BiteSoft®

history
bruxism
full arch splints
BiteSoft® design
presentation kit
clinical protocol
informed consent
screening questionnaire
examination procedures
conclusion & results
studies

History

Developed by Experts

- Dr Adrian Yap
- Mr Ian Withers
- Dr Harry Ball
- Mr Jonathan Parkinson
- Mr James Kerr

Bruxism

As important as managing Caries and Periodontal Disease

Prevalence of Bruxism

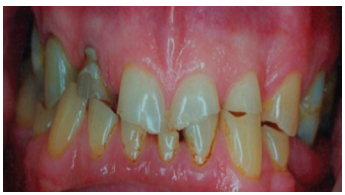
1014 subjects

27.2% prevalence

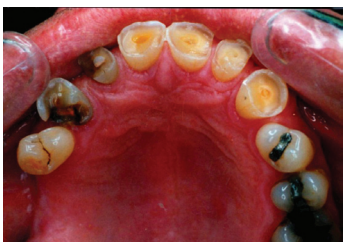
Increases to 50% with exam and s/m

Melis et al

J of Craniomandibular P April 2003 Vol 21 No.2



A disease that is so prevalent but often not detected, or worse still a wait and see approach is adopted.

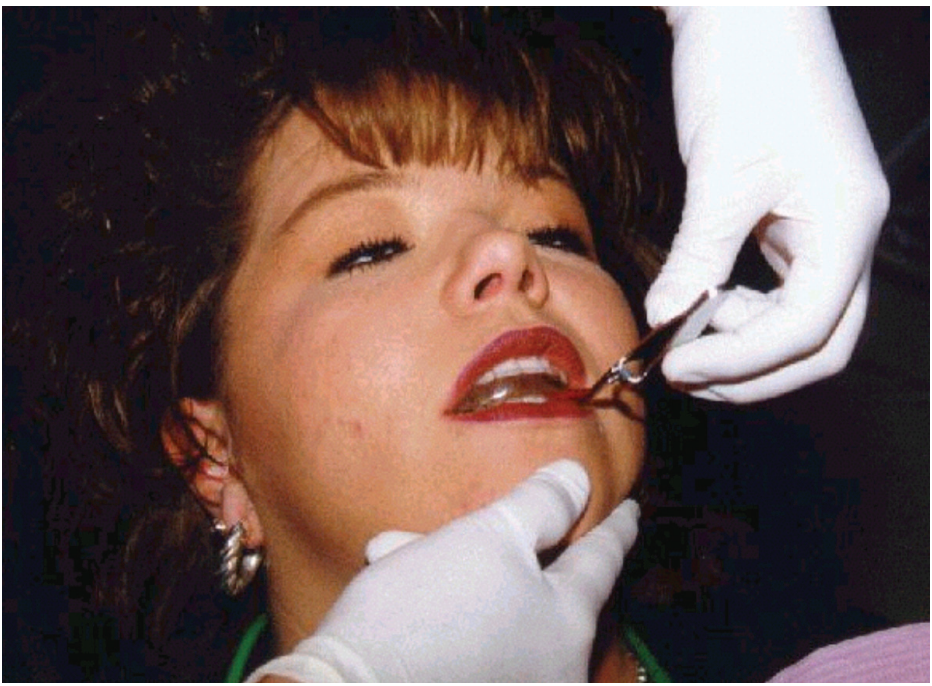


Incredible forces at work

Day Time	17,200 *lb/sec/day*
Night Time	57,600 *lb/sec/day*

Full Arch Splints

Equilibration of full arch splints can be time consuming



Negatives

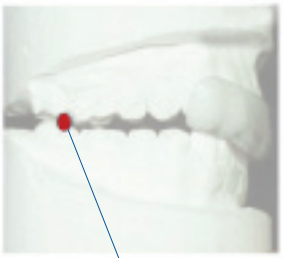
Bulky
Compliance
Difficult to refit after restorations
Retention
Patients still Brux on the splint

BiteSoft® Design Features

BiteSoft® The world's most popular custom made night guard

Almost undetectable

Patented Design Features



Minimal Posterior Vertical Opening
= Maximum Patient Comfort

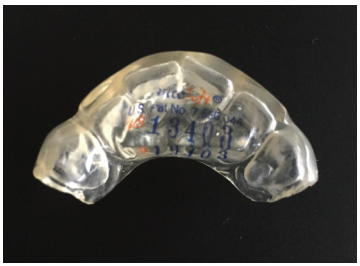
- Anterior Ramp
- Posterior Ramp
- Centric Occlusal Table

Comparisons between the BiteSoft® splint and a standard full arch splint

	BiteSoft	Full
Clinical time	Minimal	Lengthy
Bruxing Intensity	Low	Same
Patient Acceptance	High	Fair
Profitability	Very High	Low

Presentation Kit

Each BiteSoft® Patient Presentation Kit includes an individual **P**roduct **A**uthenticity **C**ode imbedded in the splint.



Unique number for every splint

A Happy Patient

comfort + aesthetics = compliance = max protection

Clinical Protocol

The BiteSoft® anterior splint is the worlds premier bruxism appliance.

The BiteSoft® is specially designed to:

- Prevent the harmful effects of nocturnal bruxism
- Be comfortable and long-lasting
- Minimise chairside time for patient delivery

product authenticity

Every BiteSoft® should contain a unique product authenticity code. This code can be seen beneath our trademark inside the incisal table. Please keep this code on file for easy reference should the need arise.

retention and stability

The thermoplastic lining of the BiteSoft® enables optimal fit and retention to be accomplished. Insert the appliance in the mouth and check for comfort, retention and stability. Ensure that the appliance cannot be easily removed with just lip and tongue pressure.

adjustment

Ensure the patient cannot retrude their mandible past the posterior edge of the ramp. This is best done with patient lying down.

occlusal load

Ensure that when the patient bites together, the posterior ramp guides the teeth onto the incisal table. Ensure that the occlusal load is distributed over 3 or 4 opposing incisor teeth.

inhibiting bruxism

1. Only the four opposing incisor teeth should contact the incisal table simulataneously. To facilitate muscle relaxation, ensure that the opposing cuspids do not contact the incisal table.
2. There should be no posterior contacts against the appliance when the opposing incisors are in contact with the incisal table or in any excursive movement. Opposing cuspids may contact the appliance in lateral excursions. Cuspid contact in lateral excursions will not diminish the inhibition effect.

vertical opening

Check that the vertical opening with the appliance in place is not excessive – minimal clearance of posterior teeth is all that is required in all positions of the mandible.

vertical loading of lower incisors

Check that the incisal table is at right angles to the long axis of the opposing anterior teeth.

information for adaption period

Advise patient that most people experience excess saliva for several days until they become accustomed to the appliance.

Occasionally some patients require a little time to adapt to their BiteSoft®. In this situation it is recommended that the patient ease into wearing ie. only wear their splint for a few hours per night until they familiarise themselves with the appliance.

occlusal stability

The use of any type of splint, including full arch and segmental splints, may sometimes result in a change to a patients bite. In particular, if the patient has had previous orthodontic treatment or the patient presents with an unstable bite, we advise further examination. Occlusal instability is largely due to a relaxation of the jaw muscles and it is therefore important to ensure your patient informs you of any such treatment.

monitoring of patient

It is recommended to make contact with the patient soon after the insert appointment to assess the BiteSoft® for comfort and compliance.

Check appliance and teeth at regular intervals.

Sample Informed Consent Acknowledgement

(Patient to tick each item as you read and understand it)

- ☐ BiteSoft® is designed to be small and comfortable and to reduce the intensity of clenching forces on muscles, jaw joints and teeth.
- ☐ BiteSoft® must only be worn during sleep and not during the day or while eating.
- ☐ During the first week or so it is common for patients to remove the BiteSoft® unknowingly while they are asleep. This is not a problem and soon diminishes as the mouth adapts.
- ☐ When not in use keep BiteSoft® moist and in its protective container.
- ☐ If the appliance becomes loose and can be dislodged with tongue or lip pressure, discontinue use and call the clinic to make an appointment for an adjustment.
- ☐ **If the appliance feels too tight or teeth become painful, discontinue use and call the clinic to make an appointment for an adjustment.**
- ☐ Occasionally staining may occur to your BiteSoft®. This can be treated by soaking the appliance in a solution containing effervescent denture cleaning tablets.
- ☐ Wearing the BiteSoft® can facilitate relaxation in tense and dysfunctional jaw muscles and a resulting change in the position of the jaw when the teeth come together. For a small percentage of patients there may be a permanent change in the way the teeth fit together. Usually this does not present any problems for the patient. However in some situations discomfort may result and further dental treatment may be required to achieve an improved biting contact of the teeth.
- ☐ The time frame for the resolution of jaw pain varies with individuals and can sometimes take up to 6-8 weeks.
- ☐ Your BiteSoft® and your teeth and gums should be checked at regular intervals as discussed with your dentist.

Patient Name: _____

Address: _____

_____

Patient Signature: _____

_____

Date: ___ /___ / _____

BiteSoft®

Sample TDM Screening Questionaire

	YES	NO
1. Do you have difficulty, pain or both when opening your mouth, for instance, when yawning?	☐	☐
2. Does your jaw get “stuck” or “locked”?	☐	☐
3. Do you have difficulty, pain, or both when chewing, talking or using your jaws?	☐	☐
4. Are you aware of noises in your jaw joints?	☐	☐
5. Does your jaw regularly feel stiff, tight or tired?	☐	☐
6. Do you have pain in or about the ears, temple or cheeks?	☐	☐
7. Do you have frequent headaches and/or neckaches?	☐	☐
8. Have you had a recent injury to your head, neck or jaw?	☐	☐
9. Have you been aware of any recent changes in your bite?	☐	☐
10. Have you previously been treated for a jaw problem? If so, when?	☐	☐

Sample TDM Examination Procedures

1. Measure range of motion of the mandible on opening and right and left laterotrusion.

Opening _____ mm Right _____ mm Left _____ mm
(Indicate presence of restriction or lack of coordination in movement)

	YES	NO
2. Palpate for preauricular or intrameatal TMJ tenderness. (Indicate presence of pain on palpation)	☐	☐
3. Auscultate and/or palpate for TMJ sounds. (Indicate presence of clicking or crepitus)	☐	☐
4. Palpate for tenderness in the masseter and temporalis muscles. (Indicate presence of pain on palpation)	☐	☐
5. Note excessive occlusal wear, excessive tooth mobility, buccal mucosal ridging or lateral tongue scalloping. (Indicate presence of above)	☐	☐
6. Inspect for symmetry and alignment of face, jaw and dental arches. (Indicate presence of asymmetry and malalignment)	☐	☐

Sample Psychological, Behavioral and Social Screening

	YES	NO
1. Are there inconsistent, inappropriate and/or vague reports of pain?	☐	☐
2. Are symptoms over-dramatized?	☐	☐
3. Do symptoms vary with life events?	☐	☐
4. Have symptoms been present for more than 6 months?	☐	☐
5. Is there a history of repeated failures with conventional therapies?	☐	☐
6. Are there inconsistent responses to medication?	☐	☐
7. Are other stress-related disorders present? (e.g. fibromyalgia, atypical chest pain etc)	☐	☐
8. Does the patient experience pain in multiple body sites?	☐	☐
9. Is the patient experiencing a major life event? (e.g. death, marriage, divorce, new job, promotion etc)	☐	☐
10. Is there a history of drug abuse?	☐	☐
11. Are there symptoms of anxiety, depression or somatization?	☐	☐
12. Is there evidence of secondary gain? (e.g. on-going litigation, attention seeking etc)	☐	☐

Sample Screening Protocol for use of Splints

	YES	NO
1. Did the patient have prior orthodontic treatment? Check for Cl II treatment with bicuspid extractions.	☐	☐
2. Are teeth stable in maximum intercuspation?	☐	☐
3. Is there a stable incisor overbite/overjet? Look for existing incomplete overbite or anterior open bite.	☐	☐
4. Is there a large centric-relation to maximum intercuspation (CR-MI) slide?	☐	☐
5. Is there tongue thrusting, adaptive swallowing, adaptive tongue postural positioning or other oral habits?	☐	☐
6. Are the lips competent and lip line normal?	☐	☐

Conclusion & Results

FDA Independent Analysis

CONCLUSION

worn only during nighttime the use of the appliance with subsequent normal dental functioning will not induce or permit tooth supraeruption

Wes Shankland DDS, MS, PhD
Past president of the Academy for Head, Neck and Facial Pain

Effect of an anterior bite stop on maximum clenching

RESULTS

Average of 70% reduction in clenching and grinding activity of the Masseter and Temporalis

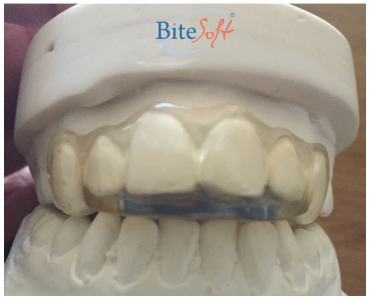
Becker et al J Prosth
Dent 1999;82: 22-6

Management of Bruxism with Anterior Deprogrammers

RESULTS

- 90% had improvement in symptoms within 6 weeks
- Average length of therapy 15.5 months
- No problems with the occlusion

Yustin D, Neff P, Rieger M, Hurst
J Orofacial Pain 1993:7:54-60



Study 1

(A) Masticatory Muscle Activity

1: Scand J Dent Res. 1989 Dec;97(6):533-8.
Immediate electro myographic response in masseter and temporal muscles to bite plates and stabilization splints.
Dahlstrom L, Haraldson T.

The immediate in fluence on masticatory muscle activity of bite plates and stabilization splints was i nvestigated in control subjects and patients with cr aniomandi bular disorders. Electro myographic surface recordings were performed from the masseter and tempo ral muscles bilaterally with and without the appliances in situ.

Activity during maximal biting on stabilization splints was not different from that without the appliance while bite plates caused a decrease in activity in both muscles in both groups. The reduced maximal activity was probably due to the smaller number and exclusively anterior positioned occlusal contacts on the bite plate.

2: J Prosthet Dent. 1999 Jul;82(1):22-6.
Effect of a pr efabricated anterior bite stop on electromyographic activity of masticato ry muscle s.
Be cker I, Tarantola G, Zambrano J, Spitzer S, Oquendo D.

This study measured the effect of a prefabricated anterior bite stop on the electro myographic activity of the anterior temporalis, posterior temporalis, masseter and anterior digast ric during clenching, and grinding tasks. A pr efabricated ante rior bite stop was fabricated for 30 randomly selected subjects. Electro myographic activity was measured during clenching and grinding both with and without the anterior bite stop.

The ante rior bite stop had a signi ficant effect in decreasing electromyographic activity for both clenching and grinding for all the tested muscles, except the anterior digastric.

3: Ann Acad Med. 2005 Oct;34(Suppl):218.
Effect of occlusal splints on masticato ry muscle EMG activity during clenching.
Loke WO, Yap A, Jee SZ, Lee WZ, Lai WP.

This study compared the effect of anterior (MCI - now known as BiteSoft®), soft (PF) and full arch stabilization (SS) splints on the activity of masticatory muscles during clenching. It was hypothesized that anterior splints would reduce both temporalis and masseter muscle activity in contrast with other splints evaluated. Methods: Twelve patients with bruxism and no debilitating TMD/psychological distress and 3 aged-matched controls were recruited. Mean age of the subjects was 23.5 year s. A cross-over design was used where the EMG activity of subjects were measured after inse rtion of each splint type. Subjects were randomly divided into 3 groups (with a control in each group) and tested in the following sequence :Group 1 – SS, BiteSoft®, PF ; Group 2 – BiteSoft®; PF, SS ; Group 3 – PF, SS , BiteSoft®. EMG measurements were repeated 3 times for each splint and with a 5 mins interval between each splint type. Results were analyzed using Kruskal Wallis and Mann-Whitney Test ($p < 0.05$).

Average percentage reduction in masseter EMG ranged from -44.8% (PF) to 49.8% (BiteSoft®) while reduction in tempo ralis EMG ranged from -38.8% (SS) to 59.4% (BiteSoft®). Signi ficant differences in percentage EMG reduction were obse rved for both masseter and temporalis muscle and were as follows: Masseter – BiteSoft® > SS > PF ;Temporalis – BiteSoft®> SS > PF.

The use of soft and full arch stabilization splints may increase masticato ry muscle activity du ring clenching . The anterior splint was effective in reducing both masseter and temporalis muscle activity du ring clenching.

Study 2

(B) Temporomandibular Joints

1: Crit Rev Biomed Eng. 2000;28(3 - 4):389-94.
Reducing condylar compression in clenching patients.
May BM, Ga rabadian C.

The two major muscle groups used during clenching activity are the masseter and temporalis muscles. EMG readings of the masseter and temporalis muscles rise significantly during times of macro-clenching. Clenching occurs when the masseter and temporalis muscles contract, pulling the mandible superiorly. The continued contraction of the masseter and temporalis muscles results in compression forces on the teeth and temporomandibular joints. Theoretical joint loading models are utilized to demonstrate the load on the TMJ due to forces generated by the masseter and temporalis muscles. This study measures the EMG readings during bilateral macro-contraction of the masseter and anterior temporalis muscles. An appliance is fabricated to disengage the posterior teeth and a second series of EMG readings are taken to record lowered EMG readings.

The vector forces of the reduced EMG's recordings demonstrate reduced condylar compression during macro-clenching.

2: Angle Orthod. 1994;64(1):53-61.
The effect of incisal bite force on condylar seating.
Wood DP, Floreani KJ, Galil KA, Teteruck WR.

The purpose of this study was to investigate the relationship between different incisal biting forces and condylar seating. Bite force was measured with strain gauges at the incisors in 22 adult subjects. The subjects were positioned with mandibles in retruded centric and with an opening not exceeding the range of hinge axis movement. Condylar movement was measured using standard true hinge axis location procedures. Condylar position was measured with no force, then with bite forces of 4.5 kg, 7.5 kg and a comfortable maximum.

Biting force significantly affected condylar movement ($p < 0.001$). As incisal bite forces increased, so did the amount of condylar seating to an average of 0.49 mm anteriorly and 0.27 mm superiorly using maximum biting force.

Therefore, when taking a centric relation record, a technique involving an anteriorstop and sufficient biting force should seat the condyles more fully.

3: J Dent Res. 2003 Jul;82(7):532-6.
Occlusal and TMJ loads in subjects with experimentally shortened dental arches.
Hattori Y, Satoh C, Seki S, Watanabe Y, Ogino Y, Watanabe M.

To determine whether shortened dental arches (SDAs) cause functional overloading of the teeth and the temporomandibular joints, which has been implicated in periodontal diseases and temporomandibular disorders, the influences of SDA on occlusal and joint loads were investigated.

Bite force and masticatory muscle electromyograms were recorded in five dentate subjects who clenched maximally on intra-oral appliances, creating symmetrical SDAs experimentally. Muscular forces estimated from the recorded electromyograms were fed into a finite element jaw model for calculating bite forces and joint loads. Comparison between the measured and the calculated bite forces ensured that the joint loads were representative. The bite force on each tooth increased with missing molar occlusions, while joint loads decreased.

The findings provide no evidence that SDA causes overloading of the joints and the teeth, which suggests that neuromuscular regulatory systems are controlling maximum clenching strength under various occlusal conditions.

Study 3

(C) Occlusal Stability / Supra-eruption
1: J Orofac Orthop. 2003 Nov;64(6):417-25.
Dynamic functional force measurements on an anterior bite plane during the night.
Wichelhaus A, Huffmeier S, Sander FG.

Anterior bite planes are used in removable and fixed appliance treatment. In removable appliance treatment the question arising is whether the delivered forces can achieve active intrusion in terms of their amplitude and duration. In fixed appliance treatment, the force effect on the incisors and associated pathologic side effects, in particular under the application of intrusion mechanics, have to be considered.

The aim of the present study was to investigate the effects of an anterior bite plane during the night. For this purpose ten subjects underwent nocturnal sleep investigations by means of a telemetric system. A silicon force sensor was integrated into an anterior bite plane for continuous measurement of bite forces and of the frequency of occlusal contact with the plate.

The occlusal forces exerted on the anterior bite planes ranged between 3 and 80 N. The average forces were 5.5-24 N. In subjects with removable appliances, no active intrusion of teeth is possible during the night owing to the small number of occlusal contacts. Due to the partially very high forces in fixed appliance therapy, the integration of an anterior bite plane has to be assessed as critical in patients with unfavorable root geometry or bruxism.

2: Int J Prosthodont. 2000 Nov-Dec;13(6):480-6.
Vertical position, rotation, and tipping of molars without antagonists.
Kiliaridis S, Lyka I, Friede H, Carlsson GE, Ahlqwist M.

There has been a general belief that permanent teeth without antagonists overerupt, creating, after some time, considerable clinical problems. However, very few studies in the literature support this statement. The purpose of this investigation was to examine the position of molars that had been unopposed for a long period and to test the hypothesis that overeruption does affect every tooth without an antagonist.

Fifty-three individuals were examined clinically, and dental casts were taken to evaluate the position of unopposed molars. There were 84 molars (61 in the maxilla and 23 in the mandible) with a documented period of at least 10 years without antagonists. Among these teeth, 25 molars had neither an antagonist nor a mesially adjacent tooth. A qualitative method was used to evaluate the position of the molars in the vertical direction: (1) teeth with no sign of overeruption, (2) teeth with slight overeruption (< 2 mm), and (3) teeth with moderate to severe overeruption (> or = 2 mm).

Of the 84 molars examined, 15 teeth (18%) revealed no signs of overeruption, 49 teeth (58%)displayed overeruption of less than 2 mm, and 20 teeth (24%) showed moderate to severe overeruption. Individuals with molars that had lost their antagonists in adult age had a lower risk for overeruption than the other subjects examined.

It is concluded that not all molars without antagonists overerupt, not even in a longterm perspective.