

Use of the Grindcare® device in the management of nocturnal bruxism: a pilot study

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IN BRIEF

- Describes a new way of providing biofeedback to manage sleep bruxism.
- Includes a brief update on the current thinking about the causes of sleep bruxism.
- Indicates a small group of myofascial pain patients used this Grindcare® device with mixed results.

Background Bruxism may be described as a diurnal or nocturnal parafunction, characterised by clenching, bracing, gnashing or grinding of the teeth and jaws. The aim of the management of bruxism should be to control or reduce the level of activity where possible. A variety of treatment strategies have been employed to achieve this including hypnosis, occlusal equilibration, splint therapy, physiotherapy and acupuncture. A more recent approach is the use of biofeedback. **Method** Nineteen consecutive patients were recruited from the temporomandibular joint dysfunction (TMD) clinic at Manchester Dental Hospital, all of whom were known bruxists. They were supplied with the Grindcare® device (Medotech) and instructed to wear it every night over the five-week observation period. By monitoring electromyographic (EMG) muscle activity, the device is able to emit low-voltage electrical impulses as it senses a clenching or grinding episode, bringing about muscle relaxation. **Results** Eleven of the nineteen patients (58%) reported a major reduction in the occurrence of headaches and discomfort of the masticatory muscles on waking. Female and younger subjects responded more favourably than male and older subjects respectively. **Conclusion** The use of biofeedback could reduce the level of parafunctional activity and bring about meaningful symptomatic improvement. No adverse effects occurred throughout the study period.

INTRODUCTION

Bruxism may be described as a primary condition in cases where there is no identifiable or pre-existing medical condition. Secondary bruxism is a condition in which the parafunctional habit occurs as a result of a pre-existing medical or psychiatric state. Conditions such as Parkinson's disease, depression and anxiety are all known to be associated with episodes of tooth grinding. Primary bruxism may be further defined as a diurnal or nocturnal parafunction, characterised by clenching, bracing, gnashing or grinding of the teeth and jaws.¹ Daytime bruxism is commonly a clenching or bracing activity without sounds.² Night-time bruxism or sleep bruxism is often associated with

loud involuntary grinding of the teeth. Sleep bruxism has been defined as a 'sleep related movement disorder' according to the international classification of sleep disorders, characterised by rhythmic masticatory muscle activity.^{3,4} The consequences of sleep bruxism can include tooth surface loss, fracture of restorations, temporomandibular joint (TMJ) and masticatory muscle pain, temporal headaches, cheek ridging, tongue scalloping and even marital problems due to the severity of grinding sounds.¹ A diagnosis of sleep bruxism can only be confirmed by a sleep clinic.

It is quoted that 85-90% of the population will experience parafunctional tendencies at some point in their lives.⁵ The aetiology of bruxism is multifactorial. Previously it was thought that peripheral factors such as occlusal discrepancy were the main causative factors. Ramfjord held the view that certain occlusal features were pivotal in initiation of the disorder, especially with regard to discrepancy between retruded contact position (RCP) and intercuspal position (ICP).⁶ However, in recent years there has been a shift towards central factors such as stress playing a pivotal

role.⁷ Certain pathophysiological factors may also be involved, which include smoking, trauma, caffeine, alcohol, medications and illicit drugs.⁸ Whilst the occlusal surfaces of the teeth can be affected by bruxism, there is no evidence that the occlusion is the cause of bruxism. Sleep bruxism is now considered to be a sleep disorder that is initiated centrally. There is no evidence that the elimination of occlusal interferences reduces bruxism.⁸

The aim of the management of bruxism is to control or reduce the level of activity where possible. A variety of treatment strategies have been employed to achieve this including hypnosis, occlusal equilibration, splint therapy, physiotherapy and acupuncture. A more recent approach is the use of biofeedback – the giving of immediate information to a subject about their bodily processes,⁹ which has been shown to reduce electromyographic (EMG) muscle activity even after a short period of treatment.^{4,10}

THE GRINDCARE®

Produced by Medotech, this is a device for the management of sleep bruxism.

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Worn at night, it has a built in biofeedback algorithm, which controls functional electric stimulation (FES) in the form of controlled low voltage electrical impulses (1-7 mA). These impulses interrupt the muscular activity and bring about local muscle relaxation, which subdues undesirable and potential harmful muscular activity without waking the user. In the short term this purportedly reduces the number of clenching/grinding episodes. In the long term it is suggested that use of the device acts to 'condition' the subject and therefore reduce their muscular parafunction.⁴

The stimulator electrode is attached using an adhesive pad so that it lies over the anterior aspect of the temporalis muscle (Figs 1-3). The temporalis is used as it is active during any mandibular parafunction while also providing a large surface area for improved skin-electrode contact compared to other sites, for example the masseter, which would be impractical. The subject sets the feedback level as required using the Grinddock, which is linked to the stimulator by Bluetooth. Incorporated within the stimulator are three electrodes that monitor EMG activity to detect muscular activity during clenching or grinding. The unit runs the user through a range of normal facial expressions followed by a clenching phase so that it is able to differentiate normal muscular activity from that of parafunction. Within these set parameters the stimulator is able to send an electrical impulse to the anterior temporalis muscle when it senses clenching or grinding. In the morning, the data from the previous evening is sent from the stimulator to the Grinddock by Bluetooth, where it is stored before it is transferred to the Grindcare® software program at the end of the treatment period.

The aim of this pilot study was to determine if the use of biofeedback, as delivered by a Grindcare® device, could control or reduce the level of parafunctional activity in a sample of known bruxists, measured by subject reported outcomes and device recorded EMG data.

METHODS

In this pilot study, 19 consecutive subjects fulfilling the criteria below were recruited from the temporomandibular joint dysfunction (TMD) Clinic at Manchester



Fig. 1 The Grindcare® stimulator unit



Fig. 2 The Grinddock



Fig. 3 Placement of the stimulator on the anterior temporalis

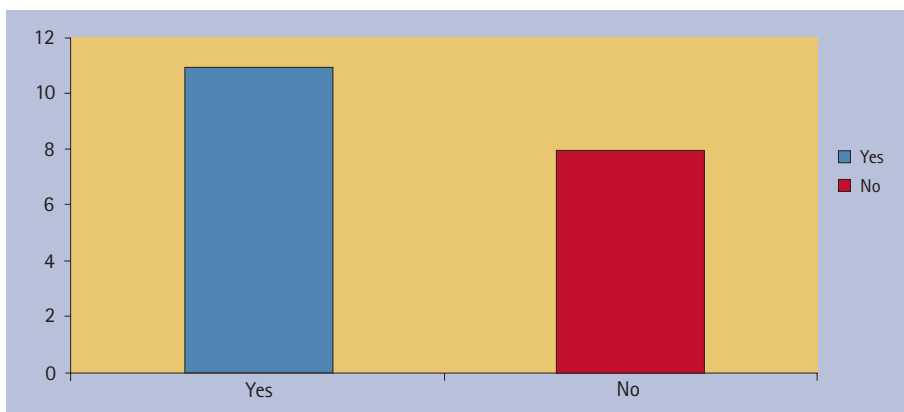


Fig. 4 A bar chart to show patient reported symptom improvement

	Mean pain on VAS: pre-intervention	Mean pain on VAS: post-intervention
Improver group	5.8	2.5
Non-improver group	6.6	4.7

Dental Hospital. There were ten males and nine females, with a mean age of 41.4 years (SD 22.7-60.1 years). All were known active bruxists, fulfilling the following criteria based on the definition of sleep bruxism as a movement disorder that is an oral parafunction characterised by grinding or clenching during sleep:³

1. They had report from a roommate or sleep partner of tooth grinding noises
2. They exhibited clinical signs of active bruxism, namely cheek ridging and tongue scalloping¹¹

3. Report of headache or discomfort of the jaw muscles upon awakening.

Consent to take part in the study was obtained and a thorough examination of the articulatory system was undertaken along with the research diagnostic criteria (RDC) – TMD classification examination sheet at the start and end of the study period (available via the RDC-TMD examination website).¹² Changes in self-perceived pain levels were assessed using visual analogue scales (VAS) along with analysis of the number of

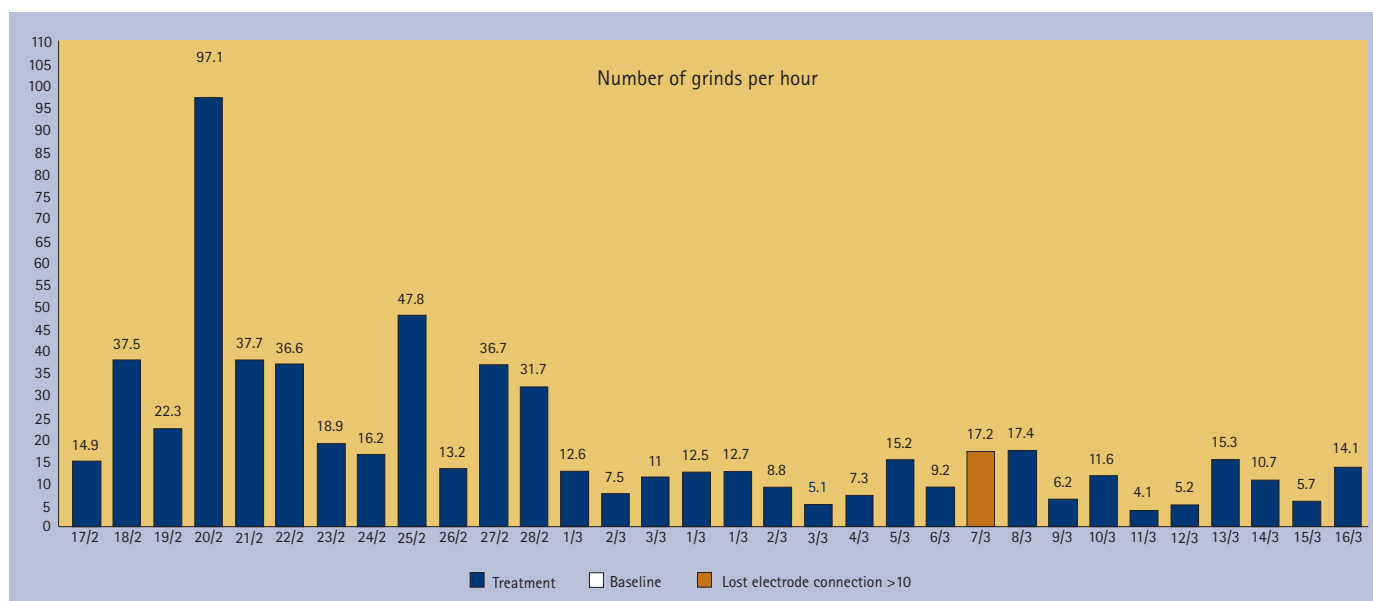


Fig. 5 Data taken from the Grindcare® manager software showing a dramatic reduction in parafunctional activity over the study period (improver)

clenching/grinding episodes throughout the observation period.

The subjects were given thorough verbal and written guidance in the use of the device. They were instructed to wear it every night over the five weeks of the study. During the first week the feedback level was set to zero, so that the device was only collecting baseline data. In the subsequent four weeks the subject set the feedback level so that it was sufficiently strong for them to only just feel the stimulus to the temporalis, while awake. This is suggested by the manufacturers to be strong enough to have an effect, but not strong enough to awaken the subject. Subjects were advised that if they did experience sleep disturbance to reduce the level further. The device recorded the data relating to the number of clenching/grinding episodes. The mean number of episodes per week was calculated for each subject, so that a comparison could be made on a week-by-week basis.

At the start of the study and following completion of the five-week period, masticatory muscle tenderness was assessed using the RDC-TMD examination sheet. One operator completed these assessments in order to maintain consistency throughout. On completion of the study period patients were asked if they felt their symptoms had improved through use of the device.

STATISTICAL ANALYSIS

A one-way analysis of variance was performed to examine any difference in

scores for the four weeks after baseline. The response was also dichotomised as symptom improvement or no improvement based on patient self-report following use of the device.

RESULTS

On average, male patients were older than their female counterparts. The overall mean age was 41.4 years (SD 22.7–60.1 years). The difference in the mean weekly scores were not statistically different ($F_{(3,72)}$, p -value = 0.9,879). The results showed that female and younger patients responded more favourably through use of the device, with greater symptom improvement (Fig. 4).

In terms of self-reported symptom improvement, it was immediately clear that there were two distinct groups. Eleven of the nineteen patients (58%) reported a meaningful reduction in the occurrence of headaches and discomfort of the masticatory muscles on wakening (improver group). The remaining 42% reported no change, positive or negative, in their symptoms (non-improvers) (Table 1).

However, importantly none of the subjects in the non-improver group reported any deterioration in their condition over the study period. There was a large range of individual variation both in terms of the number of grinding/clenching episodes and the patient's response to the biofeedback, as can be seen in Figures 5 and 6 with the x-axis representing the number of grinding episodes per hour over each day of the observation period (y-axis).

DISCUSSION

In the first instance it is important to stress this was a pilot study. The sample size was small and as such it was not possible to observe any statistically significant differences within the data. Additionally, the male:female distribution within the sample may be somewhat different to that expected for presentation to a TMD clinic. However, this is the sample of consecutive patients recruited based on the inclusion criteria set.

It was apparent from patient reports that when the Grindcare® device worked for a patient, it worked very well. It was able to bring about worthwhile symptomatic improvement measured using self-reported visual analogue scales and also as recorded by a reduction in masticatory muscle tenderness using the research diagnostic criteria for temporomandibular disorders. Table 1 demonstrates that patients within the improver group on average experienced a 56.9% reduction in pain through use of the device (VAS 5.8–2.5). Compared with the non-improver group, who on average experienced only a 28.8% reduction in pain (VAS 6.6–4.7). However, this is interpreted with caution, as visual analogue scales are very subjective and there is often a central tendency bias associated with such measures.

The expectation that the device would 'cure' bruxism, completely eradicating parafunctional habits over the study period was, maybe unsurprisingly, found not to be the case. Even in cases where

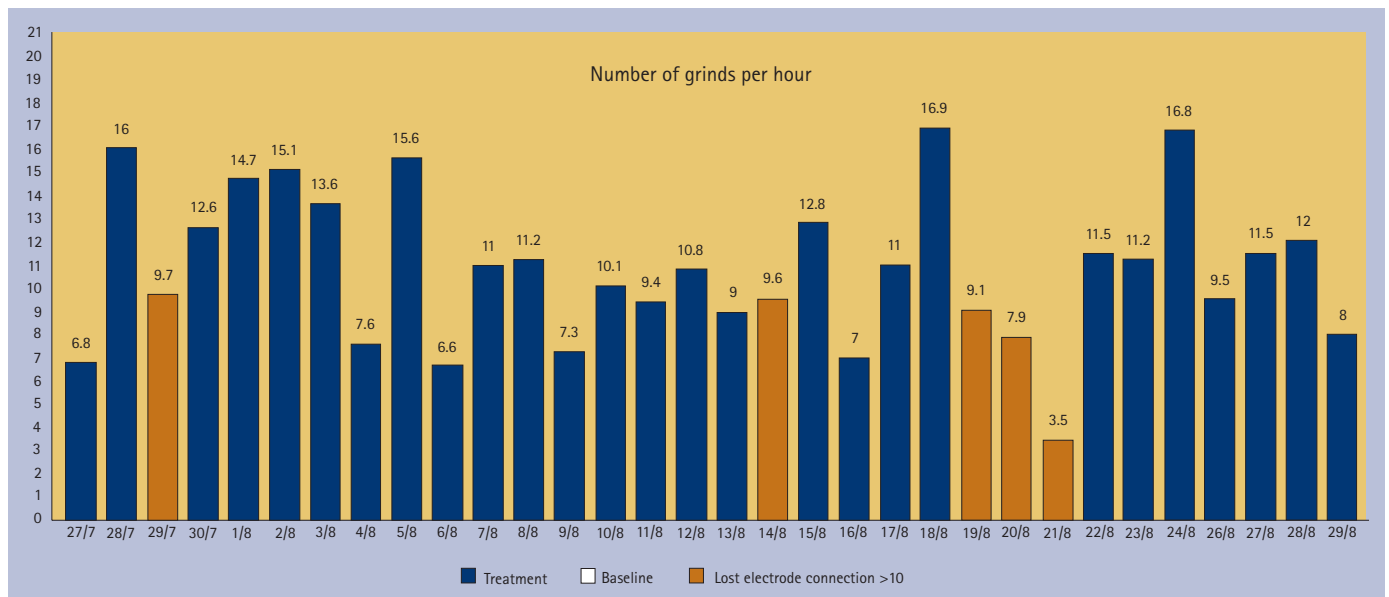


Fig. 6 Data taken from the Grindcare® manager software showing little effect of the Grindcare device in reducing parafunctional activity over the study period (non-improver)

the device had its most profound effect, parafunctional activity did not fall to zero. This leads us to one of the major disadvantages of the device – the device as used in this case series is unable to record the duration and intensity of a parafunctional episode. The manufacturers state that the effect of the device is to reduce the number of parafunctional episodes but also their duration and intensity. Therefore, the beneficial effect of the device in respect of protecting tooth structure may be underestimated by the results of this study. Hypothetically, a single prolonged parafunctional episode would be recorded in the same way as a short burst of temporalis activity. It is our understanding that future upgrades will allow for the duration and level of temporalis muscle activity to be recorded.

As demonstrated above, the results of this case series clearly showed two distinct groups. The results showed that younger subjects and females were more likely to experience meaningful symptomatic improvement through use of the Grindcare® device. Within the group of subjects who experienced no benefit (or harm) from use of the device there was an intangible sense at their initial consultation that they may not experience the desired treatment effect. It is difficult to articulate the reasons for this feeling but it is possible that factors

such as psychological status may modify the patients' response to treatment. This fact has been previously eluded to by Ramfjord who described limited success in the management of TMD in patients with neurotic tendencies.⁶ However, despite this initial feeling all patients were managed and followed up in the same way by a single operator.

CONCLUSIONS

In a sample of known bruxists, the use of biofeedback could reduce the level of parafunctional activity and bring about a clinically worthwhile symptomatic improvement based on patient self-report. Analysis highlighted age and gender of subjects to be indicators of symptom improvement with use of the device, with more benefit experienced by female subjects than male subjects and younger subjects compared to older subjects. While the device did not bring about symptomatic improvement for every subject in this case series, it was successful for 58% of subjects with the remainder experiencing no adverse effects.

FUTURE RESEARCH

Given the promising initial results observed within this pilot study we feel it would be beneficial for further research to be carried out using the device in a double blind

randomised controlled trial with a larger sample size.

The authors would like to emphasise they have no vested interest with the Grindcare® device or Medotech and no funding was received for this pilot study.

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