur 8–15 times per hour of sleep in young healthy subjects (ASDA, 1992), and a strong association has been reported between sleep bruxism and episodes of arousal activity (Huynh *et al*. 2006a). Even though more than half of microarousal episodes are associated with altering sleep stage, this alteration was found to be transient and sleep returned to the baseline. In conclusion, there are subtle changes at the microstructural level of sleep associated with microarousal-related sleep bruxism episodes; however, at the macrostructural level there was no difference (Huynh *et al.* 2006a). Microarousals are thought to reflect a natural brain response and are seen as protective in maintaining body homeostasis and vigilance during sleep (Kato and Lavigne, 2010). The cyclical recurrence of sleep microarousals is termed cyclic alternating pattern (CAP) (Macaluso *et al.* 1998). CAP

episodes are frequently associated with several physiological activations, all mediated by the sympathetic nervous system (Terzano and Parrino, 1993). Approximately 80% of RMMA episodes correlate with CAP episodes (Huynh *et al.* 2006a).

Macaluso and co-workers confirmed the association between CAP and sleep bruxism in a highly controlled polysomnographic study of six subjects (Macaluso *et al.*, 1998). In another controlled clinical trial of eight sleep bruxism patients, experimentally induced arousals and RMMA were investigated using polygraphic sleep laboratory recordings over three or four nights (Kato *et al*. 2003a). The study found that microarousals were more frequently followed by RMMA in bruxers (71% higher) than in controls. Furthermore, these episodes were usually accompanied by tooth-grinding, which supported the hypothesis that the onset of sleep bruxism is related to oromotor activity and the sequence of physiological activations in relation to microarousals (Figure 1.2) (Lavigne *et al.* 2001a).

1.2.3.5 Sleep bruxism association with an increased level of oromotor activity in jaw muscles and the role of sleep arousals

Sleep bruxism is a jaw movement that occurs without food trituration, without alternating closing pattern (as in chewing) and without cortical involvement. In contrast to other rhythmical sleep motor disorders, sleep bruxism has little impact on sleep organisation (Lavigne & Montplaisir 1994). For example, Periodic Limb Movements Disorder of Sleep (PLMD) is defined as "repetitive cramping or jerking of the legs during sleep", and is always associated with decreased sleep efficiency, major sleep disruption and increased arousal

movement. Sleep bruxism is unlike chewing, which is generated mainly in the cerebral cortex. During sleep depression of jaw opening reflexes and cortico-bulbar pathways have been observed in primates (Lavigne *et al.* 2007). Additionally, the influence of the brainstem on sleep bruxism was reported in a stimulated transcranial magnetic study in humans (Gastaldo *et al.* 2006). This study further reported that increased excitability of the central jaw motor pathways might be associated with sleep bruxism. This increased excitability could derive from brainstem inhibitory circuit impairment and not from altered cortical mechanisms (Lavigne *et al.* 2003). Recent hypotheses have been linked to the genesis of oromandibular sleep activity (Lavigne *et al.* 2007). The central and autonomic nervous systems control sleep-related mechanisms by influencing the levels of brain chemicals and maintaining airway patency (Figure 1.3)(Klasser & Greene, 2009). The brief transient reactivation of the brainstem arousal reticular ascending system contributes to an increase in autonomic network activity (Lavigne *et al.* 2007)**.** Subsequently, increases in motor activity will initiate sleep bruxism as well as rhythmic masticatory activity.
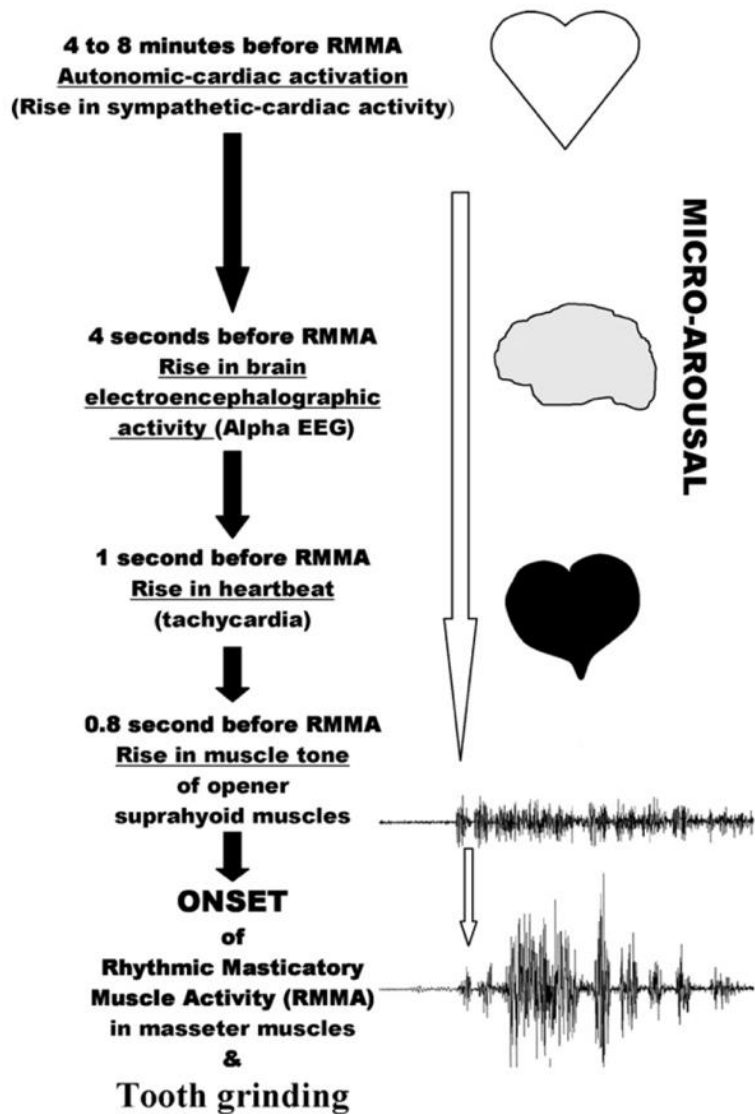
Figure 1.2. Proposed oromotor activity and physiological sequence changes in relation to RMMA, related micro-arousals (MA) and those associated with sleep bruxism tooth grinding (Lavigne *et al*., 2007).

> Some mechanisms (unknown, black circle) trigger changes in the brain or autonomic nervous system, resulting in a higher likelihood of observing SB on EMG and video recordings during sleep.
>
> **Step 1:** Increase in autonomic cardiac activity 4 minutes preceding tooth grinding or phasic jaw muscle contractions*
>
> **Step 2:** Increase in cortical brain activity 4 seconds prior to SB activity
>
> **Step 3:** Increase in suprahyoid muscle tone (possibly involved in jaw opening or airway patency), heart rate (tachycardia), and amplitude of respiration (big breath)1 second before masseter and temporalis muscle activity
>
> **Step 4:** Onset of activity of jaw-closer muscles, referred to as rhythmic masticatory muscle activity*
>
> SB | **Step 5:** Tooth grinding sounds followed by swallowing activity in about half of SB episodes

Figure 1.3. Muscle physiological sequence for sleep bruxism-associated central and autonomic nervous system episodes. Episodes were confirmed with EMG and audio-video recordings (Klasser & Greene, 2009).

There is strong evidence supporting the role of autonomic sympathetic activities and brain arousal in the genesis of sleep bruxism. Both the central and autonomic nervous systems (Lavigne *et al.* 2003) mediate oromotor mandibular activity during sleep.

The ascending and descending arousal systems are located in the brainstem and hypothalamus, and demonstrate a significant influence on vigilance and sleep (Saper *et al.*, 2005). This group of cells in the brainstem and hypothalamus regulating sleep and producing wakefulness are crucial for shutting off the arousal system during sleep. These

neurons are inhibited by α-aminobutyric acid (AABA) containing neurons during sleep. Mutual inhibition between arousal and sleep states results in switching characteristics that distinguish waking and sleeping states, with sharp transitions between the two. The arousal key switch is stabilised by orexin neurons in the lateral hypothalamus (LHA) and impairment of these neurons results in an extreme tendency to fall asleep (Saper *et al.* 2005).

Arousal-associated neurochemical transmitters such as acetylcholine, dopamine, monoamine oxidase, noradrenaline and serotonin are secreted at different levels during awake or sleep states (Lavigne *et al.* 2007). To initiate non-REM sleep, the hypothalamus arousal-related orexin/ hypocretin activities and acetylcholine, noradrenaline and serotonin brain network influences are inhibited by GABA inhibition of the arousal ascending system (Nelson *et al.* 2002). Research has demonstrated an association between brain and cardiac activity, such as a rapid increase in heart rate and the onset of RMMA during recurrent microarousal episodes (Reding *et al.* 1968). Microarousals are natural transit activities (3-10 s abrupt shifts in EEG activity occurring 8-15 times per hour of sleep) associated with increased heart rate, muscle tone and brain activity (Lavigne *et al.* 2008). In agreement with previous studies, the sleep arousal hour cycle, including a repetitive increase in heart rate, brain activity and muscle tone, occurs between 8 and 15 times per night (Saper *et al.* 2005).

Most sleep bruxism episodes are controlled by promoter arousal activity, including transient cardiac sympathetic activity shown in the rapid increase in heart rate (tachycardia)

associated with the onset of RMMA, or the decreased heart rate (bradycardia) associated with recurrent sleep arousal (Huynh *et al.* 2006a).

1.2.3.6 Association of bruxism with genetic factors and familial learned behaviour

Questionnaires and wear estimation-based studies have demonstrated a high genetic determinant in bruxism and teeth grinding in monozygotic and dizygotic twins. An increased concordance rate for the masticatory pattern in monozygotic and dizygotic twins has been reported (0.97 and 0.61, respectively)(Hublin *et al.* 1998). A Finnish cohort study of twins demonstrated that childhood sleep bruxism persists in 86% of subjects into adulthood (Hublin *et al.* 1998). Twenty to fifty per cent of sleep bruxism patients had an immediate family member who reported childhood teeth clenching (Kuch *et al.* 1979). Quantitative and validated assessments such as sleep recordings play an important role in confirming the presence of sleep bruxism. Due to study limitations, a direct association between genetic profile and bruxism could not be easily identified.

Specific gene identification will require multicentre studies of patients with valid confirmations of bruxism coming through clinical examination and EMG with audio-video recording whilst controlling for variables such as anxiety, stress and medication use. For example, gene and protein activation, as a result of stress and anxiety, cannot be easily isolated in relation to observed changes in the autonomic and cerebral arousal systems (Lavigne *et al.* 2008a). New investigative approaches for sleep bruxism pathophysiology have emerged, which include genetic factors (Figure 1.4). Previous theories had been

restricted to mechanical factors (occlusion), adoptive or maladaptive behaviour (stress) and

dopamine dysfunction.
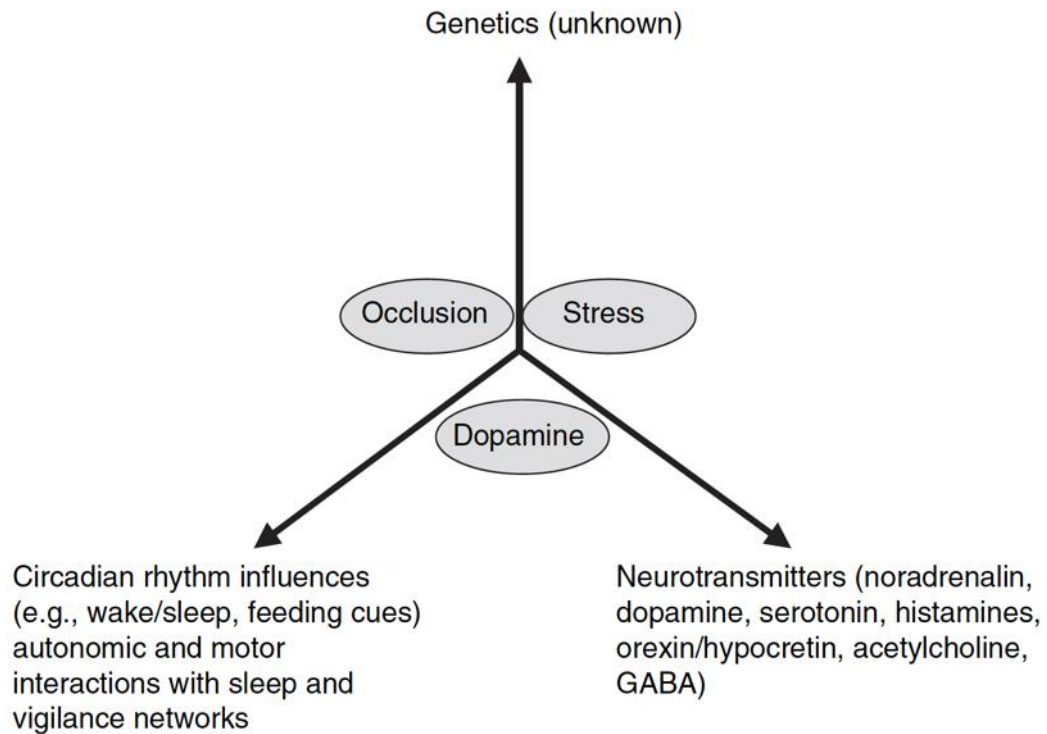
Figure 1.4 Sleep bruxism pathophysiology: old theories and new hypotheses. Old theories are contained within the circles; new hypotheses are indicated with arrows. GABA: gamma-aminobutyric acid (Lavigne *et al.* 2008a).

1.2.3.7 The role of neurochemical substances

The proposed role of neurochemical substances in relation to sleep bruxism pathophysiology is mainly based on case reports or randomised clinical studies using a range of medications (Winocur *et al.* 2003). The first possible association between tooth grinding and brain chemicals originated from a case report in which L-3,4-dihydroxyphenylalanine (L-DOPA) was prescribed to manage tooth grinding in a patient suffering from Parkinson's disease (Magee, 1970). L-DOPA, a precursor of dopamine (DA) and noradrenaline (NA), is an amino acid, which is a precursor to the neurotransmitter group known as catecholamines. However, this finding was found in only one Parkinsonian patient who presented with sleep bruxism, secondary to medication use. A controlled study with L-DOPA-treatment for healthy sleep bruxers demonstrated a modest (30%) but significant reduction in sleep bruxism activity (Lobbezoo *et al.* 1997). However, the specificity of DA in the genesis of sleep bruxism remains ambiguous, as an increase in chewing-like activity and tooth-grinding was reported in schizophrenic patients treated with DA antagonists such as haloperidol (Micheli *et al.* 1993). Furthermore, a controlled study with a direct dopamine agonist (Bromocriptine) demonstrated no obvious reduction in RMMA genesis (Lavigne *et al.* 2001c).

Neurotransmitter-modulating drugs have been investigated, since sleep bruxism has been identified as a centrally driven disorder. Several neurotransmitters (agonists and antagonists) have been studied in the treatment of sleep bruxism. The mechanism of action for these drugs is not fully understood. It may be acting directly on the motor system

(related to sleep bruxism) or acting indirectly through the sleep arousal system. Neuromuscular junction acetylcholine release inhibition drugs (e.g. botulinum toxin) reduced bruxism events through paralysis of muscle action. In a study of 18 severe bruxism patients, a total of 241 injections were administered in the masseter muscles over 123 treatment visits. It was concluded that botulinum toxin was an effective treatment for patients with severe bruxism-associated movement disorders (Tan and Jankovic, 2000). In addition, a double-blind, randomised clinical trial was conducted for 12 self-reported sleep bruxism subjects with botulinum toxin injection administrated for six bruxers in both masseters. The control patients were injected with a saline solution (Lee *et al.* 2010). Nocturnal EMG activity was recorded from masseter and temporalis muscles at baseline, 4, 8, and 12 weeks following the injection. Significant reductions in masseter muscle EMG activity were reported ($P = 0.027$) using botulinum toxin versus controls. On the other hand, similar EMG activities were recorded in the temporalis muscle of both groups. In addition, significant improvements in subjective sleep bruxism symptoms were reported for both groups ($P < 0.001$). The authors concluded that botulinum toxin injection reduced sleep bruxism activity through a local decrease in masseter muscle activity rather than central mediated effect in CNS.

Muscle relaxants (central nervous system [CNS] depressants) demonstrated a positive action on sleep bruxism. One historical study reported that using one to two grams of methocarbamol (Robaxin) per night and muscle relaxants may reduce sleep bruxism activity (Chasins, 1959).

Reduced tooth grinding has been reported in one patient study using the neuroleptic Propranolol (a catecholamine beta-adrenergic receptor blocker)(Amir *et al.* 1997). Similarly, reduced sleep bruxism activity was observed in a single patient without neuroleptic use. Polygraphic sleep laboratory recordings were carried out over four nights in a randomised controlled trial of bruxism management using two sympatholytic medications: Propranolol and Clonidine (an α2 adrenergic agonist in the CNS used mainly in the management of hypertension, severe alcohol or substance withdrawal and attention-deficit hyperactivity disorder (ADHD) in children) (Huynh *et al.* 2006b). The study reported that Propranolol, a non-selective beta-blocker, demonstrated no effect on sleep bruxism/RMMA activity. In contrast, a significant reduction (61%) in the sleep bruxism index was observed with a lower dose of Clonidine (0.1 mg) during a one-night experimental treatment (Huynh *et al.* 2006). This reduction was partly associated with a concomitant decrease in the cardiac-autonomic sympathetic dominance before rhythmic masticatory muscle activity onset (Huynh *et al.* 2006b). Clonidine prolonged the duration of sleep stage 2 and suppressed REM sleep. Diminished heart rate and sympathetic dominance as well as reduced mean R-R intervals (the time between two successive R waves on ECG) were reported using clonidine during stable sleep in the minute before the onset of sleep bruxism. Severe morning hypotension was observed in 20% of participants and considered a major side effect when using clonidine. Other adverse effects such as dry mouth and REM sleep suppression were reported (Huynh *et al.* 2006b). Moreover, chronic use of cardioactive medications is known to increase the frequency of nightmares and awakenings, to influence sleep architecture

and quality, as well as to aggravate respiratory disorders in some participants (Danjou *et al.,* 1987, Monti, 1987).

The role of serotonin in sleep bruxism genesis is unclear. The use of both a serotonin precursor, L-tryptophan, and a tricyclic antidepressant, amitriptyline, were shown to be ineffective in the management of sleep bruxism (Etzel *et al.* 1991, Raigrodski *et al.* 2001). No significant differences were reported in sleep bruxism levels during a randomised double-blind study conducted in eight patients for eight nights using tryptophan (50 mg/kg) or a placebo for eight days followed by an additional eight nights of reverse medication, suggesting that L-tryptophan treatment is ineffective in nocturnal bruxism management (Etzel *et al.,* 1991). Additionally, in a double blinded crossover randomised clinical study involving ten females (mean age 39 years old) receiving either 25 mg amitriptyline or a placebo, no significant decrease in the mean EMG activity was reported (Raigrodski *et al.* 2001). In contrast, Lobbezoo and co-workers reported that selective serotonin reuptake inhibitors (SSRIs) antidepressant medications might be associated with bruxism in some susceptible individuals (Lobbezoo *et al.* 2001b). In a further study, which involving four female patients (36, 43, 30, and 36 years old) who had not been previously aware of sleep bruxism and were positively responding to antidepressant treatment with Fluoxetine or Sertraline (SSRIs), sleep bruxism was reported 2-4 weeks following initiation of treatment (Ellison and Stanziani, 1993). This study also demonstrated relief of SSRI-associated sleep bruxism using either smaller SSRI dosages or by adding anti-anxiety medications such as Buspirone. A case report study revealed an increase in sleep bruxism activity for a patient

taking the SSRI Paroxetine. The report cited a thirty-eight-year-old female diagnosed with depression and headaches who commenced a paroxetine regimen of 10 mg/day, which was increased to 20 mg/day after one week. The patient reported an improvement in her symptoms at the three-week follow-up visit; however loud nocturnal grinding noises and teeth clenching had been noted by her husband (Milanlıoglu, 2012).

Some studies have reported the role of gamma-aminobutyric acid (GABA) in sleep bruxism. Anticonvulsant drugs, such as selective GABA reuptake inhibitors, showed a positive effect on sleep bruxism activity (Kast 2005). Several controlled polysomnographic and psychometric studies reported reductions in sleep bruxism using substances with an affinity to GABA, such as Clonazepam, Tiagabine and Gabapentin (Saletu *et al.*, 2005; Sadat Madani *et al.* 2013). However, the role of GABA in sleep bruxism is still unclear as there is no direct interaction between Gabapentin and GABA receptors or GABA reuptake (Brown and Hong, 1999). It has been demonstrated that Gabapentin increases non-REM sleep stage 3 (deep sleep) and this sleep stage is decreased in sleep bruxism, suggesting a possible mechanism whereby Gabapentin may reduce sleep bruxism (Sadat Madani *et al.* 2013).

Clonazepam, a benzodiazepine tranquillizer with hypnotic, anxiolytic, anticonvulsive, and myorelaxant effects, has been shown to improve sleep bruxism activity, as well as the sleep quality for patients with psychiatric and sleep comorbidities (Saletu *et al.* 2005; Saletu *et al.* 2010). It was also demonstrated that modest short-term benefits can be expected for this drug, although its long-term efficacy remains to be evaluated. Caution should be exercised

in prescribing Clonazepam on account of significant risk of cognitive impairment, dizziness and sleepiness (Guaita and Högl 2016). Another benzodiazepine anti-anxiety drug, Diazepam, demonstrated reduced sleep bruxism activity when used in eleven subjects (5-10 mg per night) with clinical symptoms of masticatory hyperactivity (Montgomery, 1986). Furthermore, the authors reported significant reductions in masseter electromyographic activity in subjects following the administration of Diazepam at bedtime. A high-quality double-blinded RCT with a larger sample size is needed for definitive clinical recommendations for both Diazepam and Clonazepam, as both possess undesirable collateral effects, such as dizziness, sleepiness, and risk of addiction.

1.3 Diagnostic Grading Systems

1.3.1 General Considerations

Several methods have been reported for diagnosing and grading sleep bruxism (Lobbezoo *et al.* 2013). Questionnaires are commonly used tools, which are suitable for large cohorts; however, they frequently over- or under-score the condition due to their subjective nature (Raphael *et al.* 2015). Clinical examination for manifestations, such as tooth wear can also be used in larger study populations. However, a clinical proxy, such as tooth wear, is a poor assessment method due to the presence of multiple aetiologies and the cumulative nature of multiple forms of tooth wear (Baba et al. 2004). Electromyography (EMG) is applicable for moderately large study groups, but has limited availability. Polysomnography (PSG) is considered a "gold standard" diagnostic tool for sleep bruxism, but is not widely utilised due to its high cost and limited availability. It is a multi-parametric testing method using

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highly controlled, detailed and reproducible tests that is used in sleep medicine and only suitable for small sample sizes. PSG is performed in a controlled environment, limiting factors that may disturb sleep, and provides direct real-time observational measurements as well as physiological data (Lavigne *et al.* 2003). Additionally, PSG can detect other sleep disorders that may affect sleep architecture or may be associated with sleep bruxism, which can provide a context for a diagnosis of sleep bruxism. A definitive sleep bruxism diagnosis can only be confirmed using electrophysiological diagnostic tools (Lavigne *et al.* 1996). Comprehensive understanding of the pathophysiology of sleep bruxism as a sleep disorder requires the development of modern diagnostic technologies including EMG and the use of polysomnography (Kato 2003). The definitive diagnosis of sleep disorders, including sleep bruxism, sleep apnoea, periodic limb movements and parasomnias can be objectively detected using laboratory-based PSG. However, due to the associated high cost, unfamiliar environment and inconvenience to the patient, PSG is not considered an ideal tool for identifying sleep bruxism for many patients (Lobbezoo *et al.* 2008). The main disadvantages of the laboratory-based PSG method is that the normal sleep milieu is disturbed for the first night at a minimum (Le Bon *et al.,* 2001). This is called the "first night effect", and therefore a number of nights are required to enhance the method reliability. Due to financial and logistical limitations completing sleep studies using PSG, many authors have agreed that it is difficult to justify its widespread use due to the high cost (Dutra *et al.* 2009).

The first controlled, psychophysiological laboratory study of sleep bruxism was conducted in 1968 (Reding *et al.* 1968). They reported that sleep bruxism was not detectable each

night, and that rhythmic jaw muscle movement could even be exhibited in asymptomatic subjects (Reding *et al.* 1968). The same authors also suggested scoring sleep bruxism based on the rhythmic jaw muscle movement and amplitude criteria. However, the use of rhythmic- and amplitude-based scoring raised questions regarding reliability due to the strict criteria for scoring, which left several episodes unscored (Wruble *et al.* 1989). Moreover, the sleep bruxism diagnostic criteria of sensitivity, specificity and predictive value were not tested (Mohl & Dixon, 1994). Discriminatory cut-off diagnostic criteria for sleep bruxism, which have "good" to "very good" specificity, sensitivity and predictive values have been proposed (Lavigne *et al.* 1996). According to the American Sleep Disorders Association (ASDA), the clinical diagnosis for sleep bruxism is primarily based on the self-reporting of tooth grinding or clenching combined with the presence of at least one of the following secondary criteria: tooth wear, positive grinding sounds and jaw muscle discomfort (Thorpy 1990). The research diagnostic criteria for sleep bruxism RDC/sleep bruxism criteria were based on cut-points intended to optimise sensitivity and specificity relative to the International Classification sleep bruxism definition (Medicine, 2005). The receiver-operator curves were used for cut-off values (Figure 1.5); however, it provided neither "simple yes or no results" nor absolute numbers (Mohl, 1993). Furthermore, it was proposed that the cut-offs points should not be used without patient evaluation (Mohl, 1993). The discriminatory cut-off is usually determined based on the use of the upper left point on the curve. To demonstrate, the number of bruxism bursts per hour was chosen as point 25 (Figure 1.5, outcome C), and determined based on the shape of the curve as well as confidence interval (Lavigne *et al.* 1996). Furthermore, point 20 could also have been

chosen and that would have increased the sensitivity and reduced specificity. The consequences of this would have been the inclusion of control individuals in the bruxer group. With the exception of tooth wear, the ASDA clinical diagnostic criteria for sleep bruxism could provide a reasonably predictable diagnostic method, which could be confirmed through the use of PSG cut-off values of 25 bursts of bruxism per hour of sleep and/or over four bruxism episodes per hour (Lavigne *et al.* 1996).
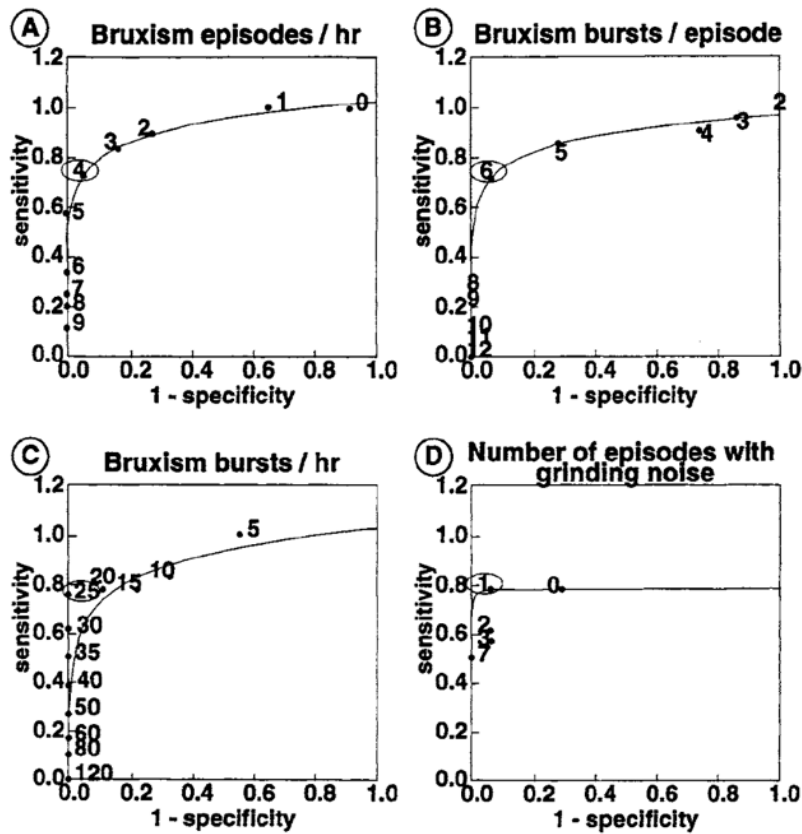
Figure 1.5 Receiver-operator curves (ROC) for selection of the discriminant cut-off point. For each of outcome A-D, the selected cut-off is circled in each graph (Lavigne *et al.* 1996).

Using standard cut-off points should not be considered optimal for clinical use in otherwise healthy subjects for several reasons. Firstly, some circularity is present in the criteria used to establish these cut-off points, which were determined for research purposes in a carefully selected study sample. Secondly, there is a growing opinion that a cut-off point should not be used to describe a potentially harmless behaviour (Lobbezoo *et al*. 2018). Thirdly, it has been shown that the number of bruxism events may not represent a risk factor, rather the overall EMG activity level, which was found to be higher in temporomandibular disorder (TMD) patients than controls (Raphael *et al.* 2013).

Reliable, cost-effective and chairside diagnostic methods were proposed by the AASM through the International Diagnostic Criteria (Medicine 2005). Based on the ICSD, diagnostic criteria for sleep bruxism were based on both patient history and clinical examination.

1.3.2 Questionnaires

Questionnaires are the most common diagnostic tool used to identify bruxism in the dental literature. Besides clinical examination, a bruxism questionnaire is routinely used in clinical practice to diagnose sleep bruxism. Questionnaires are simple to carry out, require little training and are time- and cost-efficient. However, their drawbacks as a diagnostic tool have been reported (Casett *et al.* 2017). An evaluation of studies using self-reported and/or clinician-reported tooth grinding to address the relationship between tooth grinding and temporomandibular pain and dysfunction syndrome indicated that this diagnostic method was methodically inadequate (Marbach *et al.* 1990). A lack of conscious recollection during

sleep from the patient and/or bed partner is an obvious limitation, undermining the reliability of the approach. In addition, questionnaires have limited applicability if a bed partner is not present and the leading nature of the questionnaires may overestimate the severity of the condition (Marbach *et al.* 1990; Kato, 2003), and questionnaires lack consistency and evidence-based content or detail. The validity of questionnaires can only be evaluated if compared with objective diagnostic methods. An epidemiological study completed by Maluly estimated sleep bruxism prevalence using a representative sample of 1,042 subjects who were assessed using PSG studies and previously validated questionnaires (Maluly *et al.* 2013; Braz *et al*. 1987). In that study, the presence of bruxism, based upon questionnaire responses, was not confirmed in 53% of the participants using PSG. Essentially, more than half of the cohort who complained of sleep bruxism, which was identified based on questionnaire responses, had no PSG-observed sleep bruxism diagnosis. If PSG was not used as a diagnostic criterion, an overestimated prevalence of 12.5% would have been reported. The authors concluded that questionnaires demonstrated high sensitivity and very low specificity. Conversely, other authors have reported medium to high specificity regarding the questionnaire; thus, compared to the PSG findings, the questionnaires better identified non-bruxers (Palinkas *et al.* 2016). Furthermore, there was a high specificity associated with the signs and symptoms in the questionnaire, such as "muscle pain and 'jaw locking". Self-reported bruxism may only reflect "possible" sleep bruxism as per the International Consensus Statement and is not a valid replacement for PSG-based evidence (Lobbezoo *et al.* 2013).

The direct concordance between self-reported sleep bruxism and PSG-diagnosed sleep bruxism was evaluated for both subjects with TMD and a control group (Raphael *et al.* 2015). Self-reported questionnaires failed significantly in predicting any PSG standard for subjects without TMD. Furthermore, sleep partners who self-reported grinding sounds were significant predictors for subjects with TMD. Therefore, using self-reported sleep bruxism as a proxy for PSG-assessed sleep bruxism is not useful. Pintado and co-workers established a typical sleep questionnaire, presented in Table 1.6 (Pintado *et al.* 1997). According to this questionnaire a subject is classified as a bruxer if two or more positive responses are recorded.

There are inherent limitations in relation to the questions proposed by Pintado *(Pintado et al.* 1997). The first is probable underestimation of sleep bruxism prevalence resulting from responses to the first question, as up to 80% of bruxism episodes are not associated with noise (Lavigne *et al.*, 1996). As mentioned, associations between orofacial pain and sleep bruxism, as elaborated in the questionnaire, lack reliability. Ohayon and co-workers completed one of the largest epidemiological surveys using a dedicated computer program, allowing untrained investigators to interview over 13,000 participants worldwide (Ohayon *et al.* 2001). It was designed with four baseline questions, which then prompted the investigators to ask more relevant and detailed questions. All included questions were based on diagnostic descriptions according to the minimal set of criteria from the International Classification of Sleep Disorders (ICSD) classifications. These allow recognition

of sleep bruxism occurrence based on patients self-reporting, bed partner collaboration

history and, indirectly, from the dental examination (Table 1.7).

Has anyone heard you grinding your teeth at night?
Is your jaw ever fatigued or sore on awakening in the morning?
Are your teeth or gums ever sore on awakening in the morning?
Do you ever experience temporal headaches on awakening in the morning?
Are you ever aware of grinding your teeth during the day?
Are you ever aware of clenching your teeth during the day?

Table 1.6. Sleep bruxism questionnaire (Pintado *et al.,* 1997).

According to you, or your bed partner, do you grind your teeth at night?
Have you had dental work done because you grind your teeth?
Do you have muscular jaw discomfort due to teeth grinding?
Is the tooth grinding so noisy that your partner can hear it?

Table 1.7. The four baseline questions used in an expert computer system questionnaire (Ohayon *et al.* 2001).

According to the diagnostic criteria of the AASM Diagnostic and Coding Manual (Diagnostic

& Manual, 2005), sleep bruxism was evaluated by a questionnaire based on events during

the past six months. Subjects with active sleep bruxism were identified if their answer was

positive to the first and/or second question, as well as at least one positive response to a symptom listed in question three of Table 1.8.

1. **Are you aware, or has anyone heard you, grinding your teeth frequently during sleep?**
2. **Are you aware that your dentition is worn down more than it should be?**
3. **Are you aware of any of the following symptoms upon awakening? (Yes⁄No):**   (i) **Sensation of fatigue, tightness or soreness of your jaw upon awakening?**   (ii) **Feeling that your teeth are clenched or that your mouth is sore upon awakening?**   (iii) **Aching of your temples upon awakening?**   (iv) **Difficulty in opening your mouth wide upon awakening?**   (v) **Feeling of tension in your jaw joint upon awakening and feeling as if you have to move your lower jaw to release it?**   (vi) **Hearing or feeling a ''click'' in your jaw joint upon awakening that disappears afterwards?**

Table 1.8. Self-reported questionnaire based on the diagnostic criteria of the American Academy of Sleep Medicine. (Diagnostic and Manual, 2005).

1.3.3 Clinical Evaluation

Dental professionals frequently employ clinical examination as a diagnostic tool for sleep bruxism. This has been developed as an International Diagnostic Criteria for sleep bruxism by the American Academy of Sleep Medicine (AASM, 2005)(Table 1.9).

Orofacial pain associated with sleep bruxism is a commonly reported symptom; 66%-84% patients with confirmed sleep bruxism reported pain (Bader and Lavigne, 2000, Camparis and Siqueira, 2006). In addition, significant co-morbidity between orofacial pain and sleep bruxism has been demonstrated. TMD patients (between 26% and 66%) reported bruxism-related symptoms (Fricton *et al.* 1985, Bush *et al.* 1989). Of course, this association falls short of determining the causality and the direction.

Patient history (self-reported Questionnaires)

- Recent patient, parent, or sibling report of tooth-grinding sounds occurring during sleep for at least 3 to 5 nights per week in the last 3 to 6 months.

Clinical evaluation *

- Tooth wear beyond the physiological limit

- Masseter muscles hypertrophy on voluntary clenching

- Discomfort, fatigue, or pain in the jaw muscles (and transient, morning jaw muscle pain and headache)

None of these signs and symptoms can provide direct proof of current sleep bruxism activity. PSG with audio-video recording (Full-night) is still the gold standard diagnostic tool for sleep bruxism.

Table 1.9. AASM international diagnostic criteria for sleep bruxism (AASM, 2005).

Furthermore, orofacial pain is considered more or less pathognomonic of sleep bruxism according to some researchers (Thie and Lavigne, 2001). Huang and co-workers investigated the association between myofascial pain and bruxism and reported an odds ratio of 4.8 (Huang *et al.* 2002). However, an odds ratio only represents association and does not determine its direction or causality. A large questionnaire-based epidemiological study (12,468 participants) reported that a self-report of bruxism was the main predictor of craniofacial pain (Johansson *et al.* 2006).

Associations between daytime clenching and orofacial pain have been reported (Sato *et al.*, 2006). Several authors have reported that the presence and severity of pain did not correlate with sleep bruxism activity (Rossetti *et al.* 2008; Nagamatsu-Sakaguchi *et al.* 2008). A randomised controlled clinical study investigated the relationship between orofacial pain severity and bruxism activity using EMG studies and questionnaires (Rompré et al., 2007). The authors unexpectedly found a positive finding of pain symptoms for sleep bruxers with lesser frequencies of bruxism activities. In addition, negative findings associated with TMJ tenderness have been reported for severe bruxism participants (Pergamalian *et al.*, 2003). Many of the early theories on how bruxism-initiated muscle pain arose from strain injury or overuse of various skeletal muscles. The main bruxism-related pain mechanism is ischaemic cramp associated with persistent isometric loading, delayed onset muscle pain and repetitive strain injury (Svensson *et al.* 2008). Orofacial pain trials usually involved performing various muscle movement or exercise regimes to investigate

pain character, intensity and duration (Clark *et al.* 1991; Bowley and Gale, 1987; Christensen, 1979). Common findings included:

1. Masticatory muscle overuse was predictably associated and followed by pain, and the type of muscle contraction determined the interval between applied exercise and pain.

2. During sustained clenching exercises, the time to pain onset and subsequent duration were uniformly short.

3. Delayed pain onset was associated with simulated grinding and muscle contraction.

4. With repeated exercise a gradual reduction in pain susceptibility occurred.

5. Low intensity repeated muscle use was associated with ultrastructural level muscle fibre damage in the presence of local subclinical inflammation.

Experimental models have failed to predict clinical bruxism related symptoms (Dao and LeResche, 2000). Several studies have reported the possible role of local nerve compression and neural sensitisation in the presence of an existing pain susceptibility in subjects with bruxism-related orofacial pain. Links between awake bruxism and sleep bruxism have been suggested by several authors, which may contribute to the development and persistence of orofacial pain (Svensson *et al.* 2001, Glaros and Burton, 2004). Authors reported that positive pain findings correlated with the overall masseter muscle activity during sleep and wakefulness.

1.3.4 Polysomnography (PSG)

Polysomnography is a diagnostic method used in sleep medicine that includes reproducible, detailed, highly controlled multi-parametric tests. Lavigne validated the research diagnostic criteria for sleep bruxism using PSG as a diagnostic tool, which has been supported and revised by the American Academy of Sleep Medicine (Iber & Iber 2007; Lavigne *et al.* 1996). According to the most recent diagnostic criteria, sleep bruxism diagnosis is confirmed if more than two rhythmic masticatory muscle activity (RMMA) episodes are recorded per hour of sleep, with at least one episode associated with grinding sounds/noises. According to Rompré diagnostic criteria of sleep bruxism can be characterised as follows:

1. If less than two episodes are recorded per hour, then there is no sleep bruxism.

2. If there are between two and 3.9 episodes per hour, then low-frequency sleep bruxism is confirmed.

3. If four or more episodes are recorded per hour, then high frequency sleep bruxism is confirmed (Rompré *et al.* 2007).

There are simultaneous recording and data analysis methods involved in PSG (Dukes, 2001) as follows:

1. Electroencephalography (EEG): This consists of recording the brain's electrical activity (patterns and amplitude). EEG is used to evaluate sleep patterns and features, including sleep arousals, sleep stages, arousals and respiratory events. This recording provides the informational background required for the analysis of all other information.

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2. Electromyography (EMG): This consists of recording the electrical activity for different muscle groups. In sleep bruxism analysis, the masseter or temporalis muscles are typically evaluated.

3. Electrooculography (EOG): This involves recording the electrical activity in the eye muscles. EOG is used to assess eye movement (saccade), which is associated with various sleep stages.

4. Electrocardiography (ECG): This involves recording the heart's electrical activity. During sleep bruxism, ECG records the cardiac response to sympathetic arousal episodes.

5. Respiratory parameters: These consist of recording sleep breathing rate, respiratory effort (abdominal and thoracic), airflow and peripheral oximetry.

6. Audio-visual recordings: These consist of a complete recording of all audio-visual parameters during testing. When diagnosing sleep bruxism, audio-visual recordings are a useful tool to validate data obtained from electrophysical recording.

Detection of sleep bruxism using PSG is accurate and researchers have established standardised requirement criteria to identify sleep bruxism from other oral activities. A sleep bruxism diagnosis can be confirmed by relating the recording output data to established diagnostic criteria.

Masseter and Temporalis EMG Activity
Mean EMG amplitude: at least 10% of maximum voluntary clenching activity.
When awake maximum voluntary clenching EMG amplitude is greater than 20% to exclude myoclonus.
The duration of EMG bursts must be > 0.25 seconds.
SB Episode Types
Two intervals separated by more than 3 seconds (audio-visual analysis utilised to exclude non-specific orofacial movements).
1. Phasic (rhythmic): within the duration of 0.25-2 seconds, three or more EMG bursts.
2 Tonic (sustained): EMG bursts duration lasting > 2 seconds.
3 Mixed: both phasic and tonic types.
Diagnostic Cut Off Criteria
Greater than four bruxism episodes per hour or/and > 25 EMG bursts of bruxism per hour of sleep.
Two or more bruxism episodes coincidence with grinding sound/night.
Low Frequency: **when RMMA episodes over or equal 2 but less than** 4 per hour.   High Frequency: when RMMA episodes over or equal **4 per hour.**
Heart rate increase of 10-27% is also present compared with baseline.

Table 1.10. Proposed and validated Polysomnographic Research Criteria for sleep bruxism (Carra *et al.* 2012 ; Lavigne *et al.* 1996).

Furthermore, Ikeda and co-workers established EMG-based algorithm criteria (Ikeda *et al.,* 1996). Electromyography of the masseter combined with electrocardiogram recordings during sleep (sympathetic cascade) were used to establish this diagnostic algorithm. In addition, signals over four consecutive nights were recorded in a home sleeping environment. These criteria established the maximum voluntary contraction level through describing the nature and magnitude of total masseter muscle electromyographic activity above a minimum threshold of 3%. In addition, it evaluated electrocardiography rate changes that occurred in association with these electromyographic elevations by using the R-R interval. The algorithm is presented in Figure 1.6.
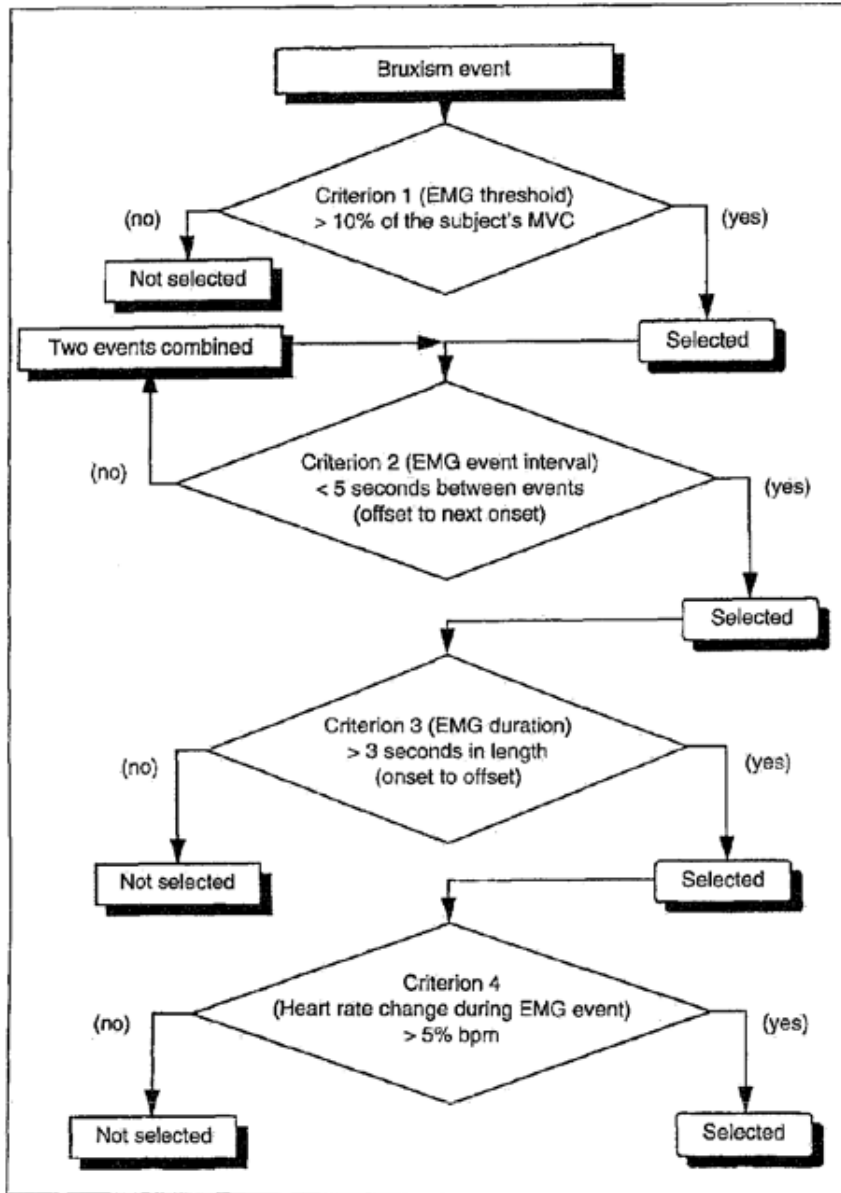
Figure 1.6. Algorithm for event detection in sleep bruxism (Ikeda *et al.*, 1996).

The PSG diagnostic method showed obvious advantages over other diagnostic tests as it recorded real-time observational data in addition to physiological data. Furthermore, PSG also detected sleep disorders that may affect sleep structure and could be associated with sleep bruxism. PSG testing can be performed both in a hospital-based sleep laboratory for one- or two-nights or in a portable PSG device (ambulatory) for use at home.

1.3.4.1 Hospital-based Sleep Laboratory PSG

Hospital-based sleep laboratory PSG is carried out in a sleep laboratory setting. In the field of sleep medicine, whole-night laboratory-based PSG is considered the gold standard because of its high specificity and sensitivity (Lavigne *et al.* 1996). A hospital-based setting will help control most factors that may affect sleep and provide reproducible recordings. However, the sleep structure could be disturbed during the first night due to the in-patient environment. This sleep disturbance is known as the "first night effect" and as a result, scoring two consecutive nights may help improve the test reliability. Since this method requires significant resources, incorporating it as a routine clinical tool is difficult to justify (Lavigne *et al.* 2009).

1.3.4.2 Portable Polysomnography

Portable PSG devices with fewer channels have been introduced to make PSG testing more accessible and easier to use in the patient's home. Although sleep laboratory PSG testing is considered the gold standard, multiple investigators have evaluated the reliability of portable PSG devices and they have been deemed a valid tool for the detection of sleep bruxism (Carra *et al.* 2012; Manfredini *et al.* 2014). The validity of the different ambulatory diagnostic devices has been evaluated using PSG recordings (Table 1.11.).

	Bruxoff device®	**Bitestrip device®**	**EMG-telemetry**	**Grind Care®**
EMG cut-off threshold	10% MVC + increase in heart rate by 20%	30% MVC	Two times higher than baseline	≥ 18 EMG/h for 3 nights and 19 EMG/h for 5 nights
PSG diagnosis	Based on Lavigne *et al.*'s criteria (1996) −10% MVC	Based on Lavigne *et al.*'s criteria (1996) − 20% MVC	Based on Lavigne *et al.*'s criteria (1996) − 20% MVC	Based on Lavigne *et al.*'s criteria (1996) − 20% MVC
Findings (95% CI)	*Automatic recording:* Accuracy (ROC) = 91% Sensitivity = 91.6% Specificity = 84.6% *Manual recording:* Accuracy (ROC) = 89% Sensitivity = 83.3% Specificity = 84.6%	Agreement = 87.8% Kappa = 0.71 Sensitivity = 84.2% PPV = 100%	Sensitivity = 98% PPV = 23.1%	90% specificity and positive likelihood ratio equal to 5
Authors	Castroflorio, 2014	Mainieri, 2012	Yamaguchi, 2012	Stuginski-Barbosa, 2016

Table 1.11. Validity of different portable diagnostic devices in sleep bruxism diagnosis using polysomnographic recordings as the gold standard. MVC: maximum voluntary clenching; ROC: receiver operating curve; PPV: positive predictive value.

1.3.4.2.1 Electromyography (EMG) Devices

Direct monitoring of masticatory muscle activity (frequency, pattern and amplitude) can be achieved using EMG devices. There are several advantages to using this approach. EMG devices provide and facilitate direct detailed measurements with easy accessibility. Several studies have demonstrated high sensitivity for EMG in detecting various oral activities (Acosta-Ortiz *et al.* 2004; Rau *et al.* 2004). When compared with a full PSG method, EMG is

inexpensive and can be performed at home. Clinical assessment of sleep bruxism can be performed using a single-channel EMG device (Stuginski-Barbosa *et al.* 2016). Recordings for twenty participants using single-channel EMG portable device (GrindCare®) and PSG were compared for five consecutive nights. The authors reported positive agreements between EMG/h (Grind Care®) and bursts/h (PSG) over three and five consecutive nights with a proper cut-off in GrindCare® (18 EMG per hour for three nights and 19 EMG per hour for five nights). This resulted in an acceptable 90% specificity and positive likelihood ratio equal to 5 in detecting sleep bruxism. The authors concluded that using a single-channel EMG device was a valid assessment tool for sleep bruxism.

However, portable device monitoring of surface EMG activity alone should be interpreted with caution, as 60% of the adult population showed RMMA as a physiological masticatory muscle activity during sleep. This means that the use of portable devices alone tends to overestimate sleep bruxism episodes (Castroflorio *et al.* 2013).

Combined monitoring of surface EMG based on rhythmic masseter muscle activity and heart rate could represent a valid method to improve the reliability of EMG portable devices (Castroflorio *et al.* 2014). An unacceptable false-positive rate of 76.9% was reported for this portable EMG telemetry device. However, this was offset by an almost ideal sensitivity (98.8%) (Yamaguchi *et al.* 2012). There are some limitations to using EMG alone as a diagnostic method. First, extreme signal sensitivity to artefacts such as swallowing and speech movement have been reported (Castroflorio *et al.* 2005), and secondly electrode

positioning and subsequent repositioning can lead to significant reproducibility errors (Castroflorio *et al.* 2006). Several factors influence reproducibility errors such as inter-electrode distance, electrodes location, orientation on the muscle, repositioning methods, operator experience and body posture.

The BiteStrip® is a small disposable electronic electromyographic-based integrated ambulatory device that is designed to measure masseter electromyographic activity during sleep, which, in turn, reflects the presence of bruxism episodes. The advantages of the BiteStrip® include low cost, suitability for home use, and the fact that it can be operated by the patient themselves. It consists of two electrodes embedded in a flexible lightweight plastic strip with incorporated EMG electrodes (Figure 1.7). It scores bruxism episodes and categorises bruxism activity based on the electrochemical display. Sensitivity and specificity values of 0.72 and 0.75, respectively, when compared with gold standard patient PSG have been reported (Shochat *et al.* 2007).
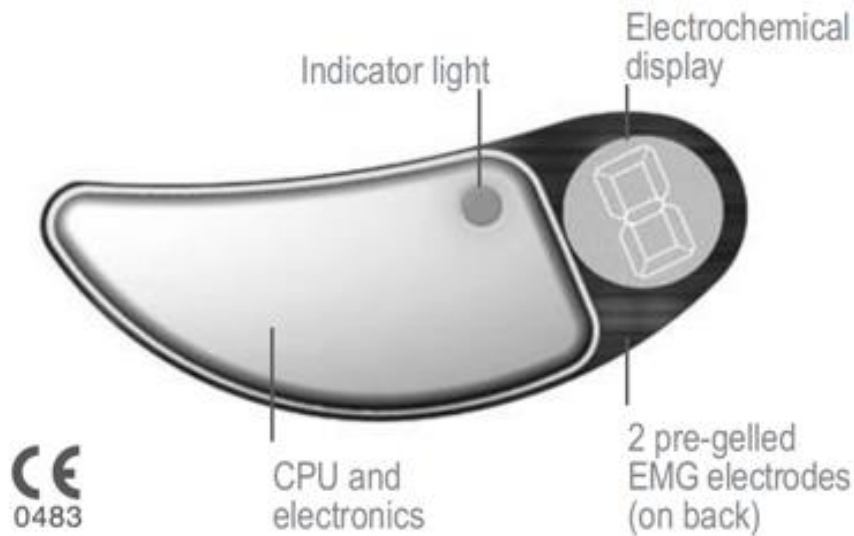
Figure 1.7. BiteStrip® components (Alldent Australia).

Mainieri and co-workers compared scoring of sleep bruxism episodes using the Bitestrip® appliance and PSG in 49 consecutive patients. Both methods demonstrated high levels of agreement at 87.8%. The Bitestrip® recorded a sensitivity of 84.2% and a positive predictive value of 100% for the sleep bruxism positive/negative test. In contrast, for a 4-scale test (no, light, moderate, or severe bruxism) the agreement was only 80.27% (Mainieri *et al.* 2012). The authors suggested that the Bitestrip® can be used as a moderate screening method for the diagnosis of sleep bruxism. The Bitestrip® demonstrated a high level of accuracy in detecting the presence or absence of sleep bruxism. However, it was less accurate in differentiating orofacial motor activities (OFA) from RMMA in participants with a clinical history of sleep bruxism.

1.3.4.3 Ambulatory PSG

In an effort to make PSG more accessible, ambulatory PSG has been proposed, which reduces the number of data recording channels. The main omitted recordings in ambulatory PSG are audio and visual recordings. However, ambulatory devices are still able to score nocturnal EMG scorings of masseter, electrooculography, electroencephalography, electrocardiography, thoracic effort and body posture, allowing for the detection of typical nocturnal masseter activity, as well as the determination of sleep stages. Electroencephalography combined with electrooculography (EOG) allows for reliable recording of sleep stages. Electrocardiography (ECG) recordings can detect arousals that are associated with sleep bruxism episodes.

High sensitivity and specificity have been reported using a double-channel PSG portable device (92.3 and 91.6%, respectively)(Castroflorio *et al.* 2014). Detection of autonomic arousals (typical of sleep bruxism) using heart rate recordings may help reduce the chances of false-positive findings that are associated with other portable devices. Since this test is carried out within a typical environment, it has been shown that using an ambulatory PSG method can eradicate the "first night effect" seen during in-patient PSG testing (Sharpley *et al.* 1988).

The Bruxoff® is a portable device with three channels that acquires EMG from the masseter (bilateral), and the ECG channel for heart frequency (Castroflorio *et al.* 2014). Single-use bipolar concentric electrodes (Code®*) were used to bilaterally detect surface

electromyography from the masseter muscle and avoid any orientation problems (Figure 1.8). A study compared sleep bruxism episode detection using the compact portable device (Bruxoff®) with the scoring of sleep bruxism episodes using PSG recordings (Castroflorio *et al.,* 2014). Twenty-five individuals were recruited in the study and divided into two groups based on probable bruxism (14) or absence of bruxism (11). The authors reported excellent agreement between PSG and the Bruxoff® device, with the highest accuracy values for the manual method for the area under the receiver operating curve (0.98), the automatic scoring method (0.96) and for synchronised events recorded (0.89-0.91) when compared with PSG scoring (Castroflorio *et al.* 2014). When utilising the Bruxoff® automatic scoring module, the sensitivity and specificity were 92.3% and 91.6%, respectively, when the cut-off was set at 4 sleep bruxism episodes per hour, according to published criteria (Thie and Lavigne, 2001a)(Table 1.12). High diagnostic accuracy was identified in delineating RMMA from other oromotor activities using the Bruxoff® device, which demonstrated the ability to record true sleep bruxism episodes (RMMA episode preceded by a heart rate increase).

Figure 1.8. Detection of myoelectric signals from the masseter muscles using the Bruxoff®*
and the CoDe®* electrode. The black line represents electrode location using the gonial
angle-cantus line as anatomical landmark.

1. **Masseter muscles EMG activity:** • **Amplitude 10% of a maximum voluntary clenching in awake.** • **Duration of EMG burst more than 0.25 s to exclude myoclonus.**
2. **Types of Sleep Bruxism episodes – separated by an interval of more than 3.0 s:** • **Phasic (rhythmic): three or more EMG bursts with the duration of 0.25 to 2.0 s.** • **Tonic (sustained): EMG burst lasting more than 2.0 s.** • **Mixed: Both, phasic and tonic types.**
3. **A heart rate increase of 10% is present during a Sleep Bruxism episode.**
4. **Diagnostic cut-off criteria (a or b):** a. **More than four sleep bruxism episodes per hour of sleep.** b. **More than 25 EMG bursts per hour of sleep.**

Table 1.11. Proposed diagnostic criteria for sleep bruxism detection using an ambulatory PSG system (Thie and Lavigne, 2001, Kato *et al*. 2003b).

1.3.4.3 Occlusal Devices as a Diagnostic Tool

Occlusal devices can be used as a diagnostic tool in sleep bruxism through two basic approaches using either wear-facet observation or direct measurement of bite forces (Koyano *et al.* 2008). The first approach uses a multi-layered material occlusal device with a different colour for each layer, which can be used to assess the severity of sleep bruxism. The amount of wear can be evaluated manually or automatically by photographic colour analysis. However, some drawbacks include manufacturing processing artefacts, a lack of

scientific validation and the fact that the approach is very time-consuming (Lobbezoo *et al.* 2008). The second approach uses a force transducer sensor embedded within a standard occlusal device to directly measure bite force (Baba *et al.* 2003; Takeuchi *et al.* 2001). Advantages include direct force measurement on both teeth/the device, which allows other oral activity artefacts to be more easily filtered than EMG readings, the ability to simultaneously undertake management and monitoring of bruxism, and reproducible sensor position. Disadvantages include complex assembly of a customised device, variable device longevity due to fracture and maintaining continuous power supply, absence of sleep staging allowance, the possibility of altering sleep bruxism activity, and high cost (Koyano *et al.* 2008).

1.4 Bruxism Management Approaches

1.4.1 Awake bruxism

Several interventions have been suggested as appropriate in the management of awake bruxism such as relaxation therapy, trigger counselling, and behaviour modification/biofeedback. However, the approaches lack randomised clinical trials to support their management effectiveness (Lobbezoo *et al.* 2008). Awake bruxers have demonstrated somatisation symptoms with high anxiety levels; therefore, management of primary awake bruxism is challenging (Bayar *et al*. 2012).

1.4.2 Sleep Bruxism

Several treatment methods have been employed for the management of sleep bruxism. Unlike awake bruxism, treatment efficacy of sleep bruxism has been investigated through several randomised clinical studies. The investigated sleep bruxism management forms include a combination of sleep hygiene measures and relaxation techniques, occlusal device therapy, pharmacological intervention and contingent electrical stimulation. As causal treatment is absent, sleep bruxism management focuses on preventing the progression of tooth wear, decreasing the tooth-grinding noise, and reducing muscle discomfort, pain and TMJ dysfunction. Behavioural interventions and counselling, occlusal device therapy, pharmacological therapy, and contingent electrical stimulation (CES) have demonstrated heterogeneous results in the management of EMG events associated with sleep bruxism (Guaita and Högl 2016).

The following are the current therapeutic approaches for sleep bruxism management:

1.4.3 Combination of Sleep Hygiene Measures and Relaxation Techniques

The management of sleep bruxism is completed through patient sleep hygiene counselling. Sleep hygiene measures include abstaining from alcohol, coffee and smoking at night, reduced mental or physical activity before sleep, and proper bedroom conditions, such as a quiet and dark room. Only one randomised clinical trial has investigated the influence of sleep hygiene measures combined with progressive relaxation techniques. Conducted over 4 weeks, the trial included 16 subjects, who were randomly assigned to either the

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experimental or control group, and recorded two polysomnographic recordings, one at baseline and the other following the treatment period. The study failed to identify a significant difference compared to the baseline (Valiente López *et al.* 2015). However, in clinical practice, sleep hygiene recommendations are still reasonable, especially considering that alcohol, tobacco and coffee consumption are risk factors for sleep bruxism.

1.4.4 Pharmacological Therapies

As mentioned in Section 1.2.3.7 The role of neurochemical substances, anecdotal studies suggest a positive effect for Gabapentin (Brown and Hong, 1999), Tiagabine (Kast, 2005), Buspirone (Bostwick and Jaffee, 1999) Topiramate, and botulinum toxin (Lee *et al.* 2010) in sleep bruxism management. However, their effectiveness and safety need to be assessed in randomised controlled clinical trials. The effectiveness of pharmacotherapy was evaluated in a Cochrane review by Macedo and co-workers who reported insufficient evidence for their use in the treatment of sleep bruxism (Macedo *et al.* 2014).

Recently, the efficacy of type A botulinum toxin injections have been evaluated in the treatment of sleep bruxism. Using PSG, a decrease was shown in muscle contraction amplitude during bruxism events following four weeks of injections; however, no changes regarding sleep bruxism episodes and rhythm per hour were observed (Shim *et al.* 2014). Lee and co-workers reported similar observations (a decrease in muscle contraction) using ambulatory EMG for eight to twelve weeks after botulinum toxin injections (Lee *et al.* 2010). In that study, no changes were observed in the reduction of tooth-grinding noise and

morning TMJ stiffness compared to placebo injections. Additionally, two systematic reviews, with particular focus on botulinum toxin injections, suggested evidence of effectiveness in using this therapeutic method through reduced intensity of muscle contractions in bruxism patients (Long *et al*. 2012; De la Torre Canales *et al.* 2017).

Potential candidates for future more specific or more potent medications are substances that regulate the wake-sleep balance (e.g., acetylcholine, noradrenaline, dopamine, orexin, histamine, and serotonin), ionic channels, and cellular receptors.

1.5 Behavioural and Occlusal Therapies

1.5.1 Occlusal Devices

As the standard treatment approach for patients diagnosed with bruxism, occlusal devices have been used for decades. In the United States, approximately 3.5 million devices were provided annually to patients at a total cost of $1 billion (Pierce *et al.* 1995). The vast majority of those devices were listed as being prescribed for patients with temporomandibular disorders (TMD) rather than for those diagnosed with sleep bruxism. Occlusal devices continue to be the mainstay in sleep bruxism management, with an emphasis on conservative, reversible and palliative effects rather than curative effects (Dao & Lavigne, 1998). In their review, Dao and Lavigne concluded that the most appropriate descriptive term for oral appliances is "oromandibular crutches", until a complete comprehensive understanding of their behavioural and physical mechanism is available (Dao & Lavigne, 1998).

Advantages to using an occlusal device include:

1. Relief of symptoms,

2. Hard tissue protection, including teeth and dental restorations,

3. A reversible approach to treatment,

4. Relatively low associated costs (Dylina, 2001).

Despite their widespread uses and benefits, there is little evidence-based literature about the occlusal device mechanism of action (Clark, 1984; Macedo *et al.* 2007). Several theories for the action of occlusal devices have been proposed. The majority of these theories have been linked to masticatory musculature harmony and balance concepts (Attanasio, 1997). These theories have advocated that the classic stabilisation appliance is designed to diminish muscle resting tension, allow the condylar centric relation or reducing proprioception of periodontal ligament (Nelson 1995). On the other hand, theories have been proposed that wakefulness avoidance of occlusal interferences, which is absent during sleep, will be irrelevant when covering teeth once a stable platform established (Tsukiyama *et al.* 2001). All aforementioned occlusal device mechanism theories lack an evidence base, as there have been no controlled clinical trials to support any proposed theory. However, due to their overriding advantages, occlusal devices still play a significant role in bruxism management (Clark *et al.* 1999; Lobbezoo *et al.* 2008).

1.5.2 Mechanism of Occlusal Devices

1.5.2.1 Proposed Therapeutic Mechanism for Occlusal Splints in Sleep Bruxism

Management

Use of occlusal devices for dental and periodontal protection against possible damage from sleep bruxism is the least contested, while information on awake bruxism is still scarce. The concept of using the occlusal device to prevent occlusal interferences is no longer valid (Ramfjord 1961; Kawazoe *et al.* 1980). Previously, such interferences were assumed to act as triggers for sleep bruxism. The therapeutic mechanisms of occlusal devices have not been fully elucidated, although theories have been proposed whereby they can eradicate occlusal interferences, reduce temporal and masseter muscle postural activity and re-establish symmetric mandibular movement (Holmgren *et al.* 1990). It has also been reported that occlusal adjustment (equilibration) did not prevent sleep bruxism (Bailey and Rugh 1981). An epidemiological study failed to distinguish between bruxers and non-bruxers based on their occlusal characteristics (Greene and Marbach 1982), and there are no valid data to support the role of occlusion as an etiological factor in sleep bruxism. Evidence supports a role for the central nervous system and behavioural factors, rather than peripheral causes as being more likely causative factors (Lavigne, 1995). Based on this information, occlusion is no longer accepted as the cause of sleep bruxism. With this in mind, the suggestion that occlusal devices work by reducing sleep bruxism activity has not been supported.

A study comparing two different occlusal device designs demonstrated that no differences were observed for both occlusal device group or modified nociceptive trigeminal inhibition

splint group (Dalewski *et al.* 2015). Ceneviz and co-workers reported input changes in peripheral oral receptor feedback mechanism following oral device use, which may lead to transient reductions in sleep bruxism. However, due to adaptive mechanisms in the stomatognathic system, the effect is not prolonged, and sleep bruxism returned to initial levels after 2-3 days (Ceneviz *et al.* 2006). These findings support the proposal that intermittent oral splint use demonstrates long-term reduction in sleep bruxism activity when compared with continuous use (Matsumoto *et al.* 2015). Masticatory muscle activity using various oral device designs have been investigated, and it was found that any design of occlusal device caused an immediate reduction of EMG activity (Arima *et al.* 2012). Three types of oral devices were used: (1) full-arch maxillary and mandibular restrictive oral appliance (restrict-MMOA). (2) full-arch maxillary and mandibular oral appliances (free-MMOA) and (3) conventional full-arch flat stabilisation appliance. The authors reported similar findings for all three types with regards to EMG activity reduction.

Other possible factors that support the use of occlusal devices include the placebo effect, an increase in the occlusal vertical dimension, condylar position alteration, and increased cognitive consciousness (Sjoholm *et al.* 2014). Forward placement of the mandible using a mandibular advancement design of occlusal devices was found to enhance the airway patency, which decreased apnoea-induced microarousals, and subsequently eliminated sleep bruxism motor activity (Clarke *et al.* 1984; Ceneviz *et al.* 2006). However, further investigations are needed to validate this association (van der Zaag *et al.* 2005). The BiteStrip® and the Sleep Assessment Questionnaire have been used to evaluate the effect

of mandibular advancement devices on sleep bruxism activity. The authors reported masseter muscle relaxation, which contributed to reduced occlusal forces in sleep bruxism patients when using mandibular advancement devices (Saueressig *et al.* 2010).

1.5.2.2 Clinical Efficacy of Occlusal Device Therapy

When discussing the efficacy or success of occlusal splint therapy, it is essential to identify the variables under examination. Some variables that should be considered for occlusal device therapy include:

1. EMG activity reduction,

2. Bruxism activity reduction,

3. Muscular and joint symptoms reduction.

1.5.2.2.1 EMG Activity Reduction

EMG-based studies have been used in bruxism research for almost sixty years (Ramfjord 1961). However, different methodological approaches significantly impacted their validity in evaluating occlusal device therapy and allowing comparison between studies. Many authors have evaluated wakeful resting masseter measurements with examinations completed at various intervals (Clark *et al.* 1979; Hamada *et al.* 1982). However, no details were provided in relation to device wear time during the night, or even the effects of treatment on symptoms. No method has been proposed to objectively assess wear compliance of occlusal devices. Apart from the clear limitations of comparing studies with marked heterogeneity and associated technical difficulties, all studies were based on the

hypothesis that awake masseter resting EMG measurement was an accurate index of previous or ongoing bruxism activity (Christensen and Rassouli, 1995). However, this hypothesis has been conclusively rejected due to a reported positive correlation between cumulative sleep EMG activity in the masseter muscles and severity of sleep bruxism (Sheikholeslam *et al.* 1986).

Several studies have shown that the use of an occlusal device was associated with reduced nocturnal EMG activity (Solberg *et al.* 1975; Treacy 1999). However, this effect was only transient as EMG activity returned to baseline values after completion of treatment (Sheikholeslam *et al.* 1986; Pierce & Gale 1988). Several small cohort studies involving bruxers have reported similar or better results in decreasing nocturnal EMG activity (Okeson 1987; Hiyama *et al.* 2003). In a split-night design study involving six participants, EMG activities of masseter muscles and anterior temporalis were recorded at one night both with and without an occlusal device (Hiyama *et al.* 2003). The authors reported a significant reduction in EMG activity and the number of bruxism events after wearing the devices. A study recording nocturnal EMG using an ambulatory EMG device compared occlusal coverage occlusal devices with palatal-only coverage splints for six weeks (Harada *et al.* 2006). Both designs demonstrated equal efficacy in reducing EMG activity. However, only a short-term effect was observed in decreasing EMG activity. Many studies have shown the same short-term effect (Lobbezoo *et al.* 2008).

1.5.2.2.2 Bruxism Activity Reduction

Randomised controlled trials using PSG recordings have evaluated the clinical efficacy of a mandibular advancement appliance and stabilisation maxillary splint, both showing a significant reduction in sleep bruxism episodes at two and three months, respectively (Singh *et al.* 2015). Furthermore, another randomised clinical study with 20 sleep bruxism patients investigated the clinical efficacy of Gabapentin and a stabilisation device using PSG recordings at baseline and 2 months following initiation of the treatment *(Sadat Madani et al.* 2013). Significant reductions in sleep bruxism episodes were reported for both groups; however, Gabapentin showed a significant improvement in slow wave sleep (stage 3) and total sleep time. One study reported a small yet significant reduction in sleep bruxism episodes following 12-week occlusal device treatment and again at a 6-month follow-up (Ommerborn *et al.* 2007). However, sleep bruxism activity was not measured utilising EMG or PSG; self-assessment and psychometric analysis were used instead, which is considered a significant methodological flaw.

1.5.5.2.3 Muscles and Joint Symptoms Reduction

One study showed a significant reduction in TMD symptoms following 6-months of occlusal device wear; however, sleep bruxism activity persisted (Holmgren *et al.* 1993). Furthermore, some authors have reported a reduction in myofascial pain using an occlusal device (Villalón *et al.* 2013), enhanced quality of life (Magdaleno and Ginestal 2010), and improved mouth opening (Naikmasur *et al.* 2008). However, another study did not report a

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reduction in the level of TMD related pain (de Paula Gomes *et al.* 2014). A combination of occlusal device therapy and massage was found to reduce the severity of TMD signs and symptoms using the Helkimo index (de Paula Gomes *et al.* 2014). For a 4-week period, 28 subjects with TMD were randomly distributed into either a massage-treatment group or an occlusal device group (intervention group) using the range of mandibular movement as a standard. Fifteen subjects without TMD were allocated to an asymptomatic comparison group according to a Fonseca Anamnestic Index, used to characterise TMD subjects. Those assigned to the massage therapy group received three 30-minute sessions per week for four consecutive weeks. The masticatory muscle massage was performed by a physiotherapist according to the protocol adapted from Biasotto-Gonzalez (Biasotto-Gonzalez, 2005). A significant increase in the range of mandibular movement was reported for both massage-therapy and occlusal device groups. Similar findings were reported in another study with decreased TMD signs and symptoms when using occlusal devices (Do Nascimento *et al.* 2008).

1.5.3 Occlusal Devices Design

Reduced masseter muscle EMG activities have been reported when clenching habits were performed during left and right lateral excursive and protrusive movements (Borromeo *et al.* 1995). In contrast, the most significant masseter muscle activity was observed when clenching occurred in centric occlusion (Manns *et al.* 1987; Borromeo *et al.* 1995). During lateral excursion and protrusion, the masseter muscle was either elongated (on the non-working side) or shortened (on the working side). Therefore, the degree of forces may be

affected by altering muscle length (Christensen 1986). When muscle fibres are stimulated greater than 150% or below 60% of original length, high contractile force was not generated (Christensen 1986). Studies have demonstrated muscle activity reduction for asymptomatic subjects when canine guidance was employed (Manns *et al.* 1987). On the other hand, several authors have reported no statistically significant differences in muscle activity when different occlusal device designs were used (Graham & Rugh 1988; Borromeo *et al.* 1995).

Rugh and co-workers demonstrated that minimal EMG activity occurred at an average 8.6 mm of increase in OVD, before reaching maximum levels at 16 mm (Rugh *et al*. 1984). Other studies have supported this finding and reported EMG activity reduction as the OVD was increased (Manns *et al.* 1981; Borromeo *et al.* 1995).

Furthermore, oral devices with mandibular advancement design may be useful in reducing sleep bruxism (Landry-Schoenbeck *et al.* 2009; Solanki *et al.* 2017). One study showed that mandibular advancement devices, prescribed for obstructive sleep apnoea (OSA) management, generated a significant reduction in sleep bruxism episodes when compared to standard Michigan-type occlusal devices (Landry-Schoenbeck *et al.* 2009). It is still unclear how mandibular advancement devices work, as they can cause muscle pain and discomfort, yet were associated with a reduction in sleep bruxism activities. It has been proposed that the muscle pain associated with mandibular advancement devices (50–75% of maximum protrusion) may be a key factor in reducing sleep bruxism episodes (Mainieri *et al.* 2014). The proposed underlying mechanism is as follows: sleep bruxism episodes are

associated with microarousal activity, which prevents deep sleep stage. Therefore, the subjects remain in light sleep stage, during which 80% of sleep bruxism activity takes place. Through advancement to deep stage sleep, the patient improves significantly. However, it was also found that mandibular advancement appliances, with a minimum protrusion of 25%, demonstrated significant sleep bruxism reduction without creating muscle pain or discomfort (Landry-Schoenbeck *et al.* 2009).

1.5.4 Types of Oral Devices

There have been a range of occlusal appliance designs prescribed for patients for the management of sleep bruxism. These devices can be fabricated using different materials, the most common materials being heat-processed polymethylmethacrylate (PMMA), soft thermoformed rubber or bilaminate appliances with hard occluding layers and soft-fitting layered designs. The efficacy between hard and soft occluding surfaces in sleep bruxism management has been investigated. Investigating EMG activity was observed in a group of 10 sleep bruxism subjects who alternated use between hard and soft occlusal devices. A significant reduction in sleep bruxism muscle activity was observed when subjects used hard devices. The authors concluded that soft devices should only be considered a short-term approach or with ongoing growth in childhood (Lindfors *et al.* 2006).

1.5.4.1 Stabilisation Devices with Flat Occlusal Planes

These devices are fabricated to completely cover the occlusal surface of the maxillary or mandibular teeth, and provide a flat occlusal table. It is mainly used for the maxillary arch,

yet there are some advantages of using the mandibular arch, including enhanced speech and aesthetics when full time wear is recommended, especially for skeletal Class III patients to improve occlusal contacts (Türp *et al.* 2004). The same efficacy has been reported for this design in both arches (Türp *et al.* 2004).

Providing canine guidance in stabilisation devices can be advantageous to improve the patient's symptoms; however, the benefits are still controversial in the dental literature (Borromeo *et al.* 1995; Conti *et al.* 2006). This device is commonly constructed using heat-processed PMMA, or a bilaminate soft inner and a hard outer-layered or soft vacuum-formed plastic material. It is suggested to keep the device thickness as thin as possible without compromising device durability, with a minimum of 2 mm of the material overlaying the second molar area (Dylina 2001). Furthermore, the device should extend 8 mm palatally from the gingival margin for rigidity or have complete palatal coverage.

1.5.4.2 Anterior Bite Plane Devices: Traditional and Mini

These appliances mainly cover 6-8 maxillary anterior teeth (traditional) or 2-4 teeth (Mini). One study has reported the advantages of preventing posterior occlusal contacts in reducing occlusal forces (Capp, 1999). Additionally, unloading the TMJs was suggested to be one of the benefits of using anterior bite plane devices, however further investigations are required to prove this effect (Okeson *et al.* 1983). Adverse effects have been reported for this splint design including intrusion of anterior teeth and extrusion of posterior teeth, tooth mobility and higher risk of inhalation (Klasser & Greene 2009).

1.5.4.3 Anterior Repositioning Devices

These devices are hard acrylic devices with an anterior ramp facing facially to maintain the

mandible in a forward position to restore a physiologic relationship between the condylar

head and the anteriorly displaces articular disk. They are mainly prescribed for patients with

internal derangement. An internal derangement has been defined as "an abnormal

relationship of the articular disk to the mandibular condyle, fossa, and articular eminence

with the disk usually displaced in an anteromedial direction" (Dolwick *et al.* 1983).

An anterior repositioning splint has been reported as an effective treatment in recapturing

the disk; however, the anterior position should be permanently maintained (Tallents *et al.*

1990). A long-term observational study demonstrated that joint clicking sounds, which

initially improved with these appliances, returned in a large number of the patients,

indicating that the suggested function of these appliances has not been fully elucidated

(Westesson 1989).

1.5.4.4 Mandibular Advancement Appliance

These appliances were initially used in patients with obstructive sleep apnoea (OSA) who

could not tolerate continuous positive airway pressure (CPAP). More recently, their use has

been advocated for the front line management of mild to moderate sleep apnoea

(Marklund *et al.* 2012). Mandibular advancement devices (MAD) provide an anterior and

inferior mandibular jaw position, creating anatomical changes in the upper airway that help

increase the pharyngeal area. Locking and stabilising the mandible and hyoid bone at this

position reduces the pharyngeal collapsibility of these tissues during the sleep preventing airway blockage (Bamagoos *et al.* 2019). Obstructive sleep apnoea signs and symptoms such as frequency of apnoea events, snoring, daytime sleepiness symptoms and cardiovascular consequences risks, can be improved with MADs. Authors have reported reduction in the apnoea–hypopnoea index (AHI), blood pressure and daytime sleepiness following MAD treatment (Marklund *et al.* 2012; Koretsi *et al.* 2018). In addition, for sleep bruxism patients, short-term positive effects have been reported with MADs appliances; determining the longer-term effects requires further research (Jokubauskas *et al.* 2018).

1.5.4.5 Hydrostatic Appliances

Hydrostatic or "pseudo" appliances have been available for decades (Lerman, 1974). These fluid-bearing appliances were initially used in the treatment of TMJ pain-dysfunction patients who did not respond to other treatment modalities (Lerman, 1974). These appliances separated the posterior teeth and decreased muscle hyperactivity in the short term until definitive occlusal devices could be fabricated (Dylina, 2001). The theory behind the appliances was that the appliance's compressible nature provided freedom of mandibular position to promote healing (Wright and North, 2009). However, there are currently no clinical studies available to support this hypothesis.

1.5.4.6 Pivoting Appliances

This pivoting design involved hard, full coverage acrylic resin appliances in either the maxillary or the mandibular arch with only one posterior occlusal contact on each side.

These pivots are placed in the most posterior position. These appliances were thought to enhance unloading of the joint articular surfaces resulting in reduced intra-articular pressure. They were recommended where unloading therapy was indicated, such as in patients with osteoarthritis or internal derangements (Klasser & Greene 2009). However, studies have shown that there is no unloading effect on the TMJ through pivoting occlusion and instead may lead to compression of the joint (Ito *et al.* 1986).

1.5.4.7 Posterior Bite Plane Appliance

These appliances are made to be worn on the mandibular arch. The design consists of a bilateral flat plane hard splint posteriorly with anterior disclusion. Advocates have suggested that the appliance facilitates changes in vertical and horizontal maxillomandibular relations. Posterior bite plane appliances were intended to provide optimal maxillomandibular relations. Occlusal procedures such as occlusal equilibration or occlusal reconstruction are usually carried out to maintain the new position. Interestingly, some authors have reported that the appliance enhanced athletic physical performance and strength (Smith 1978; Schubert *et al.* 1984). However, no controlled clinical trial has been completed in order to support this claim (Yates *et al.* 1984). The main disadvantages of these appliances is overeruption of the anterior teeth and intrusion of posterior teeth which may lead to a posterior open bite (Meibodi *et al.* 2009).

1.5.5 Drawback of Occlusal Devices

Several studies have suggested that there was an increase in sleep bruxism-related oromotor activity for some oral device patients, while others may experience no change or even a reduction in activity (Landry-Schoenbeck *et al.* 2009; Sjoholm *et al.* 2014). This variation in response is well accepted (Clarke *et al.* 1984; van der Zaag *et al.* 2005). Furthermore, it has been shown that patients with obstructive sleep apnoea who are provided with thick maxillary oral splints may increase their respiratory disturbance severity index (Nikolopoulou *et al.* 2013). Respiratory disturbances are associated with increased arousals and stimulate sleep bruxism activity (Sjöholm *et al.* 2000). Increased sleep bruxism activity is a secondary phenomenon for a cohort of bruxers as a consequence of provoking arousals due to other sleep disturbances factors (van der Zaag *et al.* 2014). These results might partly explain the variations in sleep bruxism activity in response to occlusal device therapy. The mechanism of action of occlusal devices and their impact on sleep bruxism requires further research.

1.5.6 Patient Compliance with Occlusal Device Wear

The wearing of occlusal devices is an essential component of the management of sleep bruxism, with a minimum level of wearing compliance from patients being required for a successful therapeutic outcome. To date, no evidence exists as to the level of sleep bruxism patient compliance when wearing occlusal devices. It is assumed that the patients comply but evidence from other areas of dentistry have reported that compliance is variable. Several methods used to assess the level of compliance have been reported in the

orthodontic and dental sleep medicine literature. Traditionally removable appliances wear

time has been assessed indirectly by the clinician. A survey of 107 orthodontists found that

96% of wear time was determined via patient and parent interviews, and 69–100% of

practitioners were commonly using indirect clinical parameters such as appliance

appearance and fitting, tooth movements and bite shift (Meyer-Gutknecht *et al.* 2014). In

that study clinical parameters were deemed 'very effective' for evaluating the wear time,

whereas self-reporting was deemed 'less effective'. The self-reported wear time was found

to exaggerate daily wear time (5 to 6 hours)(Schott *et al.* 2016). This over-reporting problem

may be associated with recall bias on follow-up visits, as the wear time was recorded

retrospectively. Therefore, the use of diaries or charts to obtain daily records may reduce

this problem. In addition, it is more likely that over-reporting may have arisen from

response bias in an effort to satisfy the practitioner and avoid judgement or negative

comments (Lin *et al.* 2015). To objectively measure the wear time, several methods of

varying practicality have been proposed for a wide range of orthodontic appliances, based

on electrical (Mitchell, 1976; Northcutt, 1974) or microelectronic devices (Sahm *et al.* 1990).

In 1974, Northcutt introduced for the first time a headgear timing device to objectively

measure compliance (Northcutt, 1974). He reported that, with self-reported assessment,

the mean wear time was 11 hours per day. In contrast, when the patient was unaware that

they were being recorded, the actual wear time measurement was only for 6.5 hours of the

prescribed 12 hours. A significant increase in patient compliance (double the weekly hours

used) was noted after revealing the recording methods to the patients. Later, due to false

responses from patients, the precision of these specific headgear timers became questionable (Banks and Read, 1987).

In a study monitoring 53 children with Bionator functional appliances, a micro-electronic timing device was used to objectively measure wear-time, using a reed switch combined with permanent magnets as a sensor-system. However, others have reported a high incidence of magnets debonding, breakage and difficulty in finding the correct position related to the reed switch (Sahm *et al.* 1990). Even though preliminary wear-time measurements using these methods were performed with high accuracy from a technical point of view, additional requirements had to be met in order to be used in routine daily practice. Objective daily evaluation of wear time has become available through temperature-sensitive microelectronic wear-time sensors (Schott and Göz, 2011).

1.6 In Built Appliance Sensors

Removable dental appliances such as orthodontic retainers or any other removable appliances require a minimum degree of patient compliance to successfully achieve treatment objectives (Bos *et al.* 2005). Being able to monitor real wear time in patients would allow a rational discussion regarding the effectiveness of therapy and help identify wear patterns, poor compliance and faulty appliances. Understanding the factors responsible for incomplete or unsuccessful treatment may predict patients for whom treatment will be less successful and influence treatment choices (Lee *et al.* 2008).

Several methods have been proposed to objectively determine wear times of a wide variety of removable appliances, such as electronic indicators used in headgear timing (Mitchell 1976) or microelectronic monitoring systems for removable functional appliances (Sahm *et al.* 1990; Schott & Göz 2010). These experimental methods functioned accurately from a technical perspective in measuring wear time in limited, well controlled studies. However, to be used in routine clinical practice, they will have to meet particular requirements to be accepted by patients (Schott & Göz 2010). For instance, sensors should be safe, unobtrusive, affordable and user-friendly and not involve additional burdens for the patient or operator.

Miniaturisation of wear-time sensors is a fundamental dilemma for developers. An appropriately size sensor, which can be integrated into the device without altering the appliance's dimensions and maintain the same comfortable appliance size is of paramount importance. To accurately record wear time, the addition of the sensor to the appliances should not alter the appliances in any way. The more comfortable an appliance is, the more likely the patient is to wear it on a consistent basis. Furthermore, wear-time sensors are expected to provide a long documentation period of up to 14 months, whilst maintaining power and requiring only periodic maintenance. In addition, consecutive daily wear documentation should, if possible, be measured over the briefest of intervals to provide accurate documentation of hour-to-hour wear time.

The first temperature-sensitive wear-time sensor was introduced to the market in 2009 under the name Smart Retainer® wear-time sensor (Scientific Compliance™, Atlanta, GA,

USA)(Ackerman *et al.* 2009). The Smart Retainer® generated a graphic representation of wear time with information accessible at 10, 30, 90 days and 6 and 12 months. However, Smart Retainer® wear time recognised one long, continuous period (c. 10 hours) "night-time wear time" and two interruptive intervals (of 2 hours each) as "daytime wear times". The Smart Retainer® did not provide documentation on how long a patient had worn the Smart Retainer® for each particular day. Such detailed wear documentation is essential when describing wear-time acceptance during the daytime in patients who are often unwilling to wear their appliances (Schott & Göz 2010). Another similar wear-time sensor was released one year later under the brand name TheraMon® (Handelsagentur Gschladt, Hargelsberg, Austria). Both manufacturers have claimed that their microsensors fulfil the basic requirements of a wear-time sensor, and, therefore, may make widespread sensor use in routine dental practice possible. The Thera-Mon® wear-time sensor has been successfully used to objectively measure compliance in removal orthodontics appliances and sleep-disorder breathing oral appliances (Schott and Ludwig, 2014; Vanderveken et al., 2013). To date, the Thera-Mon® sensor has still not been used to evaluate the compliance for sleep bruxism patients who wear occlusal devices.

1.7 Study Aim and Objectives

The aim of this study was to prospectively objectively determine patient compliance with occlusal device therapy for possible sleep bruxer patients who are either using an occlusal device for first time or are already wearing a device.

The study objectives were:

(1) To recruit 50 patients undergoing, or about to undergo, occlusal device therapy at the Dublin Dental University Hospital,

(2) To insert TheraMon® microsensors into each appliance and monitor them for up to 18 months (the first 90 days are to be recorded for the purpose of this thesis),

(3) To compare the objective measurement of appliance wear between new wearers and experienced wearers,

(4) To describe and analyse the patterns of occlusal device wear.

Chapter 2. Materials and Methods

2.1 Ethical Approval

An application for ethical approval was completed and submitted to the Tallaght

University Hospital/St. James's Hospital Joint Research Ethics Committee (REC). Ethical

approval was granted in April 2018 (see Appendix 1).

2.2 Recruitment of Participants

 Participants who had been provided with heat cured acrylic occlusal devices after

prosthodontic treatment at the Dublin Dental University Hospital in the previous 12-18

months were identified from Salud Electronic Dental Records. In addition, participants

planned for occlusal device provision were identified via emailing treating clinicians at the

Dublin Dental University Hospital. Once identified, Patient Approval Letters (Appendix 2)

were sent to the patients. In addition, patients were contacted via telephone by the

gatekeeper, an administrator at the Dublin Dental University Hospital, to determine if a

patient was interested in participating. Patients who declined were not contacted again.

All potential participants who responded positively to the Patient Approval

Letter/telephone contact and expressed interest in participating were mailed a Participant

Information Leaflet (Appendix 3) and an Informed Consent Form (Appendix 4).

An appointment with the primary investigator was made for the potential participant at

least seven days later. Patients who had existing occlusal devices (e.g., "experienced"

wearers) were asked to bring their devices to evaluate suitability of the appliance and

arrange the insertion of the Thera-Mon® microsensor. Patients who were to be provided with occlusal devices for the first time (e.g., "new" wearers), or "experienced" wearers who were deemed to have unsatisfactory appliances, had their microsensor inserted at the time of fabrication of their new appliance.

Participant Inclusion and Exclusion Criteria

2.2.1 Inclusion criteria:

1. Over 18 years of age,

2. Registered patient of the Dublin Dental University Hospital,

3. Capable of providing informed consent,

4. Able to attend a follow-up appointment,

5. Patients wearing a laboratory-made maxillary acrylic occlusal device provided by the DDUH in the last 12-18 months following prosthodontic treatment and who had worn the device for at least three months ("experienced" wearer group only), and

6. Possible sleep bruxism patients defined according to the diagnostic criteria of the American Academy of Sleep Medicine in 2005 (Diagnostic and Manual, 2005).

2.2.2 Exclusion criteria:

1. Patients unwilling or unable to consent, and

2. Patients unavailable for recalls.

2.3 Study Design:

This study was a longitudinal prospective clinical cohort trial of two groups of possible sleep bruxer participants who were either using the maxillary occlusal hard device for the first time (new wearers) or participants who worn the device for at least three months following prosthodontic treatment (experienced wearers). The aim of this study was to objectively measure wear time using an inbuilt microsensor.

On the day of their first appointment with the primary investigator, subjects signed Informed Consent Forms and were informed that they could leave the study at any stage. Then, all participants were asked to complete a sleep bruxism questionnaire according to the Diagnostic Criteria of the American Academy of Sleep Medicine in 2005 (Appendix 5) (Diagnostic and Manual, 2005). This questionnaire consisted of the following questions:

1. Are you aware of, or has anyone heard you, grinding your teeth frequently during sleep? (yes ∕no)

2. Are you aware that your dentition is worn down more than it should be? (yes ∕no)

3. Are you aware of any of the following symptoms upon waking? (yes ∕no)

    (i) Sensation of fatigue, tightness, or soreness of the jaw

    (ii) Feeling that your teeth are clenched or that your mouth is sore

    (iii) Aching of the temples

    (iv) Difficulty in opening the mouth wide

    (v) Feeling of tension in your jaw joint and feeling as if you have to move your lower jaw to release it

(vi) Hearing or feeling a ''click'' in your jaw joint that disappears afterwards?

Possible sleep bruxism patients were identified and recruited based upon their bruxism questionnaire responses, which acted as inclusion criteria. If their answers were positive to the first and/or second question, and they reported at least one positive response to one of the symptoms listed in Question 3, they were included in the study. Patients with negative responses were excluded from the study. After completion of the bruxism questionnaire, the main investigator then performed a comprehensive extra and intra-oral examination of each participant to exclude significant oral pathology. Participants who had existing occlusal devices had their devices evaluated, and, if satisfactory, the microsensors were activated and retrofitted into their appliances. If the appliances were unsatisfactory and deemed clinically unacceptable or if the palatal extension was not of sufficient dimensions to be inserted into the microsensor, new appliances were fabricated with microsensors by a single dental technologist at the Dental Production Laboratory at the DDUH and then fitted two weeks later. If the current appliances were deemed suitable, microsensors were retrofitted into patients' existing appliances during the same appointment. For participants who were to have their first occlusal devices fabricated, the microsensors were incorporated at the time of fabrication by the same dental technologist and the appliances placed two weeks later.

Patients were reviewed one week after sensor placement by a main investigator to ensure they were comfortable with the appliance and that it was functioning well. Any necessary

adjustments were also made at this appointment. If further appointments were necessary to adjust the appliance, they were completed as required.

All patients were recalled during the first and third months (by their own clinician or the primary investigator, when appropriate) of the study period, during which the microsensors were read and the information was transferred to a password-protected desktop computer. If the patient opted to withdraw from the study the sensor was removed and the appliance reconfigured by the dental technologist and returned to the patient.

2.4 Thera-Mon® Sensor

For objective wear-time documentation, TheraMon® (Therapeutic Monitoring Microsensor; Handelsagentur Gschladt, Hargelsberg, Austria) microsensors were used in this study. The Thera-Mon® sensor is rectangular (13 mm × 9 mm × 4 mm; see Figure 2.1). The microsensor can reliably detect fluctuations in temperature in the oral cavity and, therefore, distinguish wear-time temperatures (~35°C) from non-wear time temperatures (room temperature)(Schott and Göz, 2010). Wear time can then be graphically displayed on a computer screen according to time (hours per night) and date using compatible software (TheraMon® Software, Version 2.3.0.1) on all Windows® operating systems. Once the sensor has been activated, it starts evaluating wear time in the temperature range of 33.5 to 38.5°C and samples every 15 minutes, storing these measurement values in its integrated memory. According to the manufacturers, the documentation of wear

time could be recorded for a period of up to up to ≥18 months without the need for

recharging due to the use of an integrated battery (Schott and Göz, 2010).

Figure 2.1. TheraMon® (Therapeutic Monitoring Microsensor; Handelsagentur Gschladt, Hargelsberg, Austria).

The microsensor uses RFID technology (Radio Frequency Identification) through a Thera-

Mon® reading station linked to a personal computer (see figure 2.2). The Thera-Mon®

reading station emits a magnetic field of a very short range, which enables the sensor's

activation, registration, and the transfer of data.

Figure 2.2 Thera-Mon® reading station (Handelsagentur Gschladt, Hargelsberg, Austria).

2.5 Thera-Mon Sensor Retrofitting and Activation

The sensors were incorporated into the occlusal devices of participants who presented

with satisfactory occlusal devices by a single dental technologist at the Dublin Dental

University using auto-polymerising polymethylmethacrylate PMMA (Vertex™ Orthoplast,

Vertex-Dental, Soesterberg, The Netherlands) according to a previously published method

(Schott, 2011)(see Figure 2.3). In brief, this method involved creating the required space in

the palatal polished surface of the appliance to minimise contour change. In order to

maintain appliance durability, a minimum of 2 mm remaining thickness of acrylic resin was

preserved underneath the sensor space. After that, the microsensor was placed into the

custom space and covered with 0.5-1.0 mm of auto-cured polymethylmethacrylate

(Vertex™ Orthoplast, Vertex-Dental, Soesterberg, The Netherlands) using a salt and

pepper technique, which was followed by immersion in a pressure pot (Ivomat IP3; Ivoclar

Vivadent AG) at 55°C and 2.5 bar pressure for 20 minutes.

Thera-Mon sensors were activated, registered, and assigned to participants using

TheraMon® Software, Version 2.3.0.1 through the TheraMon® software package (see

Figure 2.4).

A

Figure 2.3. Incorporation of the Thera-Mon® microsensor into an existing occlusal device via polymerisation. Panel A demonstrates the outline of the required acrylic reduction into which the sensor is placed. Panel B shows the sensor in place, while Panel C shows the sensor in place secured using acrylic resin.

B
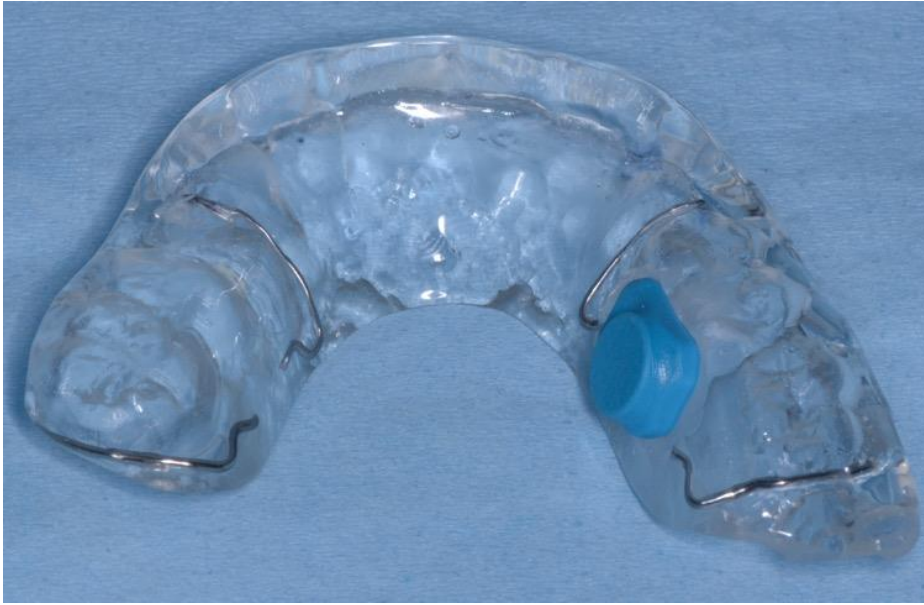
C

Figure 2.4 ctd. Incorporation of the Thera-Mon® microsensor into an existing occlusal device via polymerisation. Panel A demonstrates the outline of the required acrylic reduction into which the sensor is placed. Panel B shows the sensor in place, while Panel C shows the sensor in place secured using acrylic resin.

Figure 2.5. Sensor activation, registration, and assigning dentist client page (TheraMon®
Software, Version 2.3.0.1).

2.6 Fabrication and Fitting of New Occlusal Devices

Maxillary and mandibular dental impressions were made using polyvinylsiloxane

impression material (HS VPS Hydro, Henry Schein®). A face bow transfer was performed

using a Whip Mix® Direct Mounting Facebow (Whipmix®, KY USA). An inter-occlusal record

was made in centric relation using Moyco Wax Beauty Extra Hard (Integra York Pa., Inc.).

Type IV dental stone (Resinrock Whipmix®, KY USA) was used to pour the impressions.

Working Casts were mounted in centric relation using a semi-adjustable articulator

(Whipmix® 2240, KY USA). After mounting, the interocclusal space was set at

approximately 2mm in the molar region for the fabrication of the occlusal device. All

participants were provided with full or horseshoe coverage flat plane maxillary heat-cured

acrylic hard occlusal devices (see Figure 2.5).
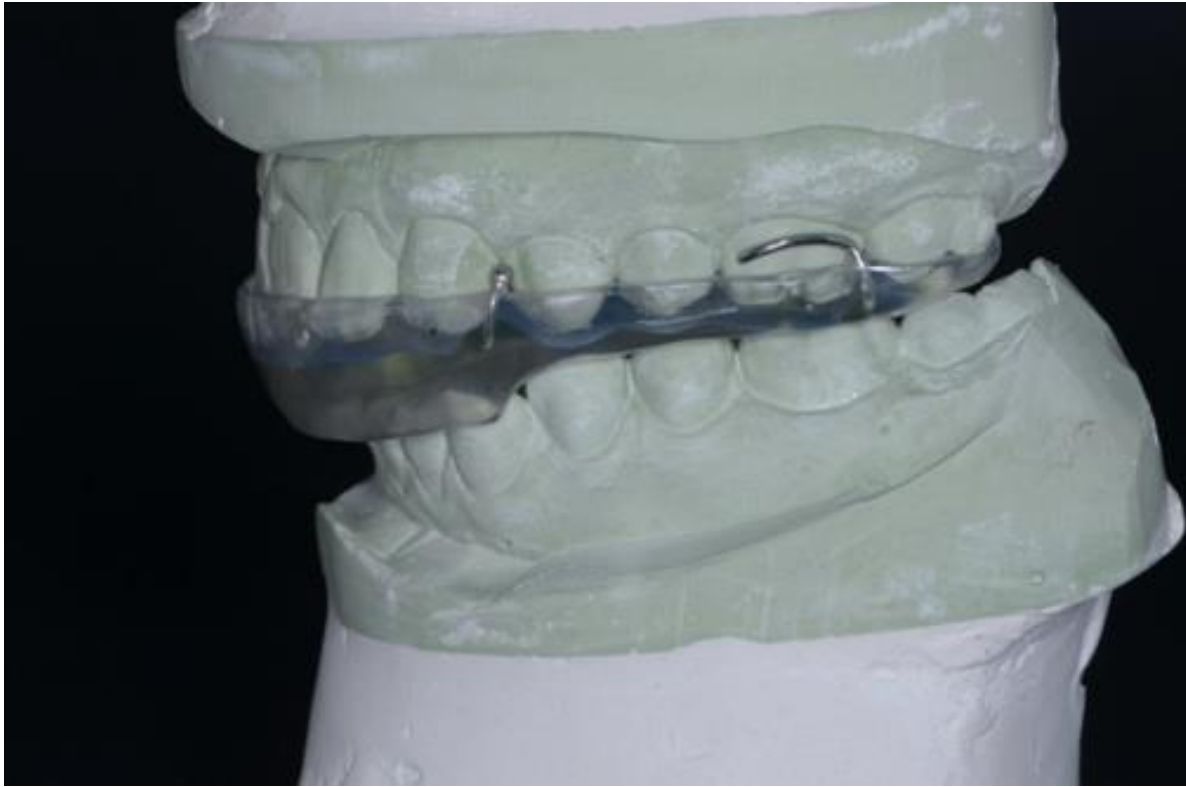
Figure 2.6. Sample flat plane maxillary occlusal device mounted in centric relation.

Occlusal devices were fabricated from heat-polymerised PMMA using a press technique (Vertex Rapid Simplified, Vertex-Dental, Soesterberg, The Netherlands). Universal prescription forms for the occlusal devices were generated and applied to all appliances, as shown in Figure 2.6. Individual modifications were made to the direct retainer location, if required, to retain the device.

Maxillary/Mandibular casts set in CMMR on articulator no ____.

Please construct:

A flat plane Occlusal Device on the Type IV stone maxillary master cast provided.

  (1)   Follow the marked outline on the master cast and provide full palatal coverage.

  (2)   Survey the master cast to:

  - Block out all lingual embrasures and identify retentive undercuts for 0.9 mm stainless steel wire retentive arms 16 & 26 and 0.9 mm stainless steel wire embrasure hooks 14-13 & 23-24 facial embrasures.

  - Block out occlusal and incisal embrasures as well as the lingual embrasures.

  - Create a FLAT PLANE occlusion rim over teeth 17-14 and 24-27. NO INDENTS FOR MANDIBULAR CUSP TIPS.

  - Occlude tips 17-14 and 24-27 on the flat rim, with anterior stop in at <u>3</u> mm.

  - Extend anterior ramp **4 mm** down over mandibular anteriors.

  - Do not place a Michigan type ramp to stop the 43-33.

  - The 43-33 edges should stand just clear of the discluding ramp. The discluding ramp should make an angle of 72° with the vertical.

  - Place a full palate design (or horseshoe where indicated) with an area of palatal extension to fit the sensor

Remount the master cast after processing to adjust occlusion 17-14 and 24-27 to the FLAT occlusion rim (no cusp tip indents) with 43-33 just out of contact with the discluding ramp.

Recover appliance from master cast and polish non-fitting surface only.

Please ensure that:

  (1)   Retentive arms/hook are adequately clear of acrylic to enable activity.

  (2)   No acrylic extends more than 1mm on the facial surfaces.

Figure 2.7. Universal prescription form for the maxillary occlusal devices.

All occlusal devices featured a full palatal horseshoe design with a palatal extension into which the sensor could be placed. This design of the occlusal device allowed for posterior disclusion using canine guidance during lateral excursive movements and incisal guidance during protrusive movement. The posterior ramp was adjusted, if necessary, to remove working or non-working side interferences, whilst providing even, bilateral and simultaneous posterior contacts.

A temperature-sensitive microsensor (TheraMon® microelectronic system; Sales Agency Gschladt, Hargelsberg, Austria) was incorporated into the occlusal device using the same acrylic resin (Vertex Rapid Simplified, Vertex-Dental, Soesterberg, The Netherlands), which was used to fabricate the occlusal devices. The sensor was incorporated into the appliance via polymerisation during processing according to the published method (Schott, 2011) (Figure 2.7).

Figure 2.8. Maxillary occlusal device with incorporated microsensor embedded during processing.

All new fabricated maxillary occlusal appliances were placed by the Principal Investigator ensuring:

1. The correct seating of the device, using silicone disclosing paste (Fitchecker® GC America, Alsip, Ill, USA) as required,

2. There was sufficient retention to retain the device when worn,

3. The presence of bilateral occlusal contacts in centric relation, verified using 40-µm articulating paper (Bausch Arti-check ®, Nashua, USA) and 8 µm-thick Shimstock (Almore Shimstock, Hanel, Langenau, Germany), and

4. The lateral disclusion of the posterior teeth and in protrusive movements through anterior guidance.

An example of the fitted occlusal devices is presented in Figure 2.8. The participants were instructed to wear the devices every night during sleep.

Figure 2.9. Maxillary occlusal device with incorporated microsensor in situ.

2.7 Sensor Readout and Recall Appointments

Once individual sensors were activated, recorded wear times were documented

graphically using dedicated TheraMon® Software, Version 2.3.0.1. A Lenovo™ Thinkstation

P330 desktop PC with the Microsoft® Windows® 10 operating system was used for reading

the wear times stored in the TheraMon® sensor. The readout data was then

demonstrated, and the daily wear times were determined as wear-time graphs (see a

sample output in Figure 2.9). Recall appointments were timed for one week, four weeks

and 12 weeks post-placement.
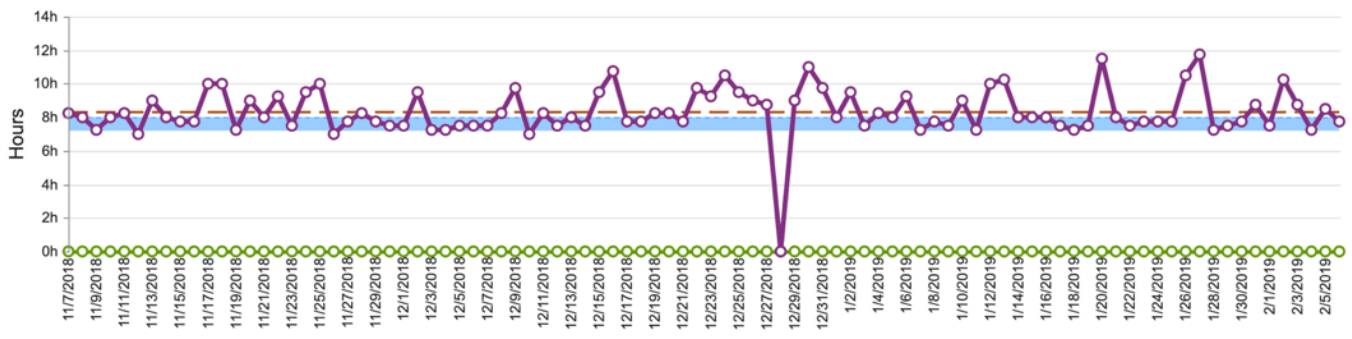
Figure 2.9. Daily wear time is indicated by the purple line and mean wear time by the red dotted line. The blue horizontal bar is the default prescribed wear time set by the TheraMon® software for orthodontic purposes. In this study, patients were asked only to wear the device at night during sleep.

2.8 Statistical Analysis

Statistical analysis of the documented wear-time data was performed using SPSS® for

Windows (IBM® SPSS® Statistics 20, Chicago, Illinois, USA). Descriptive wear time analysis

was performed as follows in order to:

1. Compare occlusal device wear time based on participant gender, age, and wear experience at the first, second, and third months (30 days) and the overall three-month period (90 days),

2. Determine differences in occlusal device wear over time based on participant wear experience (across repeated measures), and

3. Examine the relationship between age, gender, and patient experience on compliance with wearing of the occlusal device.

Due to the small sample size, the 25th percentile, median, and 75th percentile were used as statistical indices; however, the data was normally distributed (Shapiro–Wilk test). For further evaluation of the data, Mann-Whitney U-tests, nonparametric repeated measures Friedman test and a two-way nonparametric Scheirer-Ray-Hare test were performed to detect differences between the groups. The alpha level was set to 0.05.

Chapter 3. Results

3.1 Recruitment of Participants

Between September 2018 and May 2019, a total of 71 participants were identified and contacted. Forty two were identified using the hospital electronic patient records, Salud, and 29 were identified through a clinician contact at the DDUH. Fifty three participants accepted invitations to participate in the study and were interviewed by the Principal Investigator (as detailed in figure 3.1 for flow diagram). There were 24 patients in the experienced wearer group and 29 in the new appliance group.

A total of 46 participants (29 females and 17 males) were ultimately recruited based on the inclusion criteria: 19 experienced and 27 new patients. Nine participants (4 from the experienced group and 5 from the new group) were excluded from the study for reasons detailed below. A further 14 participants failed to comply with the device wear instructions and were excluded from the study. The reasons for exclusion due to non-compliance are detailed in a section 3.4.

New group
N = 29

Experienced
group N = 24

Accepted
invitation
N = 53

Excluded; did not
comply with
inclusion criteria
N = 7

New group
N = 2

Experienced
group N = 5

New group
N = 27

Experienced
group N = 19

Recruited
N = 46

Excluded; lost to follow up,
withdrew, starting other dental
treatment, lost the device, or
sensor defect
N = 9

New group
N = 5

Experienced
group N = 4

New group
N = 12

Experienced
group N = 2

Excluded; non-
compliant
N = 14

Remaining subjects
N = 23

New group
N = 10

Experienced
group N = 13

Figure 3.1 Flow chart of recruited participants.

3.2 Sleep Bruxism Questionnaire

Fifty three participants accepted the invitation and attended their first visit. After completing the sleep bruxism questionnaire, 7 participants (2 from the new group and 5 from the experienced group) were excluded, and 46 subjects were recruited (Figure 3.2). Subjects with self-reported sleep bruxism who had positive answers to the first and/or second questions in addition to at least one positive response to the symptoms listed in Question 3 were included.
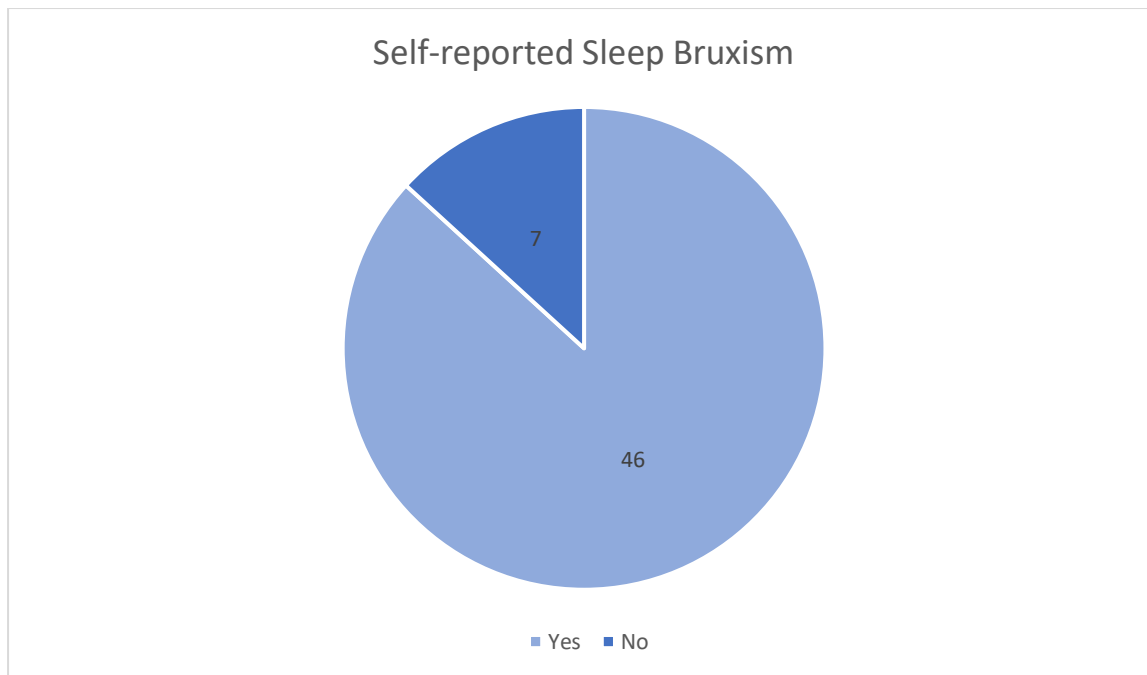
Figure 3.2 Number of participants with self-reported sleep bruxism.

New Wearer Group

More than two thirds (72.4%) of the new wearer group (21 subjects) reported a positive

history of sleep bruxism, which was either self-reported or reported by a bed partner

(Question 1)(Table 3.1). Sixty five percent of participants (19 subjects) stated they noticed

their dentition was more worn than it should be for their age. All participants, with the

exception of one, reported at least one symptom listed in Question 3.

Sleep Bruxism Questionnaire	Answer	Number	Percentage %
1. Are you aware of, or has anyone heard you, grinding your teeth frequently during sleep?	Yes	21	72.5
	No	8	27.5
2. Do you believe that your dentition has worn down more than it should?	Yes	19	65.5
	No	10	34.5
3. Are you aware of any of the following symptoms upon waking? *	Yes	28	96.5
	No	1	3.5

Table 3. 1. New participant responses to sleep bruxism questionnaire. *At least one positive
response from the six symptoms listed in the questionnaire.

Experienced Wearer Group

More than two thirds (70.8%) of the experienced wearer group (17 subjects) were aware

of their sleep bruxism either via themselves or a bed partner (Question 1)(Table 3.2).

Furthermore, more than half (58.3%) of these experienced wearers (14 subjects) believed

their dentitions were more worn than they should be for their age. A large percentage

(83.3%) of experienced wearers (20 subjects) reported at least one of the symptoms listed

in Question 3.

Sleep Bruxism Questionnaire	Answer	Number	Percentage %
1. Are you aware of, or has anyone heard you, grinding your teeth frequently during sleep?	Yes	17	70.8%
	No	7	19.2%
2. Do you believe that your dentition has worn down more than it should?	Yes	14	58.3%
	No	10	41.7%
3. Are you aware of any of the following symptoms upon waking?*	Yes	20	83.3%
	No	4	16.7%

Table 3. 2. Experienced participant responses to sleep bruxism questionnaire. *At least one positive response to the six symptoms listed in the questionnaire.

3.3. Exclusion of Participants

There were nine participants (7 male and 2 female) excluded from the study. Five were

from the new group and four from experienced group (see Tables 3.3 and 3.4).

Participants were excluded for the following reasons:

1. Three participants were excluded, as they were lost to follow-up. Two subjects

   decided to withdraw from the study as they were no longer using the device, and

   one subject failed to attend the follow-up visits despite telephone and postal

   reminders.

2. Two participants were excluded because they had begun a new course of dental treatment; thus, the decision to provide their appliance was deferred until the treatment's completion.

3. One subject underwent further prosthodontic treatment and two others began orthodontic treatment; thus, the fabrication of the devices was deferred until the treatments' completion.

4. One participant lost her device and did not want to pay for a replacement device.

5. One participant had a sensor that malfunctioned and did not want to return to have it replaced.

6. One participant was excluded because he had started CPAP therapy for sleep apnoea management and decided to withdraw from the study as he could no longer wear the device.

New Wearer Group Participants Excluded Study	
1	36 year-old male. The patient needed further prosthodontic treatment so the decision to provide the appliance was deferred until its completion.
2	25 year-old male, lost to follow up. The patient was contacted by the gatekeeper and decided to withdraw from the study, as he was no longer using the device.
3	26 year-old female. The patient needed orthodontic treatment, so the decision to provide the appliance was deferred until its completion.
4	49 year-old male. The patient started CPAP treatment for sleep apnoea and decided to withdraw from the study as he had stopped using the device.
5	71 year-old female. The patient had lost her device.

Table 3. 3. New wearer group participants excluded from the study.

Experienced Wearer Group Participants Excluded Study	
1	46 year-old male, lost to follow up. The patient was contacted several times by the gatekeeper with no response.
2	54 year-old male. The patient started prosthodontic treatment at this stage, so he stopped wearing his occlusal device, as he will be provided with a new device upon completion of the treatment.
3	29 year-old male. The patient's microsensor had a technical defect and the patient was unwilling to return to replace the microsensor.
4	57 year-old male, lost to follow up. The patient was contacted by the gatekeeper and reported he was no longer using the device and opted to be withdrawn from the study.

Table 3. 4. Experienced wearer group participants excluded from the study.

3.4. Exclusion of Non-Compliant Participants

Not all those enrolled in the study and provided with occlusal devices complied with the study parameters. Fourteen participants (9 female and 5 male) were excluded from the study during the observational period. The majority of those participants (12) were from the new users group (Tables 3.5 and 3.6). These participants either never wore the devices, were unable to tolerate the devices, began wearing the device but ceased after a short period of time, or wore them with a mean wear time of less than one hour. Participants from the new wearer group were excluded for the following reasons:

1. Nine participants were excluded due to reported adverse effects, including the following:

    a) Four subjects (three female and one male) reported discomfort and found the device cumbersome due to its size,

    b) Three subjects (all female) reported sleep disturbances and dental pain,

    c) Two subjects (all male) reported having a very dry mouth.

2. Two participants (one female and one male) reported wearing the device some nights. However, the objective microsensor measurements did not indicate any hours of wear of the occlusal device during the observational period.

3. One participant (female) stopped wearing the device, as she noticed no or little effect on her bruxism activity. Once it was explained that the device would not reduce bruxism in the long-term but provide protection for her dentition, she declined to wear the appliance.

Participants in the experienced wearer group were excluded for the following reasons:

1   One participant in the experienced group (male) stopped wearing the device

because he was hospitalised following a road traffic accident and off work with

headaches for an extended period of time.

2   One participant in the experienced group (female) stopped wearing the device due

to travel commitments.

The demographics of the participants excluded due to non-compliance are listed for both

groups in Tables 3.5 and 3.6.

New Wearer Group Participants Excluded Due to Non-Compliance	
1	25 year-old male. The patient was compliant at the beginning of the study but stopped wearing the device for rest of observational period due to its size, which caused him discomfort.
2	20 year-old female. The participant was unable to wear the device due to its size, which caused discomfort.
3	36 year-old female. The patient was compliant at the start but stopped wearing the device for the rest of observational period due to its size, which cause discomfort and felt awkward in her mouth.
4	44 year-old female. The participant was unable to wear the device, as it caused sleep disturbances and dental pain.
5	28 year-old female. The objective microsensor measuring did not indicate any hours of wear for the observational period. The participant reported that she wore it some nights, which was inconsistent with the microsensor reading. The participant withdrew from the study.
6	22 year-old female. The participant was compliant for a few days but stopped wearing the device for the rest of observational period, as she noticed no or little effect on her bruxism activity. Once it was explained that the device would not reduce bruxism in the longer term but provide protection for her dentition, she declined to wear the appliance.
7	36 year-old female. The participant was unable to wear the device, as she reported sleep disturbances and dental pain.
8	23 year-old female who was compliant initially but stopped wear for the rest of observational period due to the size of the device, which caused discomfort which she was unable to tolerate.
9	23 year-old male. The objective microsensor did not indicate any hours of wear for the occlusal device for the observational period. However, the participant reported that he wore it most nights. He withdrew from the study.
10	52 year-old male who ceased wearing the device after a few days, as he felt that the device made his mouth too dry, rendering him unable to tolerate the appliance.
11	19 year-old female. The participant wore the device initially but then stopped as it caused sleep disturbances and pain.
12	73 year-old male who only wore the device for a few days at the start of treatment. He ceased wearing the device as his mouth became too dry.

Table 3.5. New wearer group participants excluded due to non-compliance.

Experienced Wearer Group Participants Excluded Due to Non-Compliance	
1	56 year-old male. The participant was hospitalised after a RTA and reported residual headaches, which prevented him from wearing the appliance.
2	26 year-old female who stopped wearing the device during the observational period due to travel commitments.

Table 3.6. Experienced group participants excluded due to non-compliance.

3.5 New Wearer Group Recruitment

Twenty nine new users were recruited, and two participants commenced additional dental treatment. Therefore, the decision to provide their devices was deferred until the completion of this treatment. A total of 27 new maxillary hard occlusal devices with an incorporated microsensor were provided for all new group participants. Five subjects (two female and three male) were excluded as detailed above. Furthermore, 12 subjects (eight female and four male) were also excluded due to non-compliance. Ten new group participants remained and were included in the study.

3.6 Experienced Wearer Group Recruitment

Nineteen experienced wearer participants were recruited. Ten of those participants were provided with new maxillary occlusal devices with an incorporated microsensor as replacement devices, as they had either lost their previous device or presented with unsatisfactory devices. Nine participants presented with satisfactory hard maxillary occlusal devices, and had microsensors incorporated into their existing devices. Four participant were excluded as they either were lost to follow-up or had begun another course of dental treatment. Two further participants were excluded due to non-compliance. In total, 13 experienced group participants remained and were included in the study.

3.7 Demographics and Overview of Participants

The sample consisted of 23 patients, 10 of which had never worn an occlusal appliance and 13 of which had experience wearing a dental occlusal appliance previously (Figure 3.3).
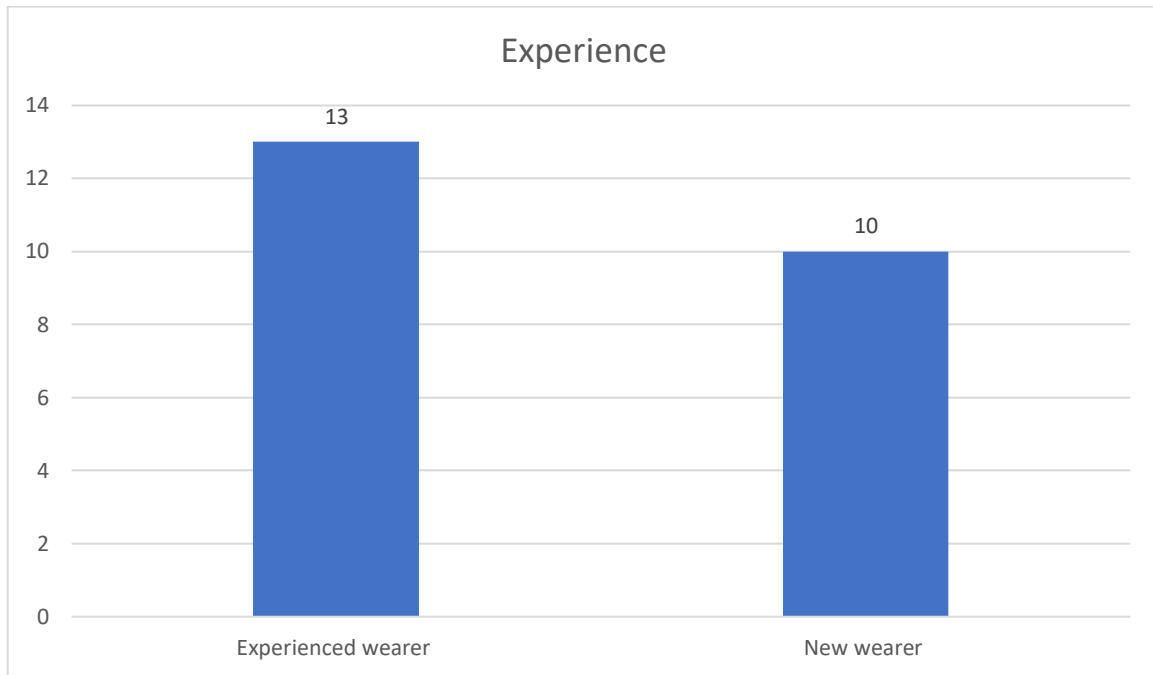
Figure 3.3 Participants included in the analysis.

Of the 23 patients, five (22%) were male, and the remaining 18 (78%) were female (Figure 3.4). The gender distributions within each of the experience levels (new patient vs. experienced patient) were unbalanced, with more female patients in each group: 70% and 85% female in the new patient and experienced patient groups, respectively (as detailed in figure 3.5).

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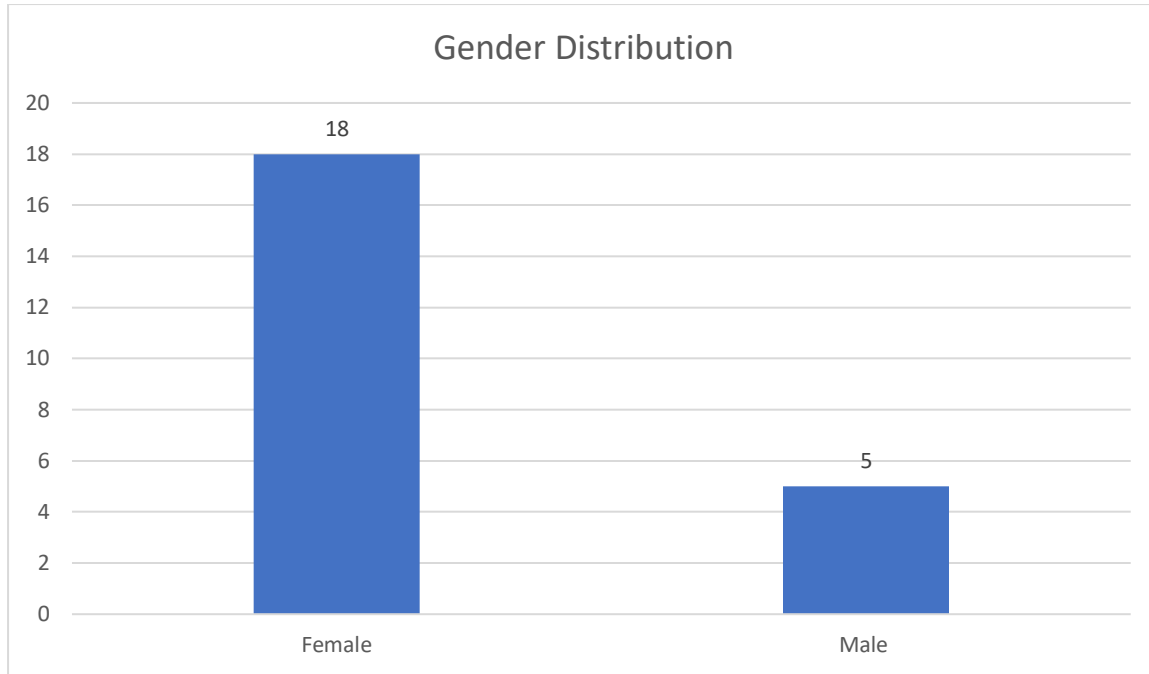
Figure 3.4 Gender distribution.
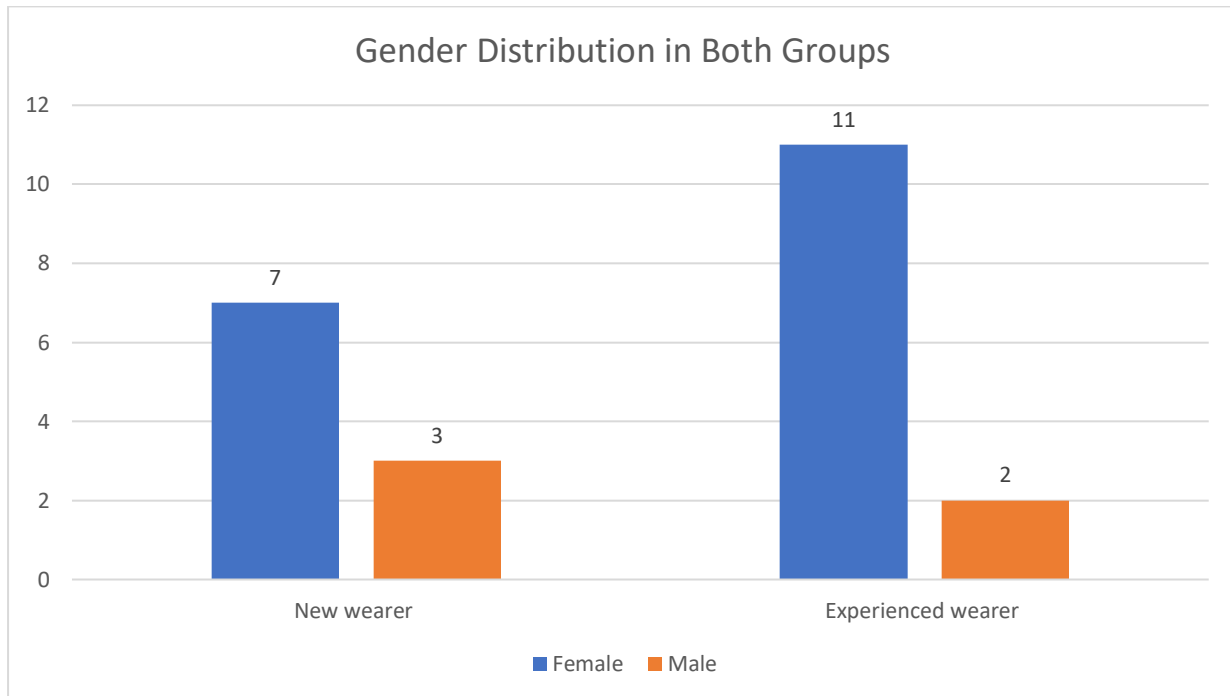
Figure 3.5 Gender distribution between the two groups.

Twelve participants were in the ≤ 45 years of age group and were between 22-45 years of age, with an average age of 38 years. Eleven participants were in the ≥ 46 years of age group and were between 46-77 years of age, with an average age of 59 (Figure 3.6). The age distributions within both groups were relatively balanced, with a 50%-50% split between <= 45 years of age and >= 46 years of age in the new patient group and a 54%-46% split between the <= 45 years of age and >= 46 years of age in the experienced patient group (as detailed in figure 3.7).
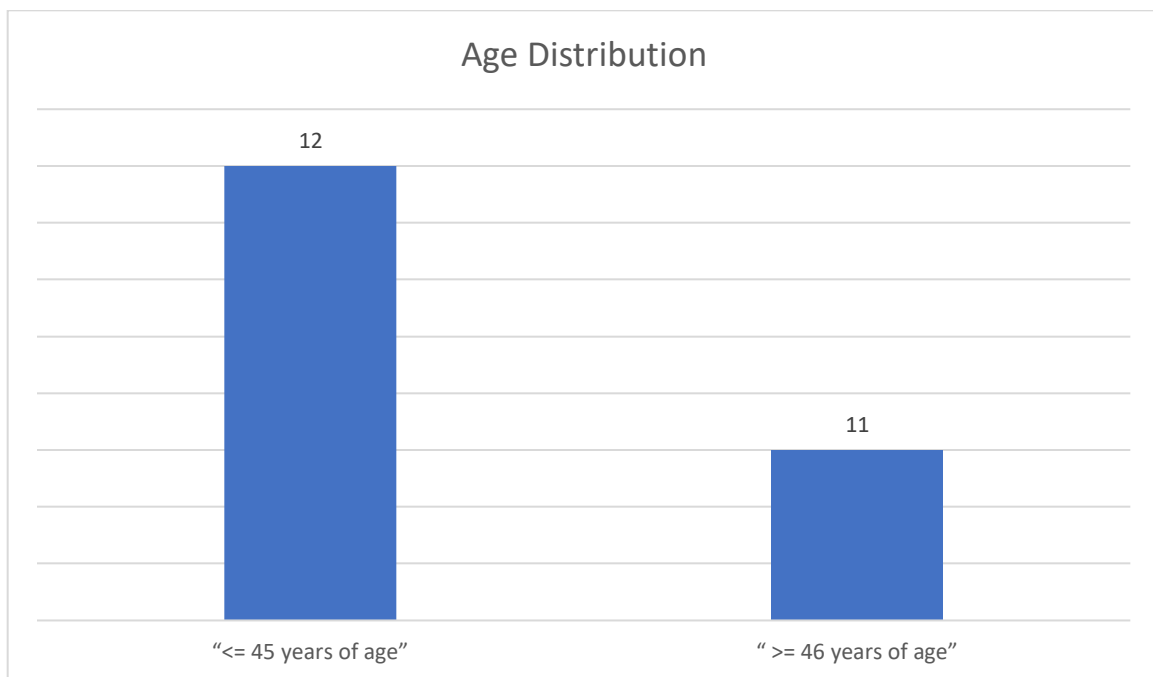
Figure 3.6 Age distribution.
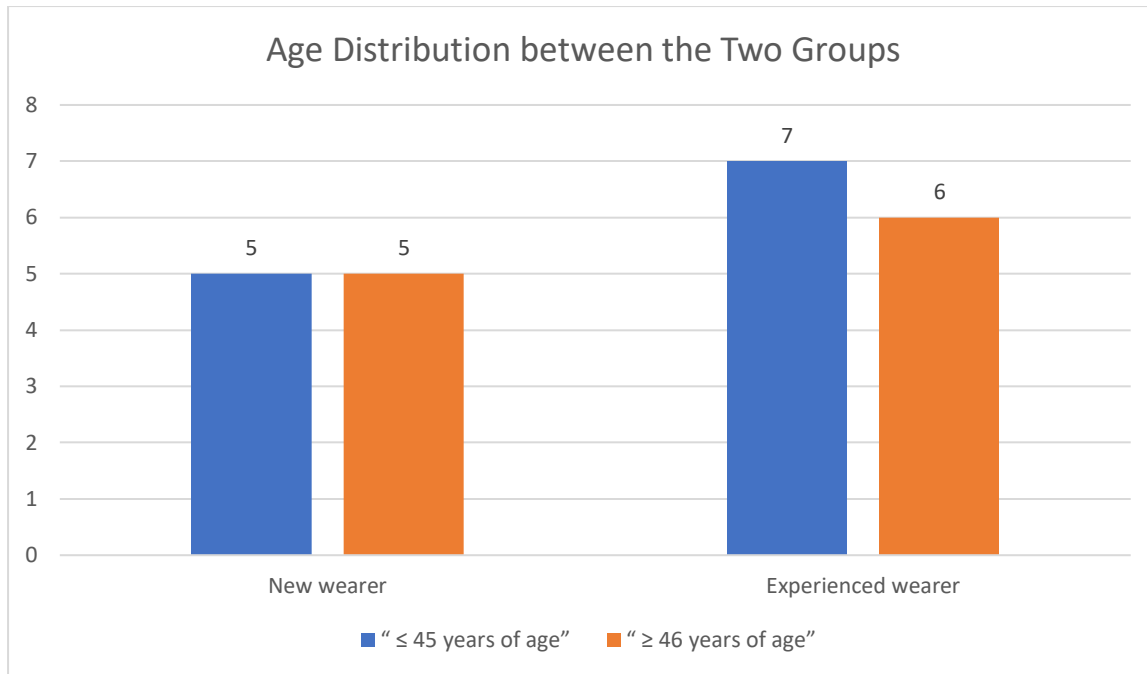
Figure 3.7 Age distributions between the two groups.

All patients completed 90 consecutive days wearing the occlusal appliance. The 90-day period was divided into three consecutive 30-day observation periods (first month, second month, and third month), with average wearing times calculated for each patient within each of the three 30-day blocks to determine if wear patterns had changed in either group.

3.8 Descriptive Overview of Occlusal Device Wear Time

An overview of the descriptive characteristics associated with the distributions of occlusal device wear time is presented. Specifically, graphical representations depicting occlusal device wear time across the entire 90-day period as well as the first month (30 days), second month (30 days), and third month (30 days), independent of experience, gender, and/or age are presented. First, the graphical overview of the distribution shape is presented

through histograms, which is followed by another overview considering the numerical descriptive measures and commentary on the distribution normality.

Distribution of occlusal appliance wear time across overall 90-day period

(a)

Distribution of occlusal appliance wear time across first month (30-days)

(b)

Distribution of occlusal appliance wear time across the second moth (30-days)

(c)

Distribution of occlusal appliance wear time across the third month (30-days)
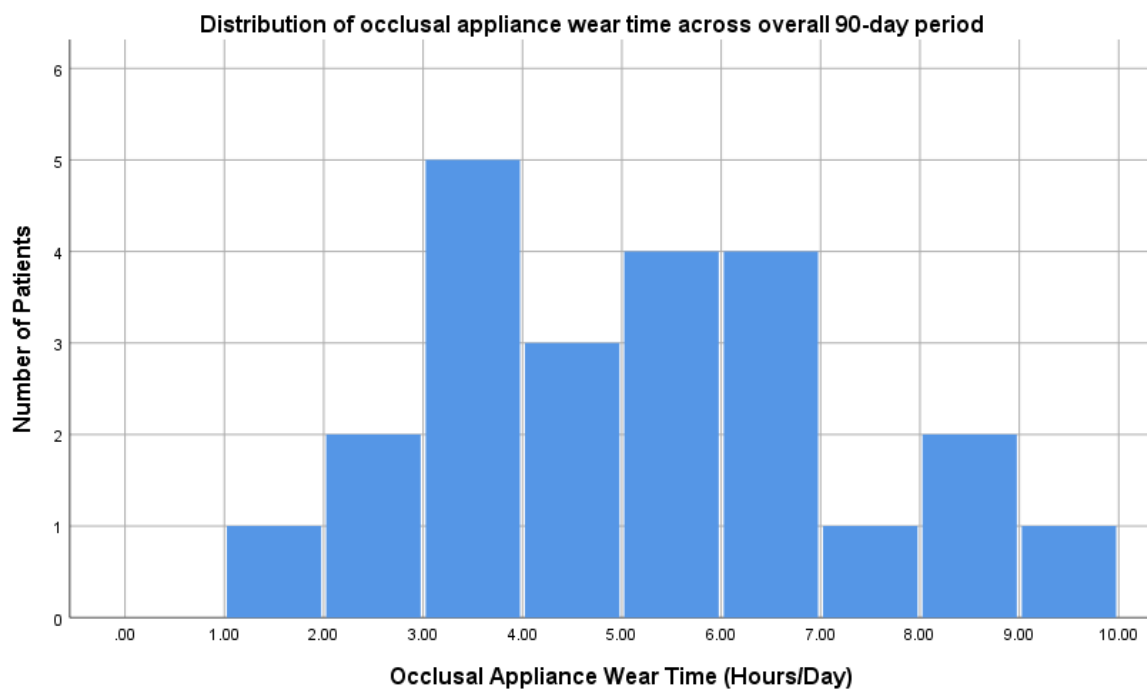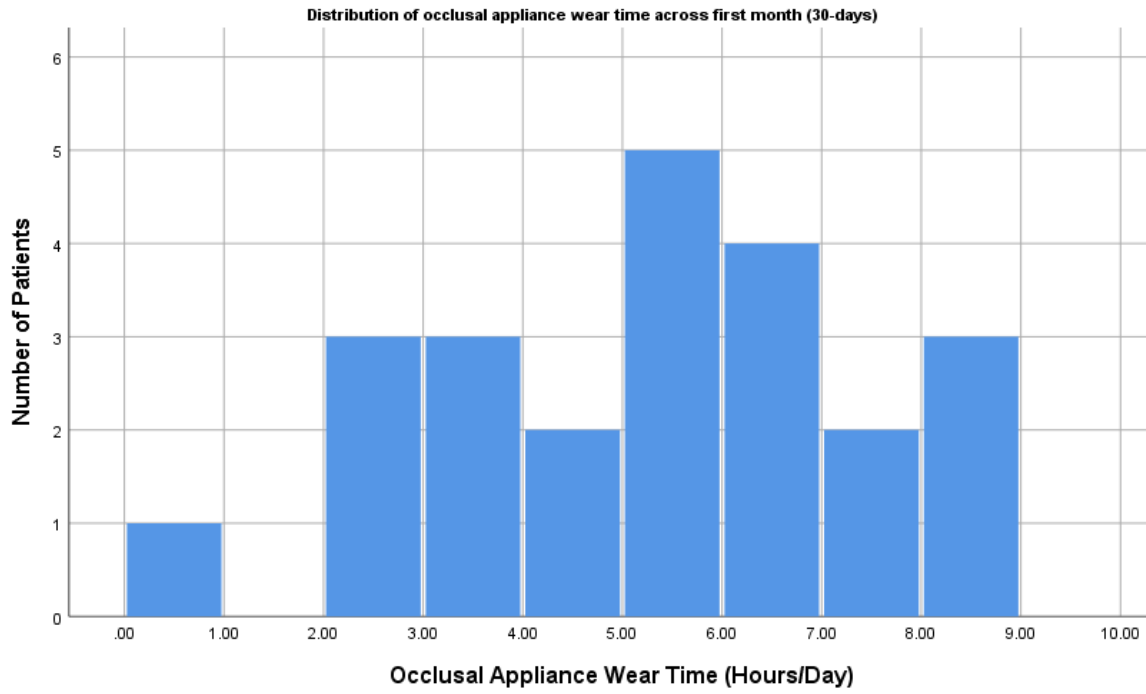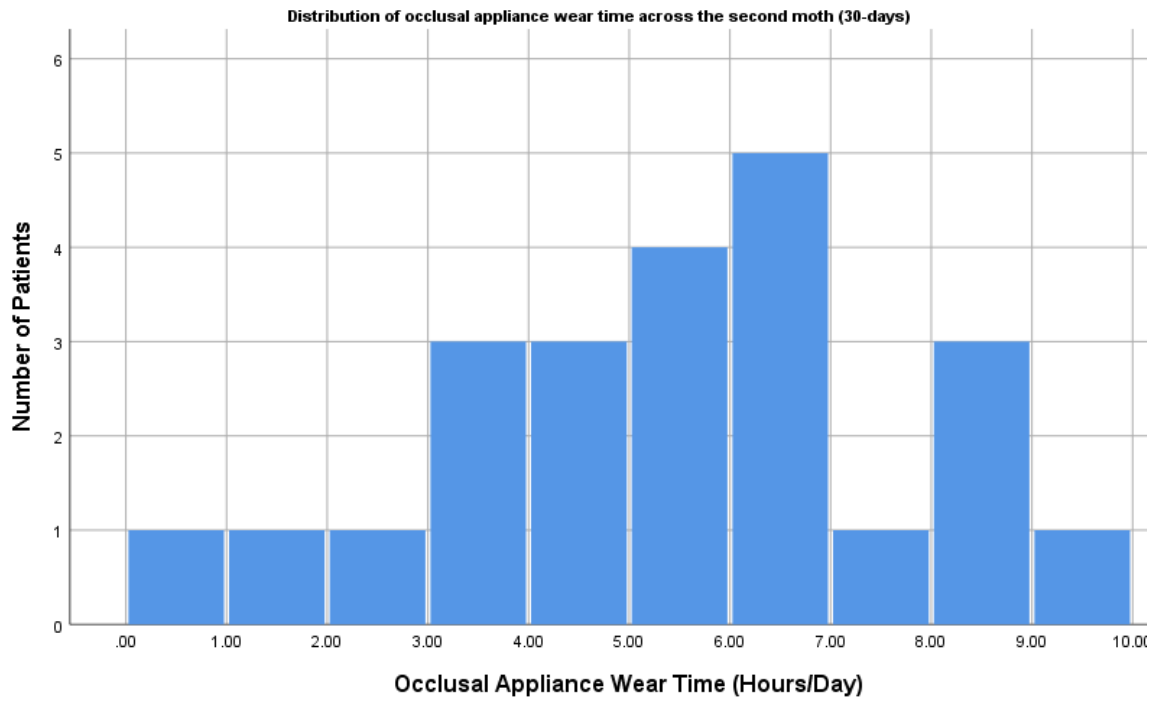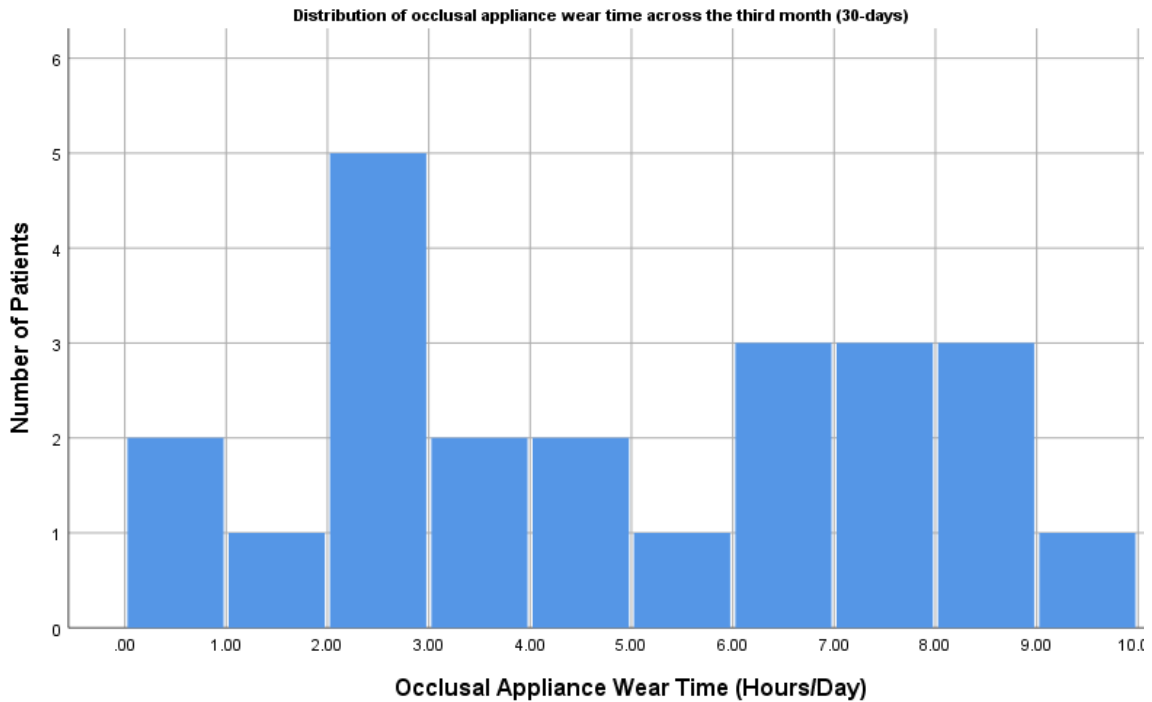
(d)

Figure 3.8 Distributions associated with (a) overall occlusal appliance wear time across the full 90-day period alongside the distributions for overall occlusal appliance wear time in (b) the first, (c) second, and (d) third month (30-day periods).

The distributions associated with overall occlusal appliance wear time are presented in Figure 3.8 (a) to (d). In all cases, the horizontal axis presents the duration of wear time, shown in hours, with the vertical axis indicating the number of patients. Figure 3.8(a) shows the overall 90-day period compliance characteristics, with patients recording compliance times ranging between 0 and 10 hours. Similar distributional ranges were present for the first month, second month, and third month periods. The overall distributional shape was relatively symmetrical for all periods, centred around five hours of wear per night. With that said, modal occlusal device wear time (tallest bars in Figure 3.8(a) to (d)) for the overall sample was between three and four hours. For the first month (30 days), modal wear was

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between five and six hours, while the second month (30 days) reported between six and seven hours, and the third month reported between two and three hours of wear per night.

A more detailed characterisation of distributional shape is presented from a numerical perspective in Table 3.7. Irrespective of measurement period, all mean occlusal device wear time durations ranged between 5.03 and 5.32 hours; ignoring the 90-day period, average occlusal appliance wear time reduced slightly across the three 30-day measurement periods, as shown in column M in Table 3.7. With that said, no increasing or decreasing trend was evident with respect to standard deviation (column SD); all average dispersions, as measured by their respective standard deviations, were approximately 2.00 hours, ranging between 2.17 hours and 2.79 hours.

Period	N	M	SD	S_k	SE	K	SE	M_d	25	75	Min	Max
90 Days	23	5.22	2.42	-0.23	0.29	-0.85	0.57	5.50	3.28	7.05	0.00	9.97
First Month	23	5.32	2.17	-0.32	0.48	-0.79	0.94	5.50	3.47	6.93	0.90	8.67
Second Month	23	5.29	2.35	-0.39	0.48	-0.20	0.94	5.57	3.50	6.73	0.00	9.13
Third Month	23	5.03	2.79	-0.02	0.48	-1.27	0.94	4.87	2.73	7.60	0.50	9.97

Table 3. 7. Numerical descriptive statistics associated with occlusal appliance wear time across the overall 90-day period alongside the first, second, and third months; featuring the mean (M), standard deviation (SD), distribution skewness (S_k), kurtosis (K), median occlusal appliance wear time (M_d) along with respective 25th percentile (25) [first quartile], 75th percentile (75) [third quartile], and respective minimum (Min) and maximum (Max) observations.

Using the coefficient of determination (relative standard deviation) as a measure of relative dispersion, the ratio of standard deviation to mean value ranged between 0.41 and 0.55. Although the standard deviation was larger in the second month (30 days) than the first month (30 days), the coefficients of variation changed in their magnitudes of relative variability from 0.41 in the first period to 0.44 in the second period.

To test for differences in the observed variation, a Levene's test of homogeneity of variances was undertaken, which indicated that there were no statistical significant differences between the variances in the first month (30 days) occlusal appliance wear time (SD = 2.17), second month (30 days) occlusal appliance wear time (SD = 2.35), or third month (30 days) occlusal appliance wear time measurements (SD = 2.79), $F_{(2, 66)} = 1.98$, $p = 0.146$.

As detailed in Table 3.7, all distributions showed a degree of negative skewness (column S_k), ranging between -0.02 and -0.39, although none were statistically different to zero, and all p-values were greater than 0.05. Similarly, although the reported levels of kurtosis would indicate that all distributions exhibited a degree of platykurtosis, none were statistically significantly different to zero with all p-values greater than 0.05. Tests for normality provided no evidence that any of the measurement periods of occlusal appliance wear time had not been normally distributed, as assessed through the Shapiro-Wilk's test of normality (Table 3.8).

Period	W	Df	Significance
First 30 days	0.963	23	0.533
Second 30 days	0.977	23	0.849
Third 30 days	0.939	23	0.168
Cumulative 90 days	0.978	23	0.866

Table 3.8. Results of the Shapiro-Wilk's test of normality detailing the magnitude of test statistic (W), degrees-of-freedom (Df), and significance.

Focusing on median occlusal appliance wear time, column M_d in Table 3.7, all measurement periods had medians ranging between 4.87 and 5.57, with the 90-day average being equal to that of the first month (30 days) and both these months only differing with the second month (30 days) by 0.07 hours (4.2 minutes). The third month (30 days) exhibited a median occlusal appliance wear time of approximately 4.87 hours. While there was a drop in compliance across the three periods, this decrease was relatively small and represented a very small effect.

Box-and-whisker plot of occlusal appliance wear time across overall three months (90-days)

(a)

Box-and-whisker plot of occlusal appliance wear times for first, second, and third months
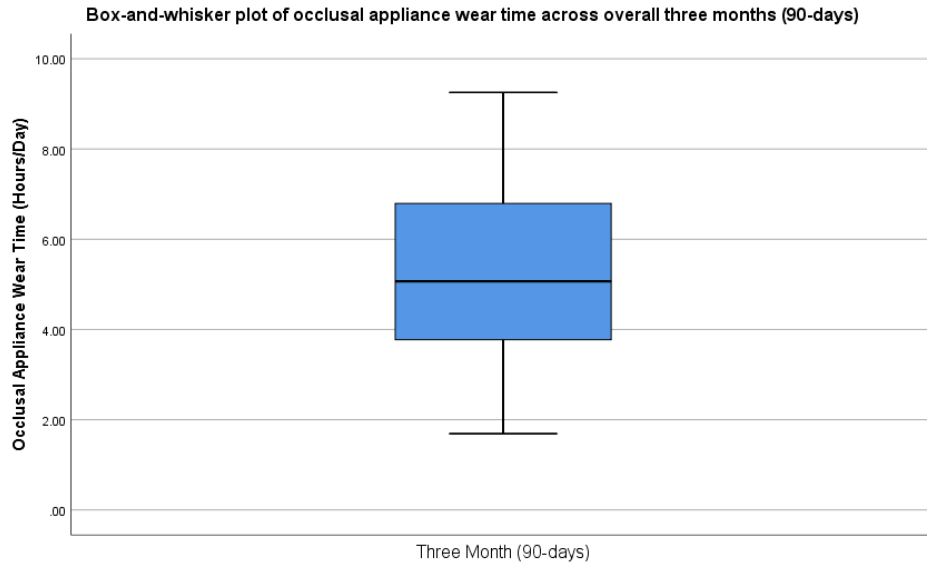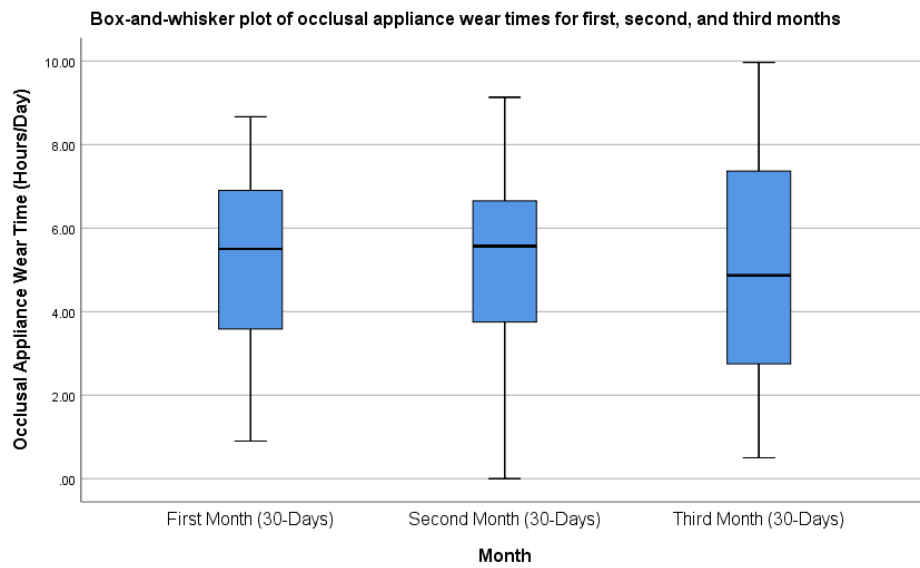
(b)

Figure 3.9. Box-and-whisker plots of occlusal appliance wear time for (a) the cumulative 90-day period and (b) for the individual first, second, and third months (30-day periods).

A quartile representation of the distributions of occlusal appliance wear time are shown for the overall 90 night period in Figure 3.9(a); while the first month, second month, and third month measurement periods are shown in Figure 3.9 (b).

3.9 Descriptive Overview of Occlusal Device Wear Time by Experience

This subsection presents an overview of the descriptive characteristics associated with occlusal device wear time and the levels of patient experience. In particular, graphical representations are presented depicting occlusal device wear time across the experimental timeframe for those that had no previous experience wearing an occlusal device and those who did. Graphical overviews of the distribution shape are presented through histograms followed by an overview of distribution shape in consideration of the numerical descriptive measures, which is provided with comments on the distribution normality.

The distributions associated between overall occlusal appliance wear time based on experience and occlusal usage are presented in Figure 3.10(a) to (h). In all cases, the horizontal axis represents the occlusal appliance wear time (in hours), and the vertical axis indicates the number of patients. Figures 3.10(a) and (b) show the overall 90-day period wear time characteristics, with new patients recording wear times between 2 and 5.5 hours. In contrast, experienced patients recorded wear times across a larger range, between 0 hours and 10 hours. Both distributions exhibited a degree of symmetry.

In contrast, the distributions associated with the first month (30 days) of occlusal appliance wear time (Figures 3.10 [c] to [d]) exhibited positive skewness for new wearers and negative skewness for experienced wearers. Wear times ranged between 2 and 9 hours for the new users and between 0 and 10 hours for the experienced users.

Distribution of occlusal appliance wear time across overall three months (90-days)
Experience: New Patient

(a)

Distribution of occlusal appliance wear time across overall three months (90-days)

Experience: Experienced Patient

(b)

Distribution of occlusal appliance wear time across the first month (30-day)

Experience: New Patient

(c)

Distribution of occlusal appliance wear time across the second month (30-day)
Experience: Experienced Patient

(d)

Distribution of occlusal appliance wear time across the second month (30-day)
Experience: New Patient

(e)

Distribution of occlusal appliance wear time across the second month (30-day)
Experience: Experienced Patient

(f)

Distribution of occlusal appliance wear time across the third month (30-day)
Experience: New Patient

(g)

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(h)

Figure 3.10. Distributions associated with overall occlusal appliance wear time across the full 90-day period for both new and experienced patients alongside the distributions for overall occlusal appliance wear time (a & b) and the first (c & d), second (e & f), and third (g & h) months (30 days) for both new and experienced patients.

The directionality of the distributional shape for the second month of occlusal appliance wear time (Figures 3.10(e)and (f)) was similar to that of the first month, with both exhibiting a degree of negative skewness. The range of observations was between 0 and 7 hours for the new group and between 0 and 10 hours for the experienced group. Figure 3.10(g) and (h) depict the third month of occlusal appliance wear time, which resembles the first month's distributional shape, which is in and opposite direction and negative for the new group and positive for the experienced group.

Across all distributions, only a single new group patient recorded occlusal appliance wear time of more than seven hours, whereas the experienced wearers, irrespective of period and in all cases, reported wear times greater than seven hours but no more than 10 hours.

Focusing on the numerical descriptive measures, as presented in Table 3.9, all measures of skewness (column S_k) agreed with the previous observations drawn from the graphical representations of each group's distribution. Specifically, the magnitude of the distributional skew ranged between -1.39 and 0.46. With that said, the significance of these observations, and in particular the evidence in regard to their deviation from symmetry, was supported only in a single case: for second month new wearers with occlusal device wear times greater than 1.96 standard units in the negative direction ($Z = -2.01$, $p < 0.05$).

With respect to distributional kurtosis, when compared with skewness, the only evidence for deviation from a mesokurtotic distribution was in the case of the new group's occlusal appliance wear time for the second month ($Z = -2.02$, $p < 0.05$ measurements), which exhibited a statistically significant degree of platykurtotic characteristics.

Period	Exp.	N	M	SD	S_k	SE	K	SE	M_d	25	75	Min	Max
First month	New	10	4.46	1.97	0.46	0.69	-0.72	1.33	4.33	2.64	6.04	2.17	8.07
	Exp.	13	5.98	2.15	-1.08	0.62	1.26	1.19	6.60	4.83	7.80	0.90	8.67
Second month	New	10	4.24	1.83	-1.39	0.69	2.68	1.33	4.38	3.41	5.71	0.00	6.20
	Exp.	13	6.10	2.45	-0.77	0.62	-0.39	1.19	6.57	4.37	8.30	1.40	9.13
Third month	New	10	3.28	2.07	0.26	0.69	-0.59	1.33	3.05	1.61	5.03	0.50	6.87
	Exp.	13	6.38	2.54	-0.69	0.62	-0.86	1.19	7.13	3.52	8.22	2.03	9.97
All	New	10	3.99	1.06	-0.46	0.69	-0.37	1.33	4.04	3.13	5.01	2.07	5.44
	Exp.	13	6.16	2.16	-0.74	0.62	0.05	1.19	6.79	4.52	7.91	1.69	9.26

Table 3. 9. Numerical descriptive statistics showing association between occlusal device wear time based on experience across the overall 90-day period alongside the first, second, and third months; featuring the mean (M), standard deviation (SD), distribution skewness (S_k), kurtosis (K), and median occlusal appliance wear time (M_d) along with respective 25th percentile (25) [first quartile], 75th percentile (75) [third quartile], and respective minimum (Min) and maximum (Max) observations.

A comparison of all the measures of centre and, in particular, mean occlusal device wear time showed what seemed to be significant effects. During the first month (30 days), new wearers reported average occlusal appliance wear time durations of approximately 4.46 hours in contrast to the 5.98 hours average reported by the experienced wearers, a difference of 1.52 hours (column M Table 3.9). This trend manifested across the subsequent timeframe, with a difference of 1.86 hours between the new wearers and experienced wearers in the second month (the experienced wearers wearing the occlusal device longer than their new counterparts). The largest difference was observed during the third month (30 days), with experienced wearers wearing the occlusal device for approximately 3.1

hours longer than the new users. Meanwhile, the cumulative 90-day period showed, on average, that experienced wearers wore an occlusal device for approximately 2.17 hours longer than their new counterparts.

Focusing alternatively on the median measures of centre, the trends associated with the mean measures were also present. Overall, median occlusal appliance wear time ranged between 3.05 hours and 7.13 hours. In all cases, median occlusal appliance wear time was greater for the experienced group than the new user group. Interestingly, the median differences were 2.27 hours, 2.19 hours, and 4.08 hours for the first, second, and third months, respectively. For the total 90-day period, the difference between the groups was 2.75 hours. All median differences, in contrast to the observed mean differences, were comparably greater for similar period groups. A line graph representation of the median trends is presented in Figure 3.11. For completeness, quartile representations of the distributions of occlusal device wear time are shown for the 90-day, first month, second month and third month measurement periods and presented in Figure 3.11(a) and (b). Each time period detailed new and experienced wearers' occlusal appliance wear time. In all cases, the red distributions (experienced wearers) exhibited a greater dispersion across each of the box-and-whisker plots underlying the five-point statistics, with the exception of a single minimum value associated with an experienced wearer in the second month period. All experienced groups reported greater minimum occlusal appliance wear times, with the first quartiles being greater for all experienced groups than the new users in addition to their medians, third quartiles, and maximum occlusal appliance wear times being greater. Two cases were highlighted as being unusually small in comparison to other observations

within their group and are depicted as unfilled circles in Figure 3.11(b). The horizontal axis represents the time measurement periods, and the vertical axis represents occlusal appliance wear time in hours. The divergence in median occlusal appliance wear time clearly changed from the second month to the third month, representing a difference of 4.08 hours (Figure 3.11 (c)).
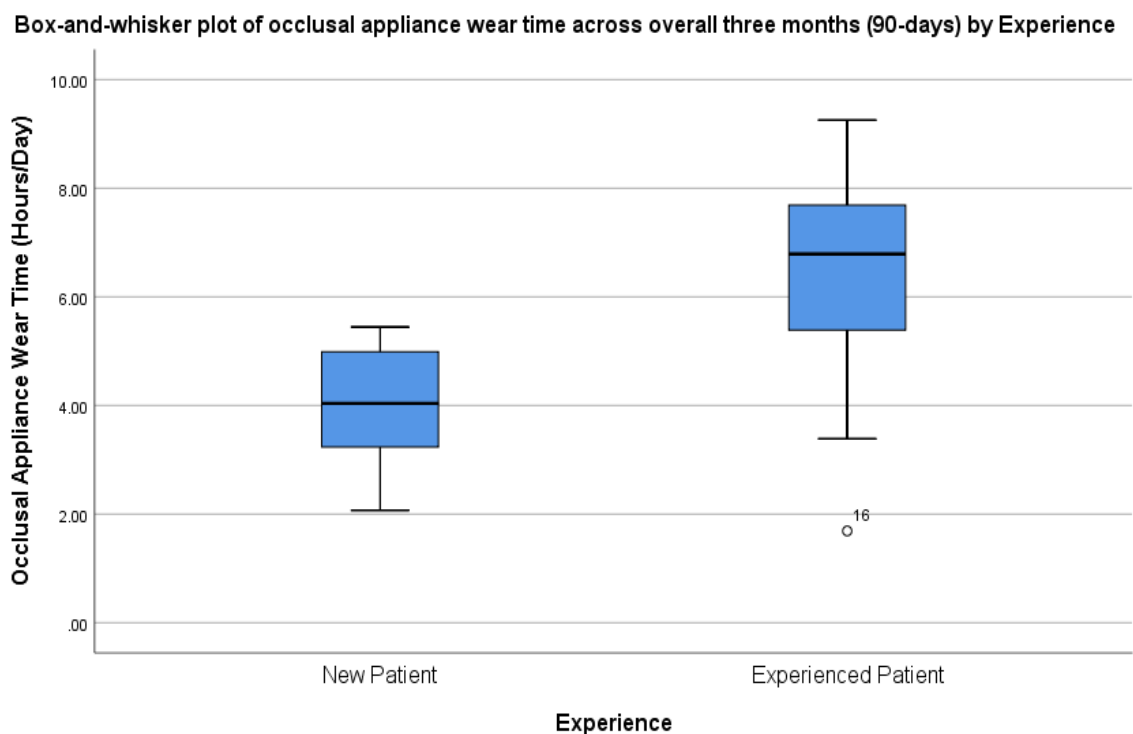
Box-and-whisker plot of occlusal appliance wear time across overall three months (90-days) by Experience

(a)

Box-and-whisker plot of occlusal appliance wear time for the first, second, and third months (30-days) by experience

(b)
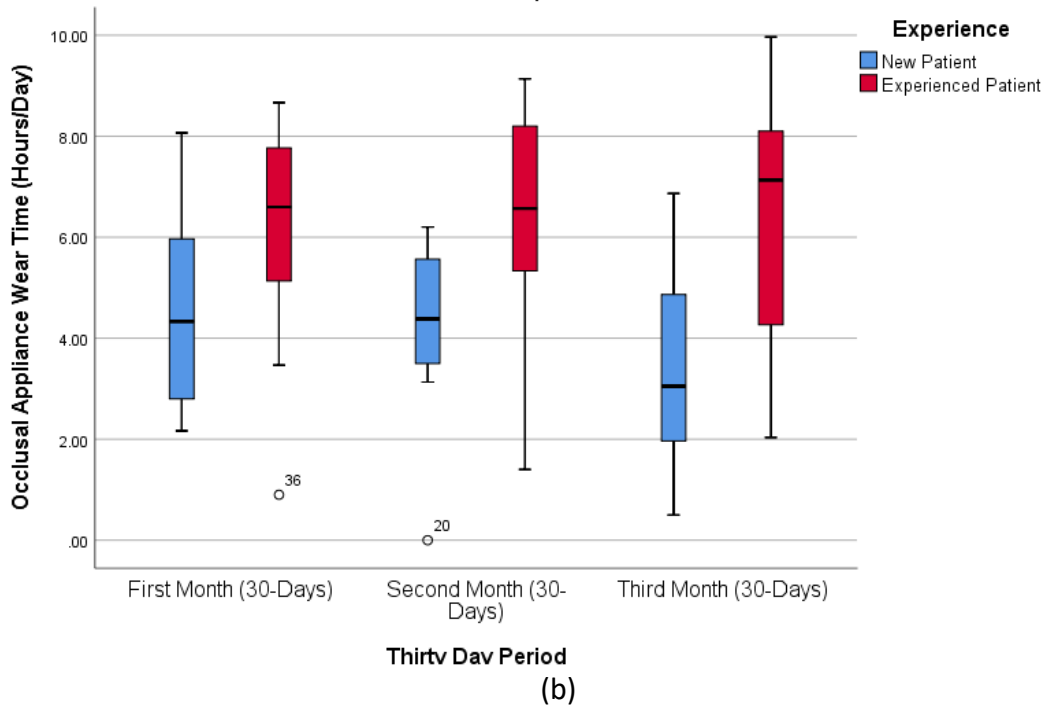
Line chart depicting Median Compliance across first, second, and third 30-day period by Experience
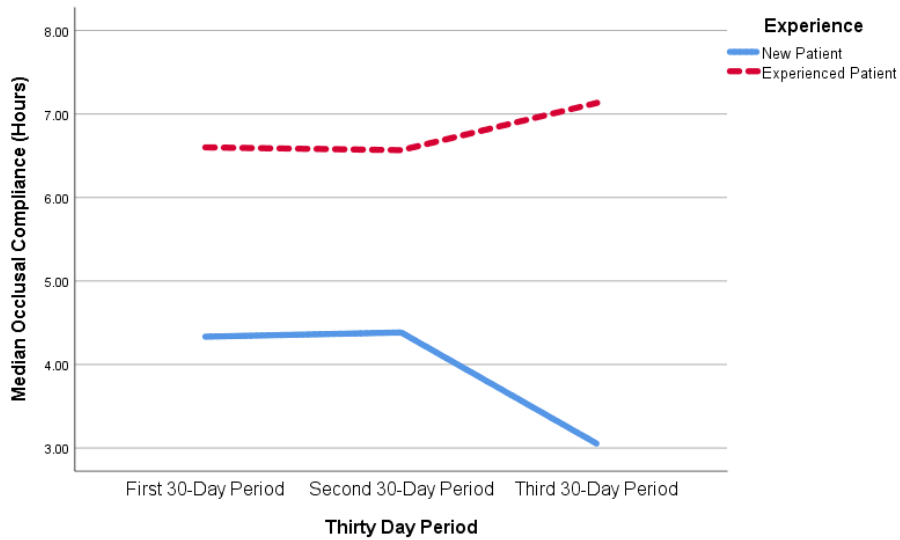
(c)

Figure 3.11 Box-and-whisker plots of occlusal appliance wear time based on experience for (a) the cumulative 90-day period and (b) for the individual first, second, and third months. In addition, (c) is a line graph of the median occlusal appliance wear times across all three periods for both experienced and new patients.

Overall tests of distributional shape provided no evidence that individual distributions deviated from normality. As detailed in Table 3.9. all distributions showed a slight degree of negative skewness (column S_k), ranging between -1.39 and 0.46. The reported levels of kurtosis indicated that all distributions had a degree of platykurtosis, ranging in values from -0.86 to 2.68. Overall, the tests of normality provided no evidence suggesting that any of the measured periods of occlusal device wear time were different to normality, as assessed via the Shapiro-Wilk's test of normality (Table 3.10).

Experience Level	Period	W	Df	Sig.
New users	First month	0.936	10	0.515
	Second month	0.884	10	0.144
	Third month	0.966	10	0.849
Experienced users	First month	0.922	13	0.270
	Second month	0.917	13	0.228
	Third month	0.872	13	0.056

Table 3.10.Results of the Shapiro-Wilk's test of normality, detailing the magnitude of the test statistic (W), degrees-of-freedom (Df) and significance (Sig.).

3.10 Descriptive Overview of Occlusal Device Wear Time Based on Gender and Age

In this subsection, an overview of the descriptive characteristics associated with occlusal device wear time based on gender is presented. In particular, graphical representations depicting occlusal appliance wear time across the entire 90-day period as well as the first, second, and third months of compliance for both genders are presented (Figure 3.12 (a) & (b)). From the boxplots, a heterogeneity between genders can be observed that limits their comparability, particularly since there were fewer males than females in the study, as can be observed in the distorted boxplots.

Box-and-whisker plot of occlusal appliance wear time across overall three months (90-days) by Sex

(a)

Box-and-whisker plot of occlusal appliance wear time for the first, second, and third months (30-days) by sex

(b)
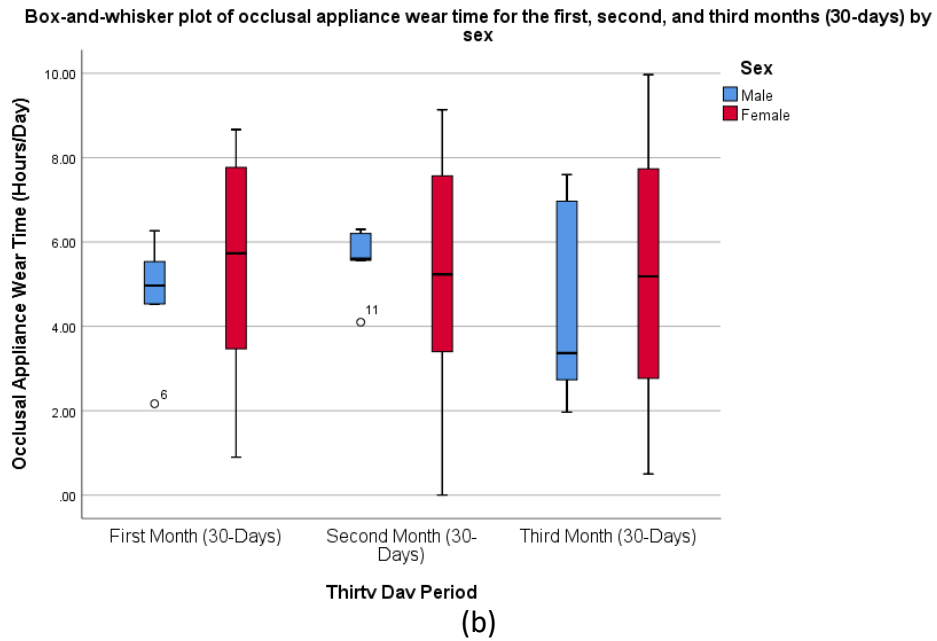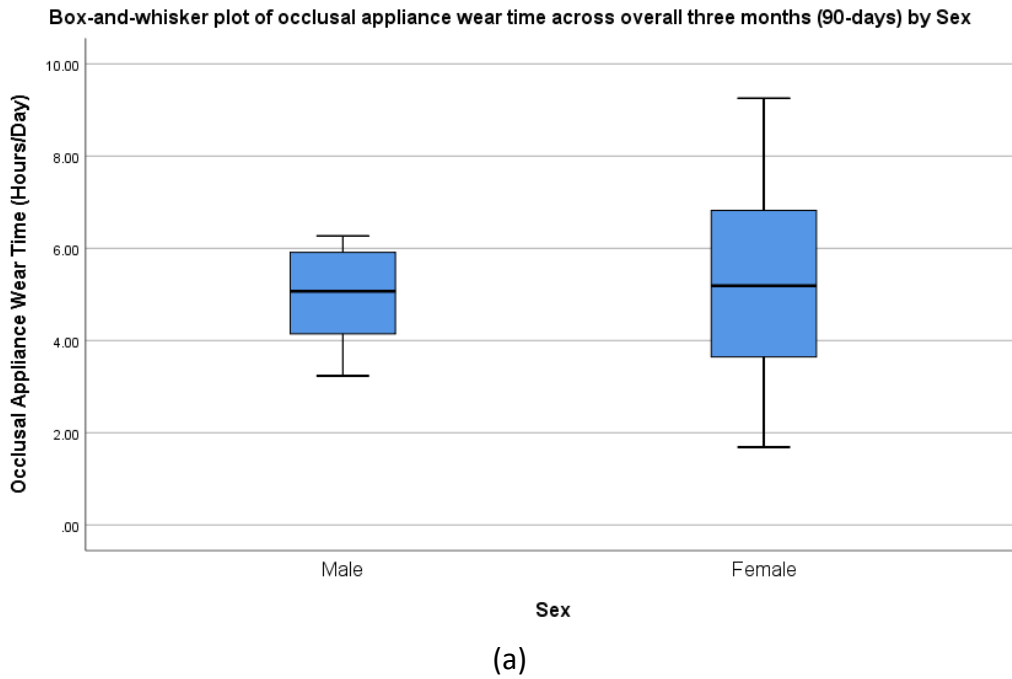
Figure 3.12. Box-and-whisker plots of occlusal appliance wear time distributions based on gender for (a) the overall 90-day period and (b) the first, second, and third months clustered based on gender.

An overview of the descriptive characteristics associated with occlusal device wear time based on age is presented. In particular, graphical representations depicting occlusal device wear time across the total 90-day period (Figure 3.13 [a]) as well as the first, second, and third months for both patients aged less and more than 46 years are shown in Figure 3.13 (b). There is heterogeneity between age groups, which can be seen in the boxplots.

Box-and-whisker plot of occlusal appliance wear time for overall three months (90-days) by age

(a)

Box-and-whisker plot of occlusal appliance wear time for the first, second, and third months (30-days) by age

(b)
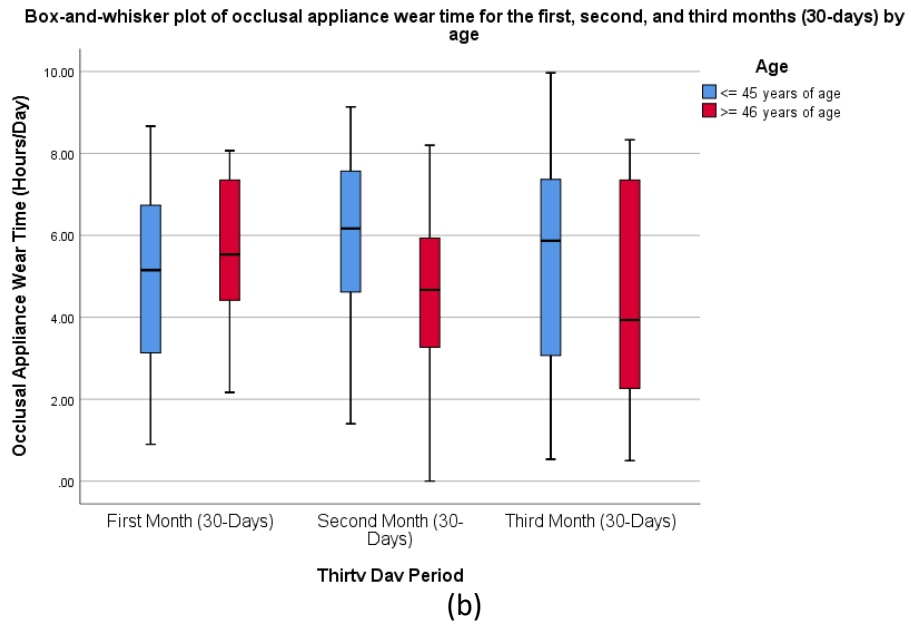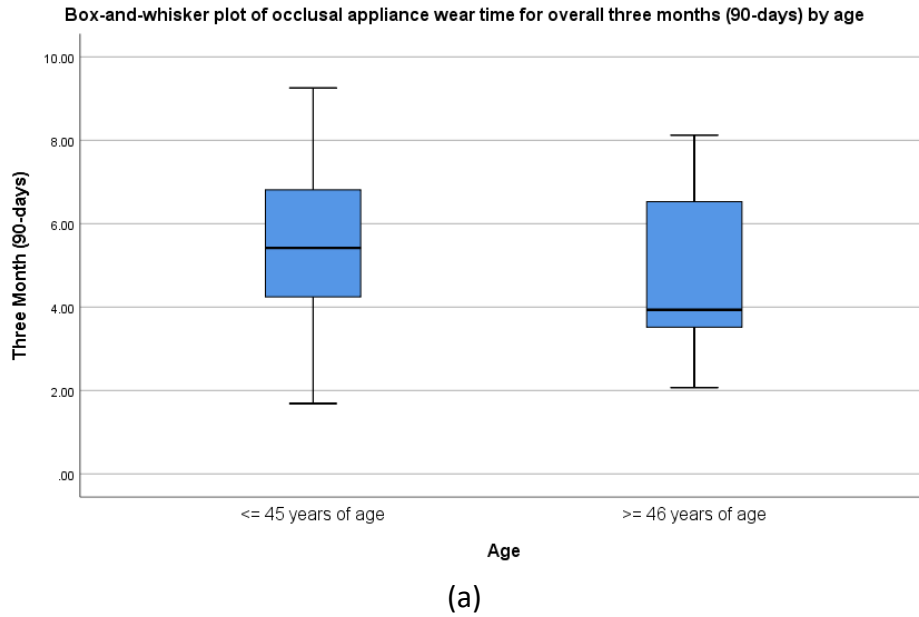
Figure 3.13 Box-and-whisker plots of occlusal appliance wear time distributions for (a) the overall 90-day period and (b) the first, second, and third month periods clustered based on age.

For gender and age, normality was assessed both statistically and visually (see Table 3.11 for statistics and Appendix 6 for visual representation through boxplots and histograms). Overall, there were issues with skew identified across the groups. In regards to kurtosis, despite both leptokurtic and playkurtic elements were present in both groups, for the most part, the kurtosis statistics were acceptable (Field, 2013). Table 3.11 shows that the Shapiro-Wilks test was not statistically significant across age and gender in terms for the total 90 days of wear ($p > .05$), which indicated that the normality assumption was not violated in either group.

	W	P	Kurtosis	Skew
Age				
≥ 46 years of age	0.93	0.39	-1.13	0.43
≤ 45 years of age	0.99	0.99	0.03	0.04
Gender				
Male	0.95	0.76	1.68	-1.30
Female	0.97	0.74	-0.79	-0.13

Table 3.11. Summary of study normality statistics for age and gender. If $p > .05$, then normality is assumed.

3.11 Occlusal Device Wear Time Differences Based on Gender

An analysis of the differences in median occlusal appliance wear time was undertaken to assess if there were differences between the male and female patients. The analysis was undertaken for each of the three months of occlusal wear time, with the average wear time for each month measured as an aggregate of the first month (30 days), second month (30

days), and third month (30 days) of wear. In addition, tests of difference between the median male and median female patient wear times for the full 90-day period were undertaken. Due to the small sample size (N = 23), non-parametric tests of difference were specifically undertaken.

Due to the small sample size, independent samples Mann-Whitney U test was undertaken to determine if median occlusal appliance wear time was different for males and females. The results of the Mann-Whitney U test indicated that there were no statistically significant differences in median occlusal appliance wear time during the first month for the males (M_d = 4.97) versus females (M_d = 5.73), U = 32.50, p = 0.363. Similarly, there was no statistically significant difference in median occlusal appliance wear time during the second month for the males (M_d = 5.60) versus the females (M_d = 5.23), U = 41.00, p = 0.801. In addition, the results of the Mann-Whitney U test indicated that there was also no statistically significant difference in median occlusal appliance wear time during the third month for the males (M_d = 3.37) versus the females (M_d = 5.18), U = 36.50, p = 0.538. Finally, a Mann-Whitney U test was performed for the cumulative three-month period, which indicated that there was no statistically significant difference in median occlusal appliance wear time for the males (M_d = 5.07) versus the females (M_d = 5.19), U = 41.00, p = 0.801. The results from all four comparisons are shown in Table 3.12.

Period	N	Gender	M	SD	M$_d$	25th	75th	U	Sig
First month	5	Male	4.69	1.55	4.97	3.35	5.90	32.50	.363
	18	Female	5.50	2.32	5.73	3.40	7.78		
Second month	5	Male	5.55	0.88	5.60	4.83	6.25	41.00	.801
	18	Female	5.22	2.64	5.23	3.33	7.73		
Third month	5	Males	4.53	3.37	3.37	2.35	7.28	36.50	.538
	18	Female	5.17	2.90	5.18	2.70	7.83		
Full 90-Day Period	5	Male	4.92	1.25	5.07	3.69	6.09	41.00	.801
	18	Female	5.30	2.25	5.19	3.58	7.04		

Table 3.12. Numerical descriptive statistics for average occlusal device wear time within a 30-day period for male and female patients (gender); featuring mean (M), standard deviation (SD), median (M$_d$), first (25th percentile) and third (75th percentile) quartile measures, the Mann-Whitney U statistic (U), and the actual significance of the test statistic (Sig).

3.12 Occlusal Device Wear Time Differences Based on Age

An analysis of the differences in median occlusal appliance wear time was undertaken to assess if there were differences in median wear times between patients <= 45 years of age and patients >= 46 years of age. The analysis was undertaken for each on three consecutive 30-day periods of occlusal appliance wear time, with average wear time for each 30-day period measured as an aggregate of the first, second, and third months of wear. In addition,

tests of differences between the <= 45 years of age and >= 46 years of age patients were performed for their median occlusal appliance wear times across the cumulative 90-day period. Due to small sample size (N=23) non-parametric tests of difference were undertaken.

Due to the small sample size, independent sample Mann-Whitney U tests were undertaken to determine if the median occlusal appliance wear times were different for the two age groups. The results of the Mann-Whitney U test indicated that there was no statistical significant difference in median occlusal appliance wear time during the first month between the <= 45 years of age patients (M_d = 5.15) and the >= 46 years of age patients (M_d = 5.53), U = 55.50, p = 0.525. Similarly, there was no statistically significant difference in median occlusal appliance wear time during the second month between the <= 45 years of age patients (M_d = 6.17) and the >= 46 years of age patients (M_d = 4.67), U = 40.00, p = 0.118. In addition, the results of the Mann-Whitney U test indicated that there was no statistically significant difference in median occlusal appliance wear time during the third month between the <= 45 years of age patients (M_d = 5.87) and the >= 46 years of age patients (M_d = 3.93), U = 52.00, p = 0.449. Finally, a Mann-Whitney U test was performed for the cumulative 90-day period, which indicated there was no statistically significant difference in median occlusal appliance wear time between the <= 45 years of age patients (M_d = 5.42) and >= 46 years of age patients (M_d = 3.93) participants, U = 51.00, p = 0.379. The results from all four comparisons are shown in Table 3.13.

Period	Age	N	M	SD	M$_d$	25th	75th	U	Sig
First month	<= 45 years of age	12	5.05	2.39	5.15	2.97	6.80	55.50	.525
	>= 46 years of age	11	5.62	1.98	5.53	3.70	7.77		
Second month	<= 45 years of age	12	5.99	2.18	6.17	4.36	7.98	40.00	.118
	>= 46 years of age	11	4.54	2.40	4.67	3.13	6.30		
Third month	<= 45 years of age	12	5.45	2.79	5.87	2.92	7.84	52.00	.449
	>= 46 years of age	11	4.58	2.85	3.93	2.03	7.73		
Full 90-Day Period	<= 45 years of age	12	5.50	2.14	5.42	4.19	6.82	51.00	.379
	>= 46 years of age	11	4.91	2.01	3.93	3.39	6.79		

Table 3.13. Numerical descriptive statistics of average occlusal appliance wear time within a 30-day period for the <= 45 years of age patients and >= 46 years of age patient groups; featuring mean (M), standard deviation (SD), median (Md), and the first (25th percentile) and third (75th percentile) quartile measures.

3.13 Occlusal Device Wear Time Differences Based on Experience

An analysis of the differences in median occlusal appliance wear time between new patients with no prior experience of wearing an occlusal device and experienced patients who had previously used an occlusal device was undertaken. This analysis was conducted for each of

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the three consecutive months, with the average wear time for each month measured as an aggregate of the first, second, and third months of wear.

In addition, tests of differences between the new and experienced patients were performed based on their median occlusal appliance wear times for the cumulative 90-day period. Due to the small sample size (N = 23), non-parametric tests of difference were undertaken.

Due to the small sample size, an independent sample Mann-Whitney U test was undertaken to determine if the median occlusal appliance wear time was different between new patients and the experienced occlusal appliance wear time users. The results of the Mann-Whitney U test indicated that there was no statistically significant difference in median occlusal appliance wear time during the first month between the new patients (M_d = 4.33) and experienced patients (M_d = 6.60), U = 37.00, p = 0.088. However, there was a statistically significant difference in median occlusal appliance wear time during the second month between the new patients (M_d = 4.38) and experienced patients (M_d = 6.57), U = 31.00, p = 0.036, with the experienced patients exhibiting greater median compliance durations in comparison to their new counterparts. Specifically, the experienced patients used the occlusal device for approximately two hours longer than the new users. Similarly, the results of the Mann-Whitney U test indicated that there was a statistically significant difference in median occlusal appliance wear time during the third month between the new patients (M_d = 3.05) and the experienced patients (M_d = 7.13), U = 20.00, p = 0.004. The experienced patients exhibited greater median compliance durations in comparison to their new counterparts, using an occlusal device for approximately four hours longer.

Finally, a Mann-Whitney U test was performed for the cumulative 90-day period, which indicated there was a statistically significant difference in median occlusal appliance wear time between the new patients (M_d = 4.04) and the experienced patients (M_d = 6.79), U = 25.00, p = 0.012. The experienced patients exhibited greater median compliance durations in comparison to their new counterparts, using an occlusal device for approximately 2.5 hours longer. The results from all four comparisons are shown in Table 3.14.

Period	Experience Level	N	M	SD	M_d	25th	75th	U	Sig
First month	New	10	4.46	1.97	4.33	2.64	6.04	37.00	.088
	Experienced	13	5.98	2.15	6.60	4.83	7.80		
Second month	New	10	4.24	1.83	4.38	3.41	5.71	31.00	.036
	Experienced	13	6.10	2.45	6.57	4.37	8.30		
Third month	New	10	3.28	2.07	3.05	1.61	5.03	20.00	.004
	Experienced	13	6.38	2.54	7.13	3.52	8.22		
Full 90-Day Period	New	10	3.99	1.06	4.04	3.13	5.01	25.00	.012
	Experienced	13	6.16	2.16	6.79	4.52	7.91		

Table 3.14. Numerical descriptive statistics of average occlusal appliance wear within each 30-day period for new patients with no prior experience wearing an occlusal device and experienced patients; featuring mean (M), standard deviation (SD), median (Md), and the first (25th percentile) and third (75th percentile) quartile measures.

3.14 Differences in Occlusal Device Wear Time Across Repeated Measures

An analysis of the changes in the repeated measures for patients new to wearing an occlusal device as well as those with experience wearing an occlusal device was undertaken. In particular, for each group, an assessment of the changes between the median 30-day periods of occlusal appliance wear time was undertaken.

The results of the nonparametric repeated measures Friedman test for the new wearers indicated there was no statistically significant change in behaviour between the median first month period (M_d = 4.33) compared to the median second month (M_d = 4.38) or median third month periods (M_d = 3.05), $\chi^2(2) = 6.00$, p = 0.150. With that said, the median third month occlusal device wear time durations were approximately one hour less than those of the previous two months, which, in particular, suggested an umbrella effect across the measuring periods (increasing from the first to the second months and decreasing from the second to third months), as depicted in Figure 3.14.

The results of the nonparametric repeated measures Friedman test for the experienced wearers indicated there was a statistically significant change in behaviour between the first month (M_d = 6.60) and second (M_d = 6.57) and third months (M_d = 7.13), $\chi^2(2) = 6.00$, p = 0.050. Specifically, the third month exhibited median wear durations of 0.5 hours longer than the previous two months, which, in particular, suggested an umbrella effect across the measuring periods (decreasing from the first to second months and increasing from the second to third months) as depicted in Figure 3.15.
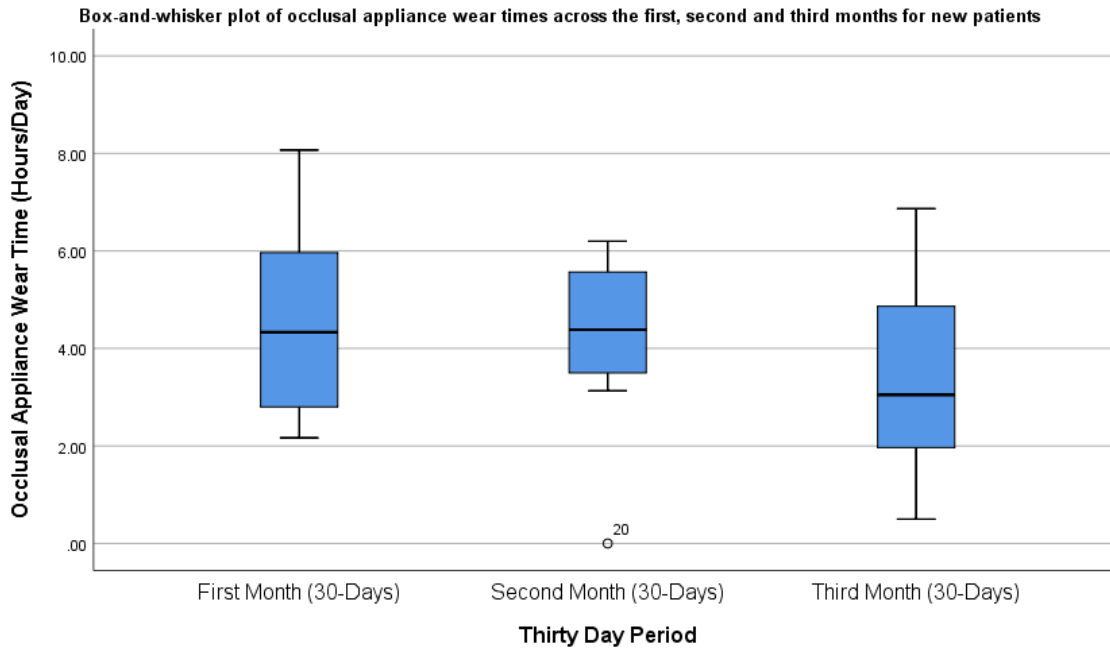
Figure 3.14. Box-and-whisker plots depicting changes in median wear durations across the three consecutive months for new occlusal device users.
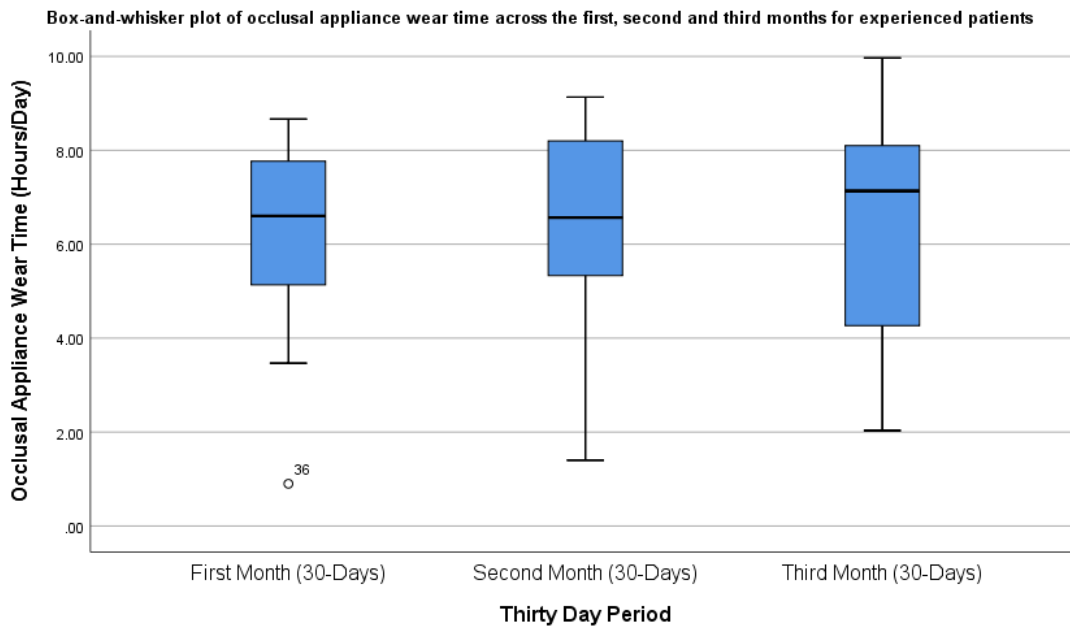
Figure 3.15 Box-and-whisker plots depicting changes in median wear durations across the three consecutive months for experienced occlusal device users.

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3.15 Interaction Effects of Experience and Gender on Cumulative 90-Day Occlusal Device

Wear Time

A two-way non-parametric Scheirer-Ray-Hare test was conducted which examined the effects of experience and gender on the median 90-day device wear times. The main effect of experience was statistically significant (H = 6.15, p = 0.013), while the main effect of gender was not statistically significant (H = 0.02, p = 0.889). There was no statistically significant interaction between the effects of occlusal appliance wear time experience and gender (H = 1.15, p = 0.997). The results are presented in Table 3.15.

Measure	Df	Sum Sq	H	Sig
Experience	1	283.08	6.15	0.013
Gender	1	0.90	0.02	0.889
Experience * Gender	1	000	0.00	0.997
Residuals	19	728.02		

Table 3.15.Results of two-way Scheirer-Ray-Hare non-parametric test of the effect of experience and gender on average 90-day occlusal appliance wear times.

3.16 Interaction Effects for Experience and Age for Average 90-Day Occlusal Device Wear Times

A two-way nonparametric Scheirer-Ray-Hare test was conducted which examined the effect of experience and age on the median 90-day occlusal device wear times. The main effect of experience was statistically significant (H = 6.15, p = 0.013), while the main effect of gender was not statistically significant (H = 0.69, p = 0.407). There was no statistically significant interaction between the effects of occlusal appliance wear time experience and gender (H = 0.07, p = 0.792). The results are presented in Table 3.16.

Measure	Df	Sum Sq	H	Sig
Experience	1	283.08	6.15	0.013
Age	1	31.62	0.69	0.407
Experience * Age	1	3.21	0.07	0.792
Residuals	19	694.09		

Table 3.16. Results of two-way Scheirer-Ray-Hare nonparametric test of the effect of experience and age on average 90-day occlusal appliance wear times.

3.17 Wear Patterns of Experienced Wearers Vs. New Wearers

There were two distinct patterns of wear identified between the experienced and new participants. A large variability in wear pattern behaviour was observed over the observational period within the two groups, as demonstrated by the representative examples in Figures 3.16 and 3.17. These microelectronic wear-time graphs show the characteristic wear-time of experienced wearer participants who wore their appliances regularly throughout the observational period (Figures 3.16 (a), (b) and (c)). On the other hand, representative samples of fluctuant wear time with frequent zero-hour wear time graphs demonstrated for new wearer group participants are shown in (Figure 3.17 (a), (b) and (c)).
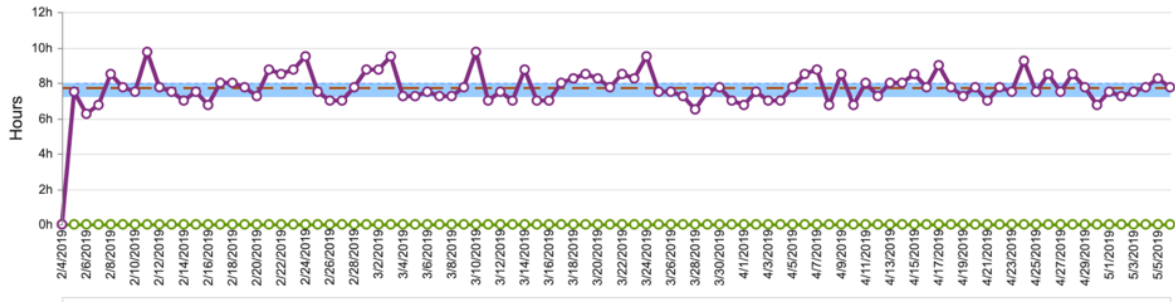
(a)
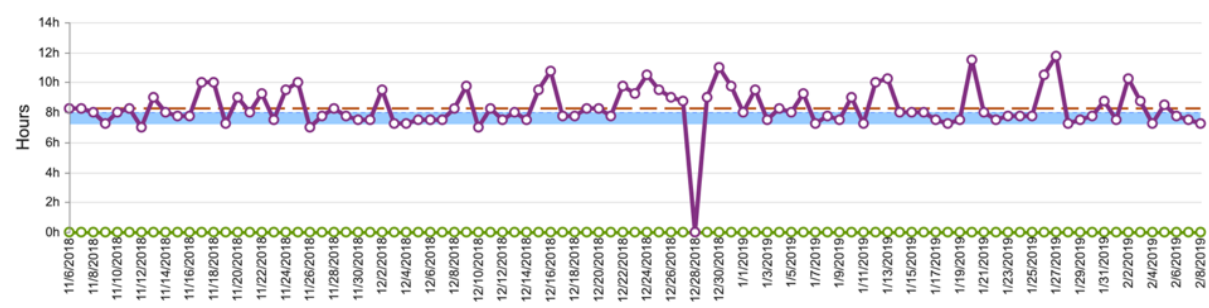
(b)
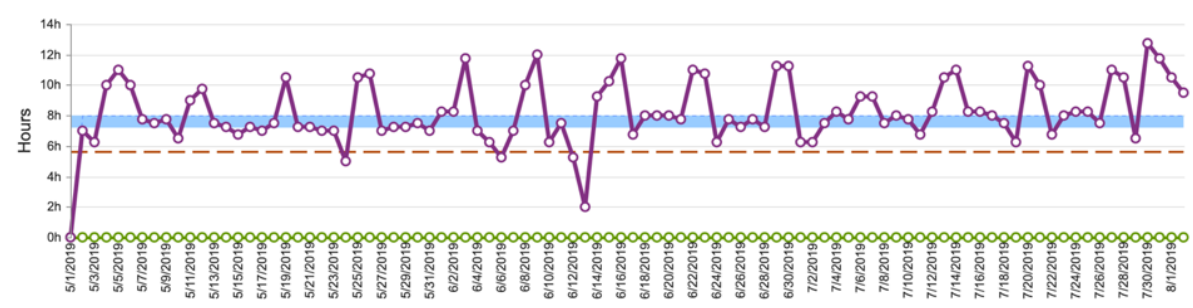
(C)

Figure 3.16 Wear time representative samples for the experienced group demonstrating regular complaint characteristic patterns. Figures (a) and (b) show that patients wore their devices almost every day, with small discrepancies in wear time between different days. (c) shows a regular wear pattern with a relatively large discrepancy in wear times between different days.
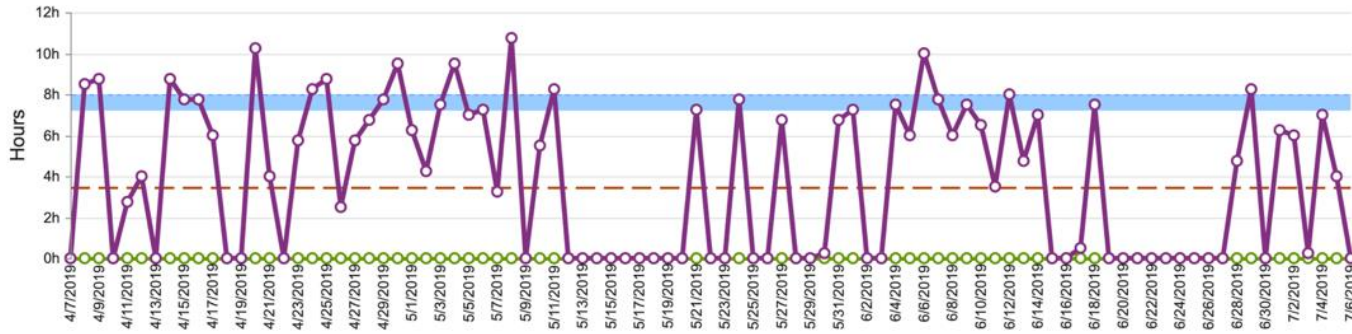
(a)
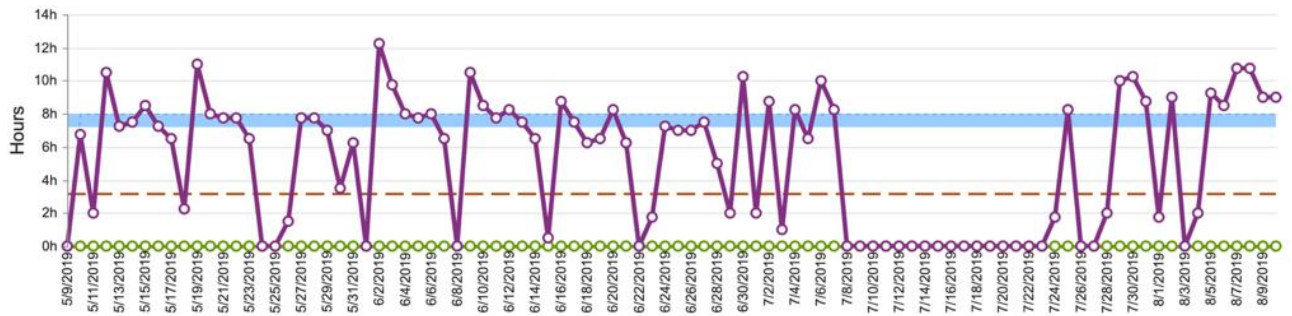
(b)
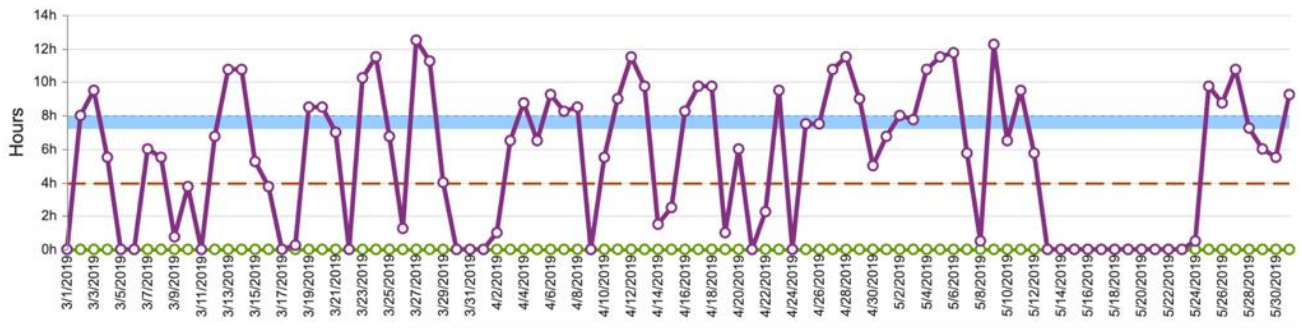
(c)

Figure 3.17 Wear time representative samples for the new user group demonstrating fluctuating and poor compliance patterns. Figures (a), (b), and (c) show similar patterns, as patients missed a large number of nights (sometimes consecutively), with large discrepancies in wear time between days.

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Chapter 4. Discussion and Future Research

This study was a prospective, clinical trial that objectively measured patient compliance with occlusal device wear for the management of sleep bruxism using a commercially available microsensor incorporated into the occlusal devices. This sensor has previously been used as part of routine orthodontic practise for monitoring removal appliance compliance, providing precise daily wear times (Schäfer *et al.*, 2014).

4.1 Self-reported Sleep Bruxism

Eighty seven percent of participants who accepted the invitation to participate and had self-reported sleep bruxism were included in the study. All those participants had been previously identified by their treating clinician as having clinically significant levels of bruxism. There was a higher percentage of self-reporting sleep bruxism (93%) of new device users compared to experienced users (79%). The reason for this high percentage may have been the recruitment protocol, which focused primarily on the prescription of occlusal devices for the management of sleep bruxism for new users, since the most experienced users had already received their device upon completion of their prosthodontic treatment, which may have been to protect new restorations as well as managing bruxism. In the general population, the prevalence of self-reported active sleep bruxism was reported to be 14% (Winocur *et al.*, 2011). The high prevalence (approximately 60 per cent) of self-reported sleep bruxism has previously been reported for TMD patients (Blanco Aguilera *et al.,* 2014). Based on the diagnostic method and

population sample, the prevalence of sleep bruxism may differ significantly as less

prevalence was reported using polysomnography as a diagnostic tool than found in the

general population sample (approximately 8%) (Lobbezoo et al., 2013). Different

diagnostic methods can be used in the diagnosis of sleep bruxism. Polysomnography

recording is the 'gold standard' for the diagnosis of sleep bruxism, However, due to high

cost and lack of resources availability, alternative methods including questionnaires and

clinical examination are being used more frequently (Lobbezoo et al., 2013). Tooth surface

loss is an unreliable diagnostic tool as it is a multifactorial process influenced by many

factors and not significantly attributed to bruxism activity (Pergamalian et al., 2003).

Although their accuracy and reliability has been questioned, bruxism questionnaires can

be used as proxies to identify possible bruxers (Lobbezoo et al., 2018). Self-reported sleep

bruxism as a screening tool of "possible" sleep bruxism is considered the lowest-rated

diagnostic tool according to the International Consensus Agreement (Lobbezoo et al.,

2013a). Self-reported sleep bruxism failed to significantly predict the presence or absence

of either moderate or severe sleep bruxism as compared to PSG, for both TMD orofacial

pain patients and controls (Raphael at al., 2015). Authors reported the high rates of false

negatives based on self-report, as many individuals who demonstrate high levels of Sleep

Bruxism assessed by PSG does not self-report sleep bruxism .

In this study, possible sleep bruxism was identified by a questionnaire based on events

during the past six months according to the diagnostic criteria of the AASM Diagnostic and

Coding Manual (Diagnostic and Manual, 2005). This questionnaire was adapted from the widely accepted questionnaires of Lavigne and Pintado and colleagues (Lavigne, 2005, Pintado et al., 1997). This self-reported questionnaire was used in this study to identify subjects with sleep bruxism. The included participants responded positively to at least one sleep bruxism self-awareness question (question 1 and ⁄ or 2), in addition to at least reporting one awakening, symptom as listed in Question 3. Awakening symptoms reporting are indicative of current active sleep bruxism (Scarlett et al., 2020).

4.2 The Importance of Occlusal Devices in Sleep Bruxism Management

In this study, heat-cured acrylic resin maxillary occlusal devices were used in the management of sleep bruxism for a patient cohort with possible sleep bruxism (only self-reported). The wearing of occlusal devices is an essential component of the management of tooth grinding (bruxism). Evidence has emerged over the last ten years that bruxism is a major cause of dental prosthesis failure. In the absence of a definitive treatment for sleep bruxism, occlusal devices are the most commonly prescribed method for its management in dentistry, acting to reduce bruxism activity or prevent its deleterious effects on the teeth, restorations and the masticatory system. A review of several fixed prostheses (190 single ceramo-metal crowns and 276 fixed partial prostheses) found that bruxism was a risk indicator for ceramo-metal restoration damage after ten years, with an odd ratios of 3.065 (95% CI 1.063 - 8.832) and 2.554 (95% CI 1.307 - 4.992) for single-crown and fixed partial prosthesis, respectively (Reitemeier et al., 2013). In a comparison of 98 patients

with bruxism and the same number of controls, it was found that those with bruxism

were:

1. Nearly three times more likely to have a dental implant fail,

2. Twelve times more likely to have a portion of their restoration fracture,

3. Eight times more likely to have the restoration come loose, and

4. 41 times more likely to have a retaining screw fracture after restoration

   (Chrcanovic et al., 2017).

These results also agreed with a meta-analysis of restorations completed in 2016,

highlighting the importance of identifying individuals who grind their teeth and their

effective management after treatment to avoid future complications with dental

restorations (Zhou et al., 2016). Occlusal devices are intended to prevent further tooth

wear and protect dental restorations. Furthermore, the consensus from anecdotal reports

is that occlusal devices play a positive role in protecting dental hard tissues (Dao and

Lavigne, 1998). The appliances reduce the effect of bruxism by placing a relatively soft

acrylic appliance between the teeth, which leads to the wear of the appliance rather than

the teeth. There has been consistent evidence regarding the efficiency of occlusal devices

for sleep bruxism management, yet the presented evidence was insufficient to support

their use in the long-term reduction of sleep bruxism activity as this reduction found to be

transit and activity returned to pre-treatment levels (Jokubauskas et al., 2018). However,

it was unknown what the compliance was in wearing the occlusal devices among patients

as this has not been reported previously in an objective manner.

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4.3 Occlusal Device Design

Full-coverage flat plane maxillary heat-cured acrylic occlusal devices with anterior discluding ramps were used in this study for all newly fabricated devices, as is standard practice in the Dublin Dental University Hospital. Simultaneous bilateral posterior occlusal contacts and anterior guidance with posterior disclusion were achieved for all occlusal devices. These occlusal devices were based on conventional occlusal design to provide optimal force distribution and guidance (McHorris, 1985, Aubrey, 1978). Specifically, during the arc of closure, the condyles were physiologically seated in their respective fossae in centric relation (centric maxillomandibular relation), and all teeth should have equal and simultaneous contact with the occlusal device. Moreover, during all excursive movements, the anterior teeth should separate the posterior teeth from the appliance smoothly. The occlusal forces should be distributed through the maximum number of teeth by using multiple, even, bilateral posterior teeth contact, with the anterior teeth in lighter contact. Uneven posterior contact may result in an interference in the arc of closure, which may concentrate force on a few teeth, causing discomfort for the patient possibly stimulating a protective neuromuscular response (Bakke and Møller, 1980). EMG recording studies of occlusal device design have demonstrated decreased masseter and anterior temporalis muscle activity during laterotrusion when clenching on an anterior ramp (Manns et al., 1987; Fitins and Sheikholeslam, 1993). The rationale for anterior guidance with posterior disclusion in occlusal device design is based on a reduction in elevator muscle activity, the favourable force distribution of the long roots (canine teeth),

which placed the TMJ in a Class III lever system, resulting in decreased force (Solow, 2013).

Discomfort due to device size was reported by four subjects in the current study and considered the main reason for discontinuing treatment. Two subjects suggested the removal of their anterior ramp as they felt it made the device too bulky at the front; one wondered if it was possible to remake the device with a thinner and lighter material; and one asked to replace the device with a softer device. For obstructive sleep apnoea patients, it has been documented that oral appliances with more comfortable designs, such as titrateable custom-made appliances lead to improved compliance (Lettieri et al., 2011).

4.4 Compliance with Occlusal Device Use

A significant number of subjects (9) either discontinued or failed to wear their devices due to adverse effects and withdrew from the study. This was particularly evident in the new wearer group, as was anticipated in that novice users might find it more difficult to adapt to the appliance. The most frequently reported adverse effects were discomfort due to device size (four subjects), sleep disturbance and dental pain (three subjects), and dry mouth (two subjects).

All subjects had been informed that the device fundamentally protected their teeth and might reduce sleep bruxism activity in the short term. One subject noticed little or no effect on her sleep bruxism activity and thus discontinued her wear.

No objective evidence is available on compliance with occlusal device wear so parallels were taken for the study of mandibular advancements appliances in the treatment of sleep apnoea and removable orthodontic appliances. Failure to comply with oral appliance treatment was reported for patients with obstructive sleep apnoea in a large survey study (de Almeida et al., 2005). Of the 251 sleep apnoea patients who answered the survey, 64.1% were still wearing their oral appliance. Discomfort was the most frequently reported reason for discontinued wear (44.4%) in addition to patients seeing little or no changes in their symptoms (33.6%), with some patients switching to continuous positive airway pressure CPAP nasal devices (23.3%). Furthermore, those who continued to wear their appliance reported more frequent and severe adverse effects such as dry mouth and tooth and/or jaw discomfort.

Previous obstructive sleep apnoea studies have observed that patients who used oral appliances for the first time reported several adverse effects as well as discomfort and tended to cease their use earlier than experienced users. It was found that the side effects reduced over time, based on their severity, after an adaptation period (O'Sullivan et al., 1995). The authors reported mild jaw discomfort at the start of treatment in 65% of the subjects. However, after a three-week adaptation period, only 21% of participants

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reported the jaw discomfort. This may explain why there was higher compliance among experienced occlusal device users than new users.

Among the 17 female participants in the new wearer group who received occlusal devices, eight withdrew due to non-compliance and six (35%) reported adverse effects. On the other hand, of the nine males in the new wearer group, only three (33%) reported side effects, including dry mouth and discomfort, which lead to their discontinuing treatment. Gender-associated side effects were reported for sleep apnoea patients using oral appliances (de Almeida, Lowe et al. 2005): 46.8% of women exhibited adverse effects and exhibited a greater tendency to abandon therapy (compared to 32.8% of males) (de Almeida et al., 2005). It should be noted that a large number of new wearers who received occlusal devices in this study were female (17/26). In the present study, all required adjustments were performed during follow-up visits to ensure patient comfort and address any issues. In spite of frequent recalls, some patients still discontinued treatment. Further investigation is required to evaluate patient difficulties adapting and adhering to the wear of occlusal devices.

In this study, one patient discontinued occlusal appliance wear, as she noticed no or little effect on her sleep bruxism activity. This was consistent with similar findings in sleep medicine, as patients who reported greater improvements in their symptoms, such as snoring, upon using oral appliances exhibited higher objective compliance rates than patients who showed less improvement (Dieltjens et al., 2015). Some studies have

demonstrated reductions in sleep bruxism activity through occlusal devices (Sadat Madani et al., 2013); yet, these reductions were found to be transient, with sleep bruxism activity returning to pre-treatment levels. Thus, there is currently not enough evidence in the literature to support long-term reductions in bruxism activity through the use of occlusal devices (Guaita and Högl, 2016). The primary role of an occlusal device is in the prevention of tooth surface loss and to protect restorations (Jokubauskas et al., 2018).

Furthermore, two patients were excluded due to non-compliance, as the objective sensor measurements indicated they had not worn their device for the entire observational period. This poses significant challenges for dental practitioners who prescribe occlusal devices, since patient reporting may not always be reliable. This problem with over-reporting has been documented for removable appliance use in patients undergoing orthodontic therapy, with a mean of five to six hours of exaggeration of daily wear time being found, despite patients being aware that their wear was being monitored (Schott et al., 2017). This may mean that those not being monitored may overestimate their wear times to an even greater extent.

Other reasons found in this study for discontinuing treatment included patient hospitalisation after a road traffic accident (one patient) and employment changes resulting in increased travel commitments (one patient). These were unforeseen and both were from the experienced user group, being the only two patients from that group excluded for non-compliance.

For the total cohort in this study, the median daily wear time was 5.5 hours/night for the 90-night observational period. All measurement periods had medians ranging between 4.87 and 5.57 hours, with the 90-day median equal to that of the first month (30 days). The third month (30 days) had a median occlusal appliance wear time of approximately 4.87 hours. There was a slight drop in compliance across the three periods; however, this decrease was relatively shallow and represented a very small effect.

No optimal occlusal device wear times have been proposed in the published dental literature, and this study was the first study to provide objective daily occlusal device wear times for the management of sleep bruxism. Further studies concerning optimal occlusal wear times would be beneficial to validate the findings of this study.

Patient adherence with hard acrylic occlusal devices was previously reported in a questionnaire-based study in both general and specialist dental practices in Sweden (Lindfors et al., 2011a). Patients who responded to the questionnaire after 1.5-2 years of wear and treated at a general dental practice reported 74% adherence versus the 54% of those treated in a specialist practice. Issues related to comfort were found to be the main reasons for not using the occlusal appliance and included:

1. Sleeping difficulties,
2. Feeling nauseated,
3. Having a dry mouth,

4. The presence of ongoing dental pain and the appliance being too tight against the teeth,

5. The device being too big, and

6. No treatment effect observed or the symptoms becoming worse.

The authors concluded that occlusal appliance adherence was associated with both perceived good treatment effects and long-term symptom management for symptoms such as tension-type headaches and bruxism; even though symptoms might fluctuate throughout the treatment period.

Further data provided by Inglehart and co-workers found that 75% of patients were continuing to use the device after five years (Inglehart et al., 2014b). It is important to note that these survey studies were based solely on patient responses, which may have included a degree of exaggeration, as previously mentioned.

The objective recording of oral appliance wear compliance during sleep was reported for the first time by Lowe and co-workers with obstructive sleep apnoea (OSA) patients, for which they used appliances with temperature sensors embedded in titrateable anterior mandibular repositioner appliances (Lowe et al., 2000). The authors reported 6.9 h/night use with a range of 5.6 to 7.5 h/night over a two-week time span in eight OSA patients. Objective obstructive sleep apnoea patient compliance was also measured using a TheraMon® microsensor incorporated into the mandibular advancement appliances (Vanderveken et al., 2013). They reported a median compliance of 6.2 and 6.4 hours per

night at one-month and three-month follow ups, respectively. No safety issues arose with

TheraMon® use, and no adverse effects were reported, with only one out of 51

microsensors having a technical issue, which was consistent with this study (Vanderveken

et al., 2013).

Compliance with occlusal device wear is essential to prevent further tooth wear and

protect any restorations that have been placed. In order to obtain the maximum

preventive and therapeutic effects of occlusal devices, patients should demonstrate

acceptable levels of compliance with occlusal device wear. To date, there has been no

data available concerning an effective compliance level for patients using occlusal devices

for the management of sleep bruxism. Kribbs and co-workers defined effective

compliance as a patient wearing the oral appliance for at least four hours a night for at

least 70% of the days of the week (Kribbs et al., 1993). However, this accepted four-hour

threshold is arbitrary and not necessarily effective for all patients. For mandibular

advancement devices there is higher rate of compliance as the patient were aware of the

therapeutic effectiveness of the appliance (de Almeida, 2011).

Furthermore, a large multicentre CPAP-based study by Pepin and co-workers proposed

more restrictive criteria for effective CPAP therapeutic use. The authors reported that

adequate therapeutic effectiveness was achieved when patients used the machine for

more than five nights per week and for more than four hours a night (Pepin et al., 1999).

According to the American National Sleep Foundation's recommendations for healthy individuals, the optimal sleep time is between seven and nine hours for young adults (18-25 years) and adults (26-65 years), and seven to eight hours of sleep for older adults (≥ 65 years) (Hirshkowitz et al., 2015). In this study, all patients were asked to wear the occlusal device each night during sleep; yet, the total median wear time was 5.5 hours/night for the 90-night observational period, which is less than the optimal sleep hours for healthy adults. A large cross-sectional study (N = 1533) of healthy older Irish adults (aged 50 years and more) objectively measured sleep time using accelerometers (Scarlett et al., 2020). An accelerometer is a device that resembles a digital wristwatch with highly sensitive sensors to measure gross motor activity and analyse it to identify sleep time. The authors reported 7.7 hours mean total sleep time for this population, which was within the previously mentioned sleep guidelines.

The reasons behind relatively low compliance with full night wear are unclear; however, they may stem from the impact of wearing the device, including discomfort during patient adaptation, particularly for new users. Age may also have an impact on occlusal wear time, as the average age for all patients in this study was 47.8 years, and, as age increases, the duration of sleep has been reported to decrease. Finally, the cohort in this study was not restricted to healthy individuals; therefore, the optimal sleep hour recommendations might not have applied.

Suboptimal compliance with removable orthodontic device wear is well documented. A recent systematic review reported that the objectively measured wear time was considerably lower than the prescribed wear time among all appliance types, with a mean discrepancy of 5.8 hours per day (Al-Moghrabi et al., 2017). There were eleven studies included, predominantly comprising adolescents (ages varying between 7 and 22 years old) who were observed for up to six months. Furthermore, microelectronic wear-time documentation for orthodontics patients using the TheraMon® system found that the median daily wear time was only 9.7 hours/day, significantly less than the 15 hours/day prescribed (Schäfer et al., 2014). This agrees with previous studies, which found similar discrepancies between prescribed wear time and objective measured time (Tsomos et al., 2013; Pauls et al., 2013). The reasons for such suboptimal compliance are not fully understood but are thought to stem from device effects, including discomfort, social effects like embarrassment, and technical issues associated with device use.

In this study, all patients were aware that their wear time was being recorded, which may have positively impacted their adherence, particularly for the experienced users who showed a statistically significant increase in median wear time over the three months observation period. Similar findings have been reported in orthodontic compliance studies (Ackerman and Thornton, 2011). Those authors reported significantly increased wear times for patients aware of wear-time recordings compared to those who were unaware. However, this was not supported by findings from another study, which reported no significant differences between the study group (with sensor) and control group (Pauls *et*

al., 2013). It was proposed that this may have been a result of patient education and motivation, which was performed equally in both groups before the start of treatment. Furthermore, when patients are unaware their wear time is being monitored (study group), they tended to over-report wear time by approximately one-third. Well-designed clinical studies are required to evaluate the effect of objectively monitoring patient awareness on their compliance with occlusal device treatment.

4.5 Effect of Age and Gender on Patient Compliance

Several factors may have a bearing on compliance levels, among which are age and gender. There was a slight decline in median wear time for the ≥ 46 years of age group from the first month (5.5 hour/night) to the third month (3.93 hour/night), a pattern not seen in the ≤ 45 years of age group. Furthermore, for the cumulative 90 days, there was greater median wear time demonstrated in the ≤ 45 years of age (5.42 hour/night) than the >= 46 years of age patients (3.93 hour/night). However, these differences were small, and no statistically significant difference was found. The reason for the relatively low compliance of the older group was unclear. Associations between sleep bruxism and age was demonstrated in a cross-sectional study of 1,930 individuals (Kato et al., 2012). The authors reported a low prevalence of sleep bruxism among participants older than 60 years of age. In this study, the mean age in the >= 46 years of age group was 59 years, so it may be possible that this group wore their devices for less time, as they were less symptomatic. A long-term follow up of patients wearing oral appliances for the management of sleep apnoea found that, after four years of using oral appliances, younger subject compliance was significantly higher than that of older subjects (age: 50.6

± 11.9 versus 56.1 ± 9.9). That study was based on patient reports alone (Saglam-Aydinatay and Taner, 2018). Furthermore, lower oral appliance adherence among older adults (aged ≥65) with obstructive sleep apnoea was also reported by Carballo and co-workers (Carballo et al., 2016). In contrast, no association between age and patient oral appliance adherence was reported by Dieltjens and colleagues (Dieltjens et al., 2013).

Associations between patient age and compliance levels have been reported for orthodontic patients (ages between 7 and 22 years) in the previously mentioned systematic review and meta-analysis (Al-Moghrabi et al., 2017). There were five studies out of eleven that demonstrated longer wear for younger participants compared to older participants. However, no association between age and patient compliance was reported in the two studies. The main reasons for the lower compliance among the older adolescents were due to social effects, such as embarrassment, which probably did not apply to the adult patients who only wore the appliances at night. Further clinical studies with large sample sizes are required to further understand the relationship between age and occlusal appliance wear time.

This study found no statistically significant difference in median occlusal appliance wear time for male (5.07 hour/night) and female (5.19 hour/night) participants. Despite this, the females did exhibit slightly higher median hours wear of the occlusal device over the observation period.

The impact of mandibular advancement device wear on the oral health-related quality of life (OHRQoL) of 233 patients was investigated (Inglehart et al., 2014a). The authors reported that both patient gender and age did not affect the occlusal device wear-related OHRQoL responses. It was found that women who received mandibular advancement therapy for treatment of sleep apnoea were more likely to predict successful treatment defined as an apnoea-hypopnea index (supine and lateral positions) of < 10 with an odds ratio of 2.5 (Marklund et al., 2004).

Some orthodontic studies have found that females were more compliant (Schäfer et al., 2015; Sahm et al., 1990); however this was not corroborated in a study by Cureton and co-workers who reported no differences in wear time between males and females (Cureton et al., 1993). A multi-centre study investigating micro-electronically recorded wear-time of 141 orthodontic patients (53 females and 88 males) treated with removable appliances over a period of three months found that female participants wore their removable devices 1.3 hours/day more than male participants (10.6 and 9.3 hours/day respectively) (Schäfer et al., 2014). Further research with larger sample sizes and equal distributions of males and females is required to further evaluate compliance levels.

4.6 Effect of Patient Experience on Compliance

There was a statistically significant difference in median occlusal appliance wear time over the second and third months for the new patients (4.38 h/night and 3.05 h/night,

respectively) compared to the experienced patients (6.57 h/night and 7.13 h/night). The

overall 90-day period indicated that there was a statistically significant difference in

median occlusal appliance wear time for the new patients (4.04 h/night) compared to the

experienced patients (6.79 h/night). Experienced wearers used the occlusal device for

longer periods than the new wearers: approximately two hours, four hours, and 2.5 hours

for the second, third, and cumulative three-month periods, respectively. Apart from the

first month, new wearers demonstrated significantly lower wear times compared to the

experienced users as well as decreased wear time from the first month to the third

month. Lower compliance due to adverse effects and adaptation periods for new wearer

patients have been reported and discussed previously. Despite continued occlusal device

wear, new wearers might still experience difficulty wearing their occlusal devices, and it

should be assumed they might require longer adaptation periods. Decreased compliance

throughout treatment was reported previously for patients receiving removable

orthodontic appliances (Bos et al., 2007; Bartsch et al., 1993). The decreased compliance

in the current study might be explained by patient burnout. It was found in studies of

mandibular advancement devices in the management of sleep apnoea that compliance

with the recommended occlusal appliance treatment was associated with positive

treatment effects (Lindfors et al., 2011b). In this study, all new wearer patients received

their occlusal device for first time and some might have noticed less therapeutic benefits

than anticipated, which might explain their reduced compliance and lower wear times.

Other explanations for the discrepancy in wear time might include self-perceived negative

treatment effects, such as discomfort, sleep disturbance, and dental pain during initial

treatment, as a large number (9) of new wearer patients discontinued their treatment due to adverse effects. On the other hand, the higher compliance of experienced wearers was not unexpected, as they had already been wearing their devices for at least three months. Additionally, all experienced wearers were regular attendees who had received comprehensive prosthodontic treatment and were provided with occlusal devices for teeth and restoration protection to mitigate potential bruxism damage, which may have made them be more compliant in using their devices. Their previous investment in their dental care may have therefore provided additional motivation to maintain their new dental health.

There was a statistically significant change in compliance between the first, second, and third months, with median wear times of 6.60, 6.57, and 7.13 hours per night, respectively. This increase may have been a result of patients being aware that their wear time was being recorded, as reported previously in orthodontic patients (Ackerman and Thornton, 2011). Additionally, the study follow-up protocol might have positively influenced patient compliance. Scheduled recall visits also provided an opportunity to address any issues the patients may have had which had resulted in increased wear times, as the appliances may have been more comfortable after adjustment. Furthermore, it has been shown that the patient-provider relationship might have a positive impact on patient compliance. Unlike new wearers, all experienced wearers had spent a substantial period of time attending the Postgraduate Prosthodontic Clinic, at which the primary investigator was one of the clinicians who provided treatment and occlusal devices. Patient

satisfaction with their clinician has been found to be associated with positive evaluation of the occlusal devices (Inglehart et al., 2014a). Wear time discrepancies between the two groups in this study were also observed, with two different wear patterns evident. Visual wear time graph analysis demonstrated clear fluctuations in the wear time patterns of new wearer group, as they only intermittently wore their devices, which was unlike the experienced wearer group who demonstrated a regular wear pattern. Placing the participants in two groups based on their wear experience helped identify such wear patterns and provide information about the possible adverse effects among the new wearer group.

4.7 Limitations of the Study

The first limitation of this study was its small sample size, as only 46 participants were recruited at the start of the study and only 23 participants were included for analysis. This sample pool was limited, as hospital records indicated that 70-100 devices are made each year at the Dublin Dental University Hospital. This total figure included hard acrylic devices as well as soft and hard-soft devices. In addition, funding for the study covered a maximum of 50 microsensors due to cost.

Among the 23 participants, there were five males and eighteen females. It can be assumed that a greater number of females reported sleep bruxism and sought treatment than males. A larger sample size with even gender distribution may provide greater insight in regard to the possible differences in wear time with respect to gender.

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A second limitation is the high number of participants who withdrew for various reasons, as only 23 participants were included for analysis. Non-compliance with the study parameters was the main reason (14 subjects) for this loss of participants. This was mainly associated with adverse effects of the device, particularly in the new wearer group. However, as this study was the first of its kind, it may be that this high rate of non-compliance may be representative of the wear patterns among patients in the wider population. Further studies are required to provide more information in this regard.

The third limitation was that sleep bruxism screening was completed using a sleep bruxism questionnaire as a proxy for recruitment. Despite being widely used, the accuracy of self-reported sleep bruxism as a diagnostic tool varies in terms of its reliability. The over-reporting and over-estimation of sleep bruxism severity has been reported previously with this diagnostic method (Lobbezoo et al., 2018). The gold standard method for diagnosing sleep bruxism is an in-patient PSG (Lobbezoo et al., 2013b). However, due to its high cost and the lack of available PSG resources, alternative methods, including questionnaires and clinical examinations as well as an ambulatory EMG recording, are being used more frequently.

The fourth limitation is that the follow up period was only for 90 days. Longer periods of wear are required, particularly for new wearers, to determine compliance in the longer term. Thus, the current study will be extended for a further 12 months.

4.8 Conclusions

1. This study exhibited the effectiveness of using a thermo-sensitive microsensor in monitoring sleep bruxism patient compliance and, for the first time, reported the objective wear times of occlusal devices for bruxer patients.

2. Only 50% of the participants (23 out of 46) wore the appliances for the duration of the study period. Fourteen participants (12 new users and 2 experienced users) were excluded from the study as they were not compliant with device wear instructions. A further 9 patients (5 new users and 4 experienced users) withdrew for reasons including being lost to follow up due to relocation, delays to device manufacture as they were undertaking additional dental treatment, losing the device, or having a defective senor which they did not want replaced.

3. The overall 90 nights median occlusal appliance wear time for all participants (N=23) was 5.50 h/night. There was a drop in compliance across the three 30-night observation periods, yet the decrease was relatively shallow and represented a very small effect.

4. Significant differences in median occlusal appliance wear time between new (4.04 h/night) and the experienced users (6.79 h/night) for the 90 night period

were identified. The experienced patients used the occlusal device for approximately 2.5 hours more per night than new users.

5. During the second and third observational periods (month 2 and month 3) further divergence was noted with experienced patients using the occlusal device for between two and four hours more per night than new users.

6. There was a statistically significant increase in median wear time over repeated measures for the experienced wearer group. On the other hand, the opposite pattern was observed for the new wearer group with a slight, but insignificant, reduction in wear time recorded.

7. No significant difference in the overall 90 nights median occlusal appliance wear time between male (5.07 h/night) and female (5.19 h/night) participants was observed. Females participants median wear time decreased from month 1 to month 3, but was not statistically significant. There was no clear pattern demonstrated for males in regards to median wear time variation over the 90 nights.

8. There was difference in the overall 90 nights median occlusal appliance wear time between the <= 45 years of age patients (5.42 h/night) and >= 46 years of age patients (3.93 h/night) participants. However, this was not statistically significant. There was also a slight decline in median wear time the ≥ 46 years of age group from month 1 to month 3, a pattern not seen in the ≤ 45 years of age group.

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5. Appendices

Appendix 1. Ethical Approval

THIS NOTEPAPER MUST NOT BE USED FOR
PRESCRIPTIONS OR INVOICING PURPOSES

SJH/AMNCH Research Ethics Committee Secretariat
Claire Hartin Ph: 4142199
email: claire.hartin@amnch.ie

**THE ADELAIDE & MEATH
HOSPITAL, DUBLIN**
INCORPORATING
THE NATIONAL CHILDREN'S HOSPITAL

TALLAGHT, DUBLIN 24, IRELAND
TELEPHONE +353 1 4142000

Prof. Michael O'Sullivan
Dublin Dental University Hospital & Trinity College Dublin
Lincoln Place
Dublin 2

12th April 2018

Re: Measuring patient compliance with occlusal device wear in the management of bruxism

REC Reference: 2018-04 Chairman's Action (4)
(Please quote reference on all correspondence)

Dublin Dental University Hospital
Letter received by administration

19 APR 2018

Department of Restorative Dentistry &
Periodontology

Dear Prof. O'Sullivan,

The REC is in receipt of your recent request to SJH/AMNCH Research Ethics Committee in which you queried ethical approval for the above-named study.

The Chairman, Prof. Richard Dean, on behalf of the Research Ethics Committee, has reviewed your correspondence and granted ethical approval for this study to commence in Tallaght.

Yours sincerely,

Claire Hartin
Secretary
SJH/AMNCH Research Ethics Committee

Appendix 2. Patient Approval Letter

Dear Sir/Madam

Title of research study:

Measuring patient compliance with occlusal device wear in the management of bruxism.

My name is Dr. Mohammad Alqhtani and I am a Postgraduate student at the

Dublin Dental University Hospital. I am conducting a research project about patient

wear compliance with occlusal devices, also known as splints. I would like to assess

precisely the occlusal device real time wear patterns using well-tested

microsensors to provide objective measures of appliance use.

The study will include two different groups, patients wearing the occlusal splint for

first time (new appliance) and current occlusal splint wears (existing appliances).

You can read more about the study in the information sheet provided and if you

have any questions about the study contact details are supplied below. If you are

interested in taking part then I can meet you in DDUH on a day and time that is

most convenient for you.

The administrative contact person for the study is Ms. Rosaleen Glackin and she

can be contacted by:

(1)   Telephone   01 612 7603

(2)   Email   rosaleen.glackin@dental.tcd.ie

(3)   By post, using the slip provided below, in the stamped and addressed

envelope provided.

  Thank you for your interest in this project.

  Dr. Mohammad Alqhtani

I am interested in taking part or learning more about the study with Dr.

Mohammad Alqhtani and I am willing for him to contact me:

NAME: _____

Telephone Number: _____

Email: _____

Signed: _____   Date: _____

Appendix 3. Patient Information Leaflet

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Title of the Study:

Measuring patient compliance with occlusal device wear in the management of bruxism.

Introduction:

My name is Dr. Mohammad Alqhtani and I am a Postgraduate student at Dublin Dental University Hospital. I am conducting a research project about patient wear compliance with occlusal devices, also known as splints. I would like to assess precisely the occlusal device real time wear patterns by using well tested microsensors to provide objective measures of appliance use.

I would like to invite you to participate in this postgraduate research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask me if there is anything that is not clear or if you would like more information.

You are being asked to participate as you have an existing appliance provided for you or are planned to have one in the near future. The appliance has been recommended to you based on your clinical need.

Background:

Nocturnal tooth grinding and clenching (sleep bruxism) is a major and increasing problem in dental practice. Sleep bruxism is caused by arousals during sleep that cause rhythmical jaw muscle activity in certain individuals. The grinding can generate forces in excess of 150 Kg between opposing teeth, leading to a number of problems including:

a)   Tooth attrition (wear)

b)   Restoration (filling) fracture

c)   Tooth loosening

d)   Dental implant fracture or loss

e)   Tenderness/pain in teeth, muscles, headache

f)   Disturbance of bed partner's sleep.

The effects of bruxism are managed most frequently through occlusal devices (also called splints) which are acrylic appliances worn on one arch of teeth. The appliances reduce the effect of bruxism by placing a softer acrylic appliance between the teeth leading to wear on the appliance rather than the teeth.

Appliances are prescribed for patients but there is no indication of compliance with treatment. It is assumed that patients wear the appliances but evidence is available from other areas of dentistry such as orthodontics and dental sleep medicine that compliance with intra-oral appliance wear can be very variable. Compliance with occlusal device wear is essential, in susceptible individuals, to prevent further tooth wear and protect any restorations that have been placed.

Innovative work is being undertaken in Trinity and elsewhere looking at providing sensors within occlusal devices that can provide essential feedback on the frequency and intensity of bruxism. The aim of this study is to examine the compliance of dental patients with occlusal device wear using microsensors within the occlusal device.


What does the Sensor Look Like?

The TheraMon (Therapeutic Monitoring Microsensor) measures 9 x 13 mm in size and once activated starts to sample at regular intervals the wearing of the occlusal splint and stores those measurement values into the integrated memory.

The microsensor will be embedded into the occlusal splint by a dental laboratory technician and is covered entirely with dental plastic (acrylic) material. Direct contact to the patient's mouth or mucosa is not possible.

To send and receive data the microsensor uses RFID technology (Radio Frequency Identification). A dedicated reading station emits a magnetic field of very short range

which enables the sensor to transfer data. The antenna of the sensor can only be

activated if it is positioned near the reading station (approx. 2-3 cm) - in the mouth of the

patient the antenna is not active and cannot emit any radiation.

TheraMon® microsensors are designed for single use only. The lifetime of microsensors is

granted over a minimum period of 18 months. To enable evaluation over the entire

treatment, several sensors of a single patient can be combined in the TheraMon®

Software.
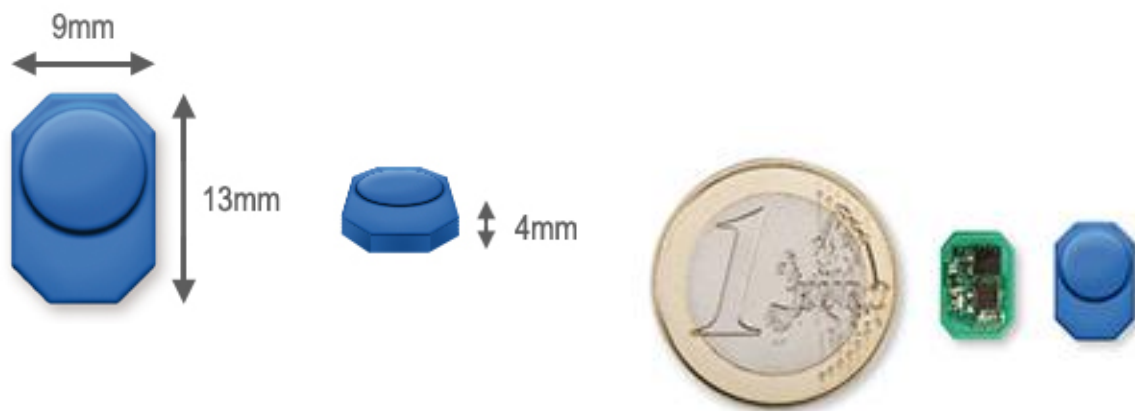
TheraMon microsensor

Study Details:

An appointment will be arranged at Dublin Dental University Hospital on a day and a time, which is most convenient for you.

The study will include two different groups, patients wearing the occlusal splint for first time (new appliances) and current occlusal splint wears (existing appliances). Microsensors will be fitted into new occlusal appliances by a dental laboratory technician. The second group (current occlusal device wearers) will booked for appointment and during the appointment the occlusal splint will be send to the dental laboratory technician and the microsensor will retrofitted.

Patients shall be recalled as standard for this appliance type, initially at one week, one month and three monthly thereafter by myself at Dublin Dental University Hospital. At those reviews the microsensors will be read and information transferred to a password protected desktop computer.

The study period will be 12-18 months, after which the microsensor shall be removed and the appliance reconfigured by a dental laboratory technologist and the appliance returned to the patient. The patient will then be reviewed as standard in the Dublin Dental University Hospital or with their own general dental practitioner.

Eligibility:

1) Patients over 18 years of age who are willing for provide informed consent.

2) Patients who are able to attend for recall appointments.

3) Patients who are wearing an occlusal device provided by the Dublin Dental University Hospital (the existing appliance group only).

Patient questionnaire:

Bruxism questionnaire will be incorporated in this study to evaluate subjective reported awake and sleep bruxism will be constructed according to the recommendations of Lavigne and co-workers. Nocturnal bruxism will be evaluated by questionnaire based on American Academy of Sleep Medicine Diagnostic Criteria (2005).

Lavigne GJ, Manzini C, Kato T. Sleep bruxism. In: Kryger MH, Roth T, Dement WC, ed. Principles and Practice of Sleep Medicine, 4th edn. Philadelphia, PA: Elsevier & Saunders, 2005:946–959.

American Academy of Sleep Medicine (AASM). The International Classification of Sleep Disorders Revised: Diagnostic and Coding Manual (ICSD), 2nd edn. Westchester, IL: American Academy of Sleep Medicine, 2005.

Risks and Benefits:

No increased risk is foreseen by sensor placement as it is in routine use and is CE marked. The sensor is securely embedded in the occlusal device and covered with standard acrylic

resin. It will provide both the researchers and the patients with detailed information about their device wear. Patients may be interested to have an objective measure of compliance. The researchers will be able to determine the patterns of wear of the devices. This will inform future projects that may look at the frequency and more in depth characteristics of bruxism. The results of the study will also be published in journals or presented at dental conferences.

Confidentiality:

Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the research study group. All data will be anonymised in any reports presented and no individual will be identified.

Voluntary Participation:

It is up to you to decide whether to take part or not. If you decide to volunteer to participate in this study, you may withdraw at any time without giving a reason. If you decide not to participate, or if you withdraw, you will not be penalised and it will not affect the standard of care you receive.

Further information:

If you have any questions or require more information about this study, please contact Ms Rosaleen Glackin using the following contact details:

Ms Rosaleen Glackin

Dublin Dental University Hospital

Lincoln Place

Dublin 2

Tel: 01 612 7603

Email: rosaleen.glackin@dental.tcd.ie

Appendix 4. Informed Consent Form

CONSENT FORM

Please complete this form after you have read the Information Sheet

PROJECT TITLE: Measuring patient compliance with occlusal device wear in the management of bruxism.

Principal Investigator: Dr Michael O'Sullivan, Associate Professor /Consultant in Restorative Dentistry. Dublin Dental University Hospital, Trinity College, Dublin.

Co-Investigator: Mohammad Alqhtani, Postgraduate Student, Dublin Dental University Hospital, Trinity College, Dublin.

Thank you for considering taking part in this research. The persons organising the research must explain the project to you before you agree to take part. If you have any questions arising from the research participant information leaflet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

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I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data up to the point of publication 30th of January 2019.

Please tick or initial   ☐

I agree to participate in a research project which is being carried out by Dr. Michael O'Sullivan and Dr. Mohammad Alqhtani. The study is designed to assess precisely the occlusal device (splint) real time wear patterns utilising well tested microsensors to provide objective measures of appliance wear.

I agree to participate in this project and wear the occlusal device with an integral microsensor. I was informed that the study period will take between 12-18 months and the follow up will be initially at one week, one month and thereafter three monthly and I have the commitment to participate in the project. Any information or data which is obtained from me during this research will be treated confidentially and stored securely. Data from this research project may be published in future.

Please tick or initial   ☐

DECLARATION:

I have read, or had read to me, the information leaflet for this project and I understand the contents. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I understand that I may withdraw from the study at any time and I have received a copy of this agreement.

PARTICIPANT'S NAME: …………………………………………………..

CONTACT DETAILS: ………………………………………………..

PARTICIPANT'S SIGNATURE: …………………………………………**Date: …………………………..**

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

INVESTIGATOR'S SIGNATURE: …………………………………………. Date: …………………..…

Appendix 5. Patient Bruxism Questionnaire

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Patient Bruxism Questionnaire

Patient Name: _____

1. Are you aware, or has anyone heard you, grinding your teeth frequently during sleep? (yes ⁄ no)

2. Are you aware that your dentition is worn down more than it should be? (yes ⁄ no)

3. Are you aware of any of the following symptoms upon awakening? (yes ⁄ no):

   (i) Sensation of fatigue, tightness or soreness of your jaw upon awakening?

   (ii) Feeling that your teeth are clenched or that your mouth is sore upon awakening?

   (iii) Aching of your temples upon awakening?

   (iv) Difficulty in opening your mouth wide upon awakening?

   (v) Feeling of tension in your jaw joint upon awakening and feeling as if you have to move your lower jaw to release it?

   (vi) Hearing or feeling a ''click'' in your jaw joint upon awakening that disappears afterwards?

Criteria of the American Academy of Sleep Medicine (2005)

Appendix 6. Gender and Age Histograms

Histogram

for Sex= Male

Mean = 4.48
Std. Dev. = 1.711
N = 4

First_Month_M

Histogram

for Sex= Female

Mean = 5.50
Std. Dev. = 2.253
N = 19

First_Month_M

216

Histogram

for Sex= Male

Mean = 3.97
Std. Dev. = 2.476
N = 4

Frequency

Third_Month_M

Histogram

for Sex= Female

Mean = 5.26
Std. Dev. = 2.772
N = 19

Frequency

Third_Month_M

217

Histogram

for Sex= Male

Mean = 5.37
Std. Dev. = .893
N = 4

Histogram

for Sex= Female

Mean = 5.28
Std. Dev. = 2.573
N = 19

Histogram

for Sex= Male

Mean = 4.56
Std. Dev. = 1.174
N = 4

Histogram

for Sex= Female

Mean = 5.36
Std. Dev. = 2.184
N = 19

Histogram

for Age_R= Young

Mean = 5.05
Std. Dev. = 2.386
N = 12

First_Month_M

Histogram

for Age_R= Old

Mean = 5.62
Std. Dev. = 1.976
N = 11

First_Month_M

Histogram

for Age_R= Young

Mean = 5.45
Std. Dev. = 2.654
N = 12

Third_Month_M

Histogram

for Age_R= Old

Mean = 4.58
Std. Dev. = 2.836
N = 11

Histogram

for Age_R= Young

Mean = 5.99
Std. Dev. = 2.176
N = 12

222

Histogram

for Age_R= Old

Mean = 4.54
Std. Dev. = 2.398
N = 11

Second_Month_M

Histogram

for Age_R= Young

Mean = 5.50
Std. Dev. = 2.151
N = 12

M_First_3_Months

Histogram

for Age_R= Old

Mean = 4.92
Std. Dev. = 1.982
N = 11

Frequency

M_First_3_Months