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Surface Electromyographic Evaluation of Nocturnal Masticatory Muscle Activity

A Thesis Submitted to the Faculty of the Graduate School

of the University of Minnesota

By

Randall Judson McDaniel, D.M.D.

In Partial Fulfillment of the Requirements for the Degree of

Master of Science in Dentistry

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Abstract

Research has demonstrated a strong correlation between diurnal oral parafunctional activities and signs and symptoms of TMD. It is widely accepted that morning jaw pain is a result of nocturnal oral parafunctional activity, but to date, no cause and effect relationship has been demonstrated. This preliminary investigation used a portable EMG system to record all nocturnal masseter and ipsilateral temporalis muscle activity to a notebook computer. Twenty subjects were enrolled, ten into a morning jaw muscle pain group (JP) and ten into a non-pain control group (NJP). All subjects received a clinical examination to include the Cranio-Mandibular Index (CMI) and Symptom Severity Index (SSI). A baseline clinical measurement (BCM) was obtained by having each subject maximally clench three times and recording the average. Each subject was requested to wear the EMG electrodes for ten nights of data. The data were analyzed with EMG graphing software to determine the percent of time each subject spent below the 15%, 20%, 40%, 60% and 80% levels of the BCM. A 2-sample t-test was performed to compare the JP and NJP groups at each percent level, group BCM mean values, group mean ages, gender, mean recorded minutes and total recorded minutes. No statistically significant difference was found with any of the above parameters, including the percent of BCM levels. Based on this study the JP and NJP groups were not different with respect to the duration of nocturnal masticatory muscle activity and specific intensity levels. Difficulties were encountered with electrode pad disconnections possibly contributing to the excessive intra-group variability and inter-group overlap.

UNIVERSITY OF MINNESOTA

This is to certify that I have examined this copy of a master's thesis by

Randall Judson McDaniel

And have found that it is complete and satisfactory in all respects,
And that any and all revisions required by the final
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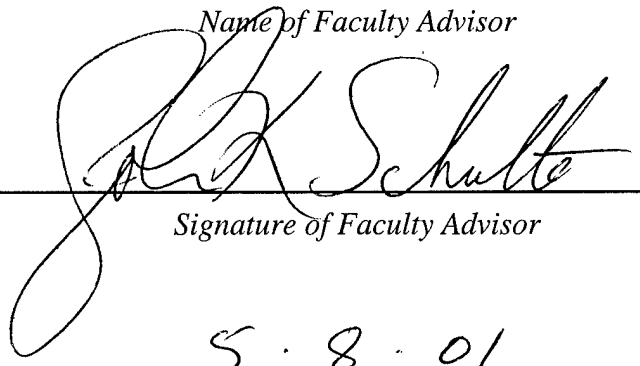
John Schulte

Name of Faculty Advisor



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Dr. John Schulte

Dr. James Fricton

Dr. Jim Hodges

Table of Contents

List of Figures

List of Tables

1. Introduction and literature review

The American Academy of Orofacial Pain (1) has recently defined bruxism, an often-implicated component of temporomandibular disorders, as "diurnal or nocturnal parafunctional activity including clenching, bracing, gnashing, and grinding of the teeth". This general bruxism definition does not attempt to distinguish diurnal, awake, from nocturnal, sleep, bruxism. Studies to connect the signs and symptoms of masticatory myofascial pain, jaw pain (JP) with bruxism have suggested a relationship, but to date, none has definitively asserted a cause and effect association (2,3,4). Although evaluation methods to identify sleep bruxism are numerous, most are subjective measurements analyzing the result of the action rather than objectively recognizing the activity. Controversy and confusion over the importance of bruxism to the etiology of JP, as well as its progression, has led to continued investigation to objectively identify and link sleep bruxism to JP.

Research findings by Magnusson et al. (3), that bruxism is more common in JP patients than in the non-JP population, support the notion that there is an association. The authors followed 293 subjects longitudinally over a 10-year period. Signs and symptoms of craniomandibular dysfunction increased as oral habits increased. A number of studies find TMD signs and symptoms positively correlated with oral parafunctional movements (3,4,5). Each of these investigations evaluated individual oral habit levels as compared to craniomandibular signs and symptoms. Findings supported the hypothesis that those individuals with a greater number of oral habits suffered with significantly more craniomandibular sign and symptoms.

The prevalence of TMD in the general population has been well documented in the literature with one such study by Dworkin *et al.* (6) that performed an epidemiologic survey of adults enrolled in a large HMO and found an overall rate of TMD to be 12.1%; of this the female prevalence was 17.4%, and male prevalence was 9.3%. The rates of sleep bruxism are 6 – 12% in the general population and clenching is at 9.6% (6,7). Though these rates are parallel in number, the causal relationship between bruxism and TMD has not been clarified.

1.1. Bruxism detection methods

Most past and current methods of patient evaluation for sleep bruxism have measured the consequences thought to be a result of bruxism, but not the act itself. A common clinical assessment for parafunction involves monitoring an intraoral splint for wear or other signs of bruxism (9). Problems associated with this procedure include potential proprioceptive changes connected with the use of an intraoral device resulting in an alteration of behavior and bruxing patterns of the individual; subjective interpractitioner and intrapractitioner variability interpreting the wear data; and failure to identify a particular parafunctional habit with the fluctuating patterns of bruxism among individuals. A second method for identifying bruxism is by noting intraoral tooth wear. This method attempts to relate existing loss of tooth structure to bruxism, overlooking a multitude of potential confounding variables such as diet, chemical erosions, or facticial habits. Wear of the teeth measured over time by intraoral evaluation or monitored quantitatively with epoxy casts (10) may not be practical for the clinical environment needing an initial diagnosis or treatment protocol for the patient, and as well, wear identifies past events and may or may not be indicative of present activity.

Other sleep bruxism identification techniques can only be implemented in large treatment centers due to cost and degree of involvement with the particular analysis. These techniques include, but are not limited to, sleep laboratory electromyography (EMG) recordings and physiologic measurements of cardiovascular and pulmonary functions (11,12,13,14), as well as devices to quantify contact pressures between the dental arches. Among the weaknesses of these techniques are the artificiality of the sleep lab, the possibility that an intraoral device may replace normal behaviors with an induced variant and that bruxism cycles require multiple nights recordings that precludes the sleep lab because of costs.

1.2. Portable EMG devices

In response to the cost and unnatural sleep laboratory surroundings, home EMG recording systems have been adapted in some studies to measure muscle activity and bruxism during sleep (9,15). Critics of home EMG devices for monitoring bruxism have cited research demonstrating data variability owing to such factors as age, sex, height, skeletal type, subcutaneous fat, influences from normal physiological facial movements of swallowing and talking, and technical variables such as electrode placement (16,17,18,19). However, many of investigations have differentiated functional and parafunctional muscle activities utilizing computerized pattern recognition with acceptable reproducibility, sensitivity and specificity (20,21,22). In 1993, Bowley et al. (23) had normal subjects perform clenching activities over a specified time period, and data were recorded on a portable EMG device and the information was then transferred to polygraphic tracings through pulse identification. The data were then evaluated for reliability and validity among three "blind" scorers. The results

of this study showed reliability and validity. Gallo et al. investigated the ability to distinguish between chewing soft and hard food, swallowing, speaking, laughing, clenching, grinding and no activity, and found they could correctly identify the different muscle actions associated with each activity (24). Some studies have been implemented with patients trained to perform the muscle activities to be measured, in addition they have employed a threshold on the EMG device that is above the normal physiologic movements (facial expression, swallowing, smiling and others) in an attempt to measure oral parafunction, so that only those muscle activities that exceeded the threshold were recorded (11,13,25). There is concern that if the threshold is set excessively low differentiation of oral and facial functional activities from bruxism events will not be possible and if set high, bruxism events will be missed (26). An unpublished preliminary study by Acosta-Ortiz and Schulte (27) sought to determine differences between functional and parafunctional activities in healthy subjects. Subjects in the Acosta-Ortiz study were not trained for the various requested tasks, and no predetermined threshold above physiologic movement was employed. The patients performed a total of three recording sessions in a clinical setting spread over at least a ten-day period. Each were asked to perform maximum clenching, right side chewing, left side chewing, grinding soft and hard with the anterior teeth, grinding soft and hard with the posterior teeth on the right and left side, tapping their teeth together, smiling, pushing the tongue against the teeth, speaking and resting. EMG recordings were obtained for the temporalis and masseter muscles bilaterally during the events. The EMG results were quantified by Biopack software, which displayed the values on the computer screen. The result was a relatively high level of sensitivity and specificity for differentiation of the

functional activities (rest, swallowing, tongue movements, smiling, and speaking) and parafunctional (tooth tapping, clenching, grinding hard and chewing) activities. When statistical analyses were performed to adjust outcome variables for weight, height, and age there were no statistical influences from these factors identified.

1.3. Quantifying bruxism events

Nocturnal bruxism events and bruxism duration vary widely with respect to current published data (9, 10, 11, 12, 13, 14, 15, 19, 22, 23, 24, 25, 26, 29, 31, 32, 33, 34, 36). Much of the discrepancy may relate to a lack of standards with respect to bruxism definitions, pre-study threshold levels attempting to eliminate functional and parafunctional crossover, diverse equipment used for EMG measurements, different refractory periods separating events or environments for sleep study application. In addition, previous investigations employed a baseline clench measurement defining a minimum threshold, labeling activity in excess of this measurement a bruxism or parafunctional event.

Among the available EMG research about the duration of a brux event, a trial of six males with no jaw pain showed that conscious masseter static contractile activity led to muscle fatigue at approximately 30 seconds duration, though the particular amplitude (intensity) of nocturnal brux events have not been reported for a sustained duration (28). Above or below the predetermined baseline is primary inclusion factor of an event. Over a 24-hour period tooth-to-tooth contact has been observed at about 17 ½ minutes, with 1.3 of the minutes occurring during sleep and the remainder while awake (29). For an 8-hour sleep period,

Brewer and Hudson (30) reported tooth contact to be 3 minutes to 2.5 hours. Kydd and Daly (31), recording bruxism events and duration, found an 11.4-minute total mean duration while single episodes typically lasted 20 – 40 seconds each. In 1968 Reding (32) described brux events to be 9 seconds on average. The 1990 study by Okeson et al., published EMG nocturnal parafunctional activity findings in a geriatric population. Predetermined parameters included a minimum threshold of 40% of the maximum voluntary clenching level to eliminate functional activities, such as swallowing, which was reported as approximately 30% of the voluntary clench level. Also an event had to last greater than 2 seconds to be classified a brux event. The result was an average 3.03 events per hour within this population and event average length was 5.95 seconds while the range was 2 – 375 seconds (6.25 minutes). Ikeda et al. (33), reporting on a variety of threshold levels, found on average, an event to last 3 to 73 seconds, and a 1984 study by Clark et al. (34) stated that bruxism events lasted 3.0 to 16 seconds per event using a predetermined 2 second minimum duration and 1 second interval minimum between events.

1.4. Sleep Latency

Sleep latency, the time for a patient to fall asleep, is rarely reported. Many EMG investigations are performed in a sleep laboratory where sleep onset is easily determinable. For home EMG studies, compensation should be made for the sleep latency period though no standard presently exists within the parameters of oral muscle activity EMG measurement studies. Once again a definition conundrum presents itself; how to measure this period? Describing sleep latency as the period from sleep preparation to sleep would certainly be

different from a measuring sleep latency as from lights out to sleep onset. As one might imagine this will be highly variable from one individual to the next, not to mention the possible variances that may exist in diverse patient populations such as pain groups. A 1995 publication by Ellis, Lemmens and Parkes (35) evaluating pre-sleep behaviour in normal subjects reported sleep latency, the lights out to sleep period, to have a mean of 26 minutes +/- 45 minutes.

2. Study Objective

2.1. Study Objectives

With identification of sleep bruxism from oral and facial functional movements being the ultimate goal, reproducible sleep studies under the most natural conditions comparing JP patients with a non-JP control group are warranted. The objective of the present preliminary study is to use a portable home EMG device to provide continuous monitoring and recording of all EMG activity with respect to amplitude, the intensity of the activity measured, through the entire sleep phase. This study is based on the assumption that there is no difference in the functional activity among JP patients and the JP pain controls. For the purposes of this pilot study, sleep (nocturnal) bruxism is defined as oral parafunctional activity; tooth tapping, tongue thrusting against the teeth, clenching, grinding hard and chewing. The data collected by Acosta and Schulte showed the parafunctional activity (tooth tapping, grinding, grinding hard, chewing, clenching) intensity of the individual subjects to be between 27.6% and 81.9% (mean of 37.3%) of the Baseline Clinical Measurement (BCM), a measurement of an awake maximum clenching or maximum voluntary clenching as often referred to in the literature (26, 28, 33, 34, 36) Functional activity (resting, swallowing, tongue movements, smiling, speaking) for these same subjects was 1.7% to 11.9% (mean of 6.5%) of maximum clenching. It is widely accepted among researchers and clinicians that morning jaw pain is related to increased masticatory muscle activity during sleep in the form of bruxism and/or clenching. The authors are not aware of research showing this to be true. The project by Acosta and Shulte provides a method to distinguish parafunctional from functional activities

in healthy individuals. This preliminary study will make statistical comparison between a morning (JP) group and a non-JP (NJP) groups.

2.2. Null Hypothesis

The operating primary null hypothesis is that no difference exists between these two populations with respect to the duration each group spends in the functional range of temporalis and masseter muscle activity. Nocturnal EMG activity will be measured as to the percentage of sleep time each group spends in the orofacial activity functional range.

2.3. Alternative Hypothesis

A difference exists between the two groups according to recorded muscle activity in the functional range while sleeping.

3. Methods

3.1. Subject Selection

Twenty human subjects between 18 and 65 years of age were recruited through advertisements placed throughout the University of Minnesota Medical and Dental School system. Prior study approval was obtained through the University of Minnesota Medical Center Institutional Review Board: Human Subjects Committee. All subjects were screened through a brief telephone interview and individuals appearing appropriate for enrollment were scheduled for a clinical evaluation. The clinical appointment consisted of completion of the University of Minnesota Dental Clinic Medical and Dental Information Questionnaire, review of the medical history with the patient, subjective TMD history, completion of the University of Minnesota TMJ and Orofacial Pain Department's written screening questionnaire, completion of the IMPATH:TMJ and written consent for study participation. Evaluation based on the Craniomandibular Index - Research Diagnostic Criteria (CMI-RDC) for TMJ and Orofacial Pain was performed on each of the twenty subjects in the University of Minnesota Dental School's Department of TMJ and Orofacial Pain Clinic. Subjects were recruited for assignment to the morning jaw pain (JP) group or to the group with no morning jaw pain (NJP). Ten subjects were assigned to each group and were age and sex matched. Exclusion criteria for the NJP group included those subjects that were unable to read and write English, were pregnant, subjects that had experienced cutaneous local irritation or allergies to adhesives (i.e. Band-aids, adhesive tapes, EKG/EEG/EMG/EOG adhesive pads etc.); or had a history and/or treatment for any of the following: morning jaw muscle pain (masseter or temporalis), myofascial pain disorders, fibromyalgia, headache disorders, sleep

apnea, autoimmune disorders, arthralgias (any joint disorder), neurological disorders, vascular disorders, temporal arteritis, trauma to the head and/or neck region, taking medications for sleep, pain control, psychiatric behaviors, psychiatric disorders, steroids or recreational drugs and any other significant medical finding or disorder. The ten JP subjects also completed the same written questionnaire and clinical examination. Those included for the study as JP subjects were eliminated using the same exclusion criteria as the NJP group, except that morning jaw muscle pain became an inclusionary stipulation. Also the JP subjects had to experience daily morning jaw pain with a minimal intensity of 4 as measured on a 0 – 10 visual analog scale. Assessment of the above was through the subjective patient history, the University of Minnesota Dental Clinic Medical and Dental Information Questionnaire and the CMI-RDC questionnaire.

3.2. Electrophysiologic Recording

The data were recorded on a portable BioEMG system consisting of an electromyographic device and electromyographic amplifier (Bioresearch Inc., Milwaukee, Wisconsin, USA) connected to a Compaq Presario1200 notebook personal computer (Compaq Computer Corporation, Houston, Texas, USA) running *Windows* (Microsoft Corporation, Redmond, Washington, USA) (25). EMG leads and electrodes were commercially available standard EMG (surface) electrodes and leads. The four channel amplifier has a bandwidth of 30 to 600 Hz, an impedance >100 million (10^8) ohms and input range of 1550 microvolts (peak to peak). The common mode rejection ratio is >120 dB (dc to 60 Hz, falling off to >105 at 500 Hz) and the common mode voltage range from –6.5 to +6.5 volts dc. Analog to digital

conversion is performed at a sampling rate of 1,000 samples per second per channel with a maximum resolution of 0.625 microvolts per bit. There is an additional 26 dB of 60 Hz noise reduction from the program, reducing record line-frequency interference by 95% in the EMG signals. The digitized data of the BioEMG signals were stored directly into the computer software, BioPAK (Bioresearch Inc., Milwaukee, WI, USA) (25). The clinician performing the examination, following the protocol of Acosta and Schulte, obtained a clinical determination of the BCM level while each subject sat in the upright position of a standard dental chair. Each were instructed, "clench your teeth together as hard as you can and hold". The measurements were taken as the subject's masseter, ipsilateral sternocleidomastoid (used by the EMG system as a reference electrode) and contralateral temporalis muscles were connected to the EMG and notebook computer system. The BCM level was measured three consecutive times and the software recorded the average of the three masseter muscle levels as the masseter BCM (BCM-M) and the average of the three temporalis muscle levels as the temporalis BCM (BCM-T). These EMG levels established as BCM-M and BCM-T for that particular patient were used for all ten nights' data comparison.

Each of the 20 subjects was trained in the setup, utilization and shutdown of the notebook computer, BioEMG device and amplifier, as well as skin site preparation, electrode pad placement and connection of the electrode leads. The subjects also, during the clinical examination appointment, demonstrated proficiency and consistency in all aspects and each were provided with written instructions that included electrode pad placement diagrams.

3.2.1 System Reliability

Acosta and Schulte (25) evaluated the BioEMG and BioPAK systems for reliability. Analysis was accomplished with intra-class correlation measures. The intra-class correlation was greater than 99% for each channel.

3.2.2. Recording Technique

Each of the 20 subjects provided ten nights sampling of continuous electrophysiologic EMG activity. One TMJ and Orofacial Pain provider conducted all subject training, giving the same instructions of proper placement of a 2-lead EMG electrode over an anterior temporalis muscle (chosen with the flip of a coin), a 2-lead electrode over the contralateral masseter muscle and a 1-lead electrode over the mid-anterior surface of the sternocleidomastoid muscle of the same side as the masseter lead. The subjects then demonstrated proficiency in system set-up and operation. Self-Adhesive, disposable, pregelled silver-silver chloride, bipolar electrode pads (25) were placed at bedtime with the assistance of a mirror. The skin was cleansed with prepackaged gauze pads containing 70% isopropyl alcohol (Triad Disposables, Inc., H&P Industries Inc, Mukwonago, Wisconsin, USA) prior to electrode placement and allowed to dry to reduce impedance (25). Upon completion of the ten night recordings, subjects returned the EMG system with all accessory components.

3.2.3. Software Data Analysis

The data was viewed with EMGVIEW software (Bioresearch Inc., Milwaukee, WI, USA). The EMGVIEW software displays a graph of the EMG masseter and temporalis muscle

activity for each sleep period and a summary of the muscle activity expressed as percent of activity compared to the BCM of each muscle. The summary included total sleep time and sleep time minus the first thirty minutes of recordings to compensate for sleep latency, which was established by convention as 30 minutes. This thirty-minute period was not included in the data analyses. A period of 120 minutes (2 hours) was subjectively selected as the minimal period of time that must be recorded for a particular night to be included for evaluation. Also the software listed the percentage of time the subject's EMG recordings were below 15% and above 15% for each respective muscle as compared to the respective BCM. The 15% level was based on the findings of Acosta and Schulte separating oral functional and parafunctional muscle activity. Percents of muscle activity below 20%, 40%, 60% and 80% were calculated as well. The 40% parameter is similar to the threshold selected by Okeson et al., with the rationale of exceeding the functional activity of swallowing. Functional and parafunctional muscle activity parameters established in the awake subject in a clinical environment may be grossly different than activity of the natural sleep environment of the subject's own bedroom and therefore, the additional muscle activity levels were empirically included for statistical evaluation.

3.3. Statistical Analysis

3.3.1. Hypothesis Calculations

Analysis of the primary hypothesis of functional activity times at the 15%, 20%, 40% 60% and 80% levels with respect to the BCM, group temporalis and masseter BCM and the age and sex comparisons were calculated using 2-sample t-tests. Significance was assessed at the

conventional 0.05 level (i.e., $p<0.05$). An alternative analysis was performed weighting individual night data according to the number of minutes recorded. However, results of the weighted analysis were very similar to the simple t-test referenced above, therefore only the results of the t-test are presented.

4. Results

4.1. Telephone Screening

Fifty-eight individuals called for telephone interview. Twenty-two subjects were selected for clinical evaluation following the telephone screening. Of the subjects accepted for clinical evaluation two were rejected from participation. Despite telephone screening for present or past temporomandibular disorder treatment, one person, during the subjective history portion of the clinical evaluation, admitted to present treatment for TMD and therefore was excluded from study participation. One additional person was excluded due to a recent diagnosis of fibromyalgia at the Mayo Clinic of Rochester, Minnesota. The fibromyalgia diagnosis came after the telephone screening, but prior to the clinical evaluation appointment. Both subjects excluded from study participation were accepted for treatment at the University of Minnesota Dental School, TMJ and Orofacial Pain Clinic.

4.2. Subject Demographics

The patients were predominantly female. Of the twenty study subjects accepted for participation there were 4 males and 16 females. Each group, JP and NJP, consisted of 8 females and 2 males. Male and female subject data were combined based on findings that no differences in bruxing patterns could be identified based on subject gender (33). The youngest participant was 21 years of age and the oldest 56 years of age (Table 1). Jaw Pain subjects ranged in age from 21 years to 56 years of age and NJP subject ages were from 22 to 53 years. Overall mean age was 36.6 years, while JP and NJP subject mean ages were 35 and

38.2 years respectively. No statistically significant difference was found between the 2 groups with respect to age ($p = 0.55$) or gender distribution ($p = 1.0$).

Table 1. Subject Group, Subject Numbers, Sex and Age

JP-subject #	Sex	Age	NJP-subject #	Sex	Age
1	M	27	1	M	33
2	F	38	2	F	22
3	F	21	3	F	33
4	M	56	4	F	46
5	F	33	5	F	46
6	F	43	6	F	45
7	F	24	7	M	34
8	F	21	8	F	45
9	F	55	9	F	53
10	F	32	10	F	25
Average		35.0			38.2

4.3. Baseline Recordings

At baseline the JP group average BCM was 115.7 and the NJP group average was 140.0. Between group comparison of temporalis muscle BCM (BCM-T) resulted in a P-value of 0.25, while the masseter BCM (BCM-M) P-value was 0.082. Though electromyographic recordings of masseter and temporalis muscle activity intensity varies widely from individual to individual, statistical comparison of JP versus NJP subjects in this investigation found no significant difference in initial group BCM values.

4.4. Subjective Patient Report

Three Symptom Severity Index (SSI) questions of the Craniomandibular Index – Research Diagnostic Criteria (CMI-RDC) Questionnaire were answered by the JP group at the initial clinical evaluation. The exclusion criteria dictated that JP subjects experience morning jaw pain (PI) at a minimum level of 4 on a 0 – 10 visual analog scale (VAS) at the time of the telephone interview and clinical examination. There were no minimum standards established for the two remaining SSI questions; duration of facial pain (DFP), recorded in months, and interference in daily activities (IDA), measured by VAS (Table 2). The PI ranged from 4mm to 8mm on the VAS with a 5.1mm mean. Range of DFP was 3 to 180 months with a 53.7 months mean duration of facial pain, and IDA mean was 3.3 and ranged 0 to 8mm on the VAS. The PI, DFP and IDA, per the predetermined exclusion criteria, were all 0 in the control group. No between group comparison calculations or reports were justified due to the obvious nature of the outcome.

Table 2 lists the PI, IDA and DFP reported at the initial clinical examination for the subjects with jaw pain (JP). These measurements are all 0 for the controls (NJP) and are therefore not listed below.

Table 2. JP Initial Subjective Reports

JP – Subject #	PI (VAS)	IDA (months)	DFP (VAS)
1	4	4	24
2	5	4	180
3	4	0	36
4	6	4	30
5	6	2	84
6	2	1	60
7	8	8	72
8	4	3	3
9	8	5	24
10	4	2	24
Average	5.1	3.3	53.7

4.5. Study Period

Each participant was given written instructions that included provider telephone numbers, ensuring 24-hour per day availability. Subjects with questions and concerns contacted providers twice over the course of the study. The first caller inquired as to the minimum sleep time per night required for the study. Study instructions requested each subject to wear the sleep apparatus during their entire sleep period, though minimum time standards were not dictated. The second call involved a computer error message that occurred while accessing the EMG sleep software. The difficulty was resolved via telephone and the patient continued without further computer complications.

4.5.1. Acquired Data

One hundred and eighty-seven nights of sleep data were acquired, 94 from the NJP group and 93 from the JP subjects. Of the twenty subjects, 11 provided ten complete nights of data, 6 from the NJP and 5 of the JP individuals (Table 3). The most common error resulting in exclusion of data was an apparatus disconnect. Patients reported electrode pad disconnect to be the most common drawback of the system while disengagement of the EMG device from the notebook computer PC Card Port and EMG interface was the second most frequently encountered fault.

4.5.2. Sleep Duration

Total sleep time for the twenty subjects was 66,739 minutes with an average of 356.9 minutes (5.95 hours) per night. Time included for data analysis was 31,928 minutes for the JP group, a 343.3 minute per night average (5.72 hours), and 34,811 minutes for NJP subjects, 370.3 minutes per night average (6.17 hours). No statistical significant difference existed between the two groups with respect to analyzed sleep time ($p = 0.31$).

Table 3. Duration of Recorded Sleep

JP subject #	nights of data	minutes
1	9	3,057
2	9	1,976
3	10	3,523
4	7	1,631
5	10	3,170
6	9	3,267
7	10	3,442
8	10	4,652
9	9	2,644
10	10	4,566
Total	93	31,928
Per night Mean		343.3

NJP subject #	nights of data	minutes
1	10	3,470
2	9	2,584
3	10	3,647
4	8	3,349
5	10	3,208
6	9	3,674
7	8	2,662
8	10	3,878
9	10	4,638
10	10	3,701
Total	94	34,811
Per night Mean		370.3

4.5.3. Functional Activity Time

According to the Acosta and Schulte findings, conscious healthy subjects performed functional orofacial muscle activities at a level below 15% of the BCM. The present investigation found temporalis EMG muscle activity to be below 15% of the BCM 54.8% of the time for JP subjects and 63.8% of the time for NJP (control) subjects. Though the JP group performed less in the functional range (had greater duration of parafunctional activity) statistical comparison of this parameter between groups ($p = 0.49$) found no significant difference.

Similarly, between-group comparison of masseter muscle activity below 15% BCM also found no statistically significant difference ($p = 0.43$). Sixty-five percent of masseter activity was below 15% BCM in the JP group while the NJP activity was below 15% BCM 68.8% of the time (Figures 1 and 2). The remaining variables of fraction of time below 20%, 40%,

60% and 80% of BCM did not differ between JP and NJP groups (Table 5). Though statistical significance was negative in all levels evaluated, a trend existed in that the JP group maintained less functional activity at each of the evaluated levels (Figures 1 and 2). Not only was there a lack of statistical significance between groups with the temporalis and masseter activity below 15% of BCM, but also the intragroup variability and intergroup overlap was extensive (Tables 4a and 4b).

Figure 1. Group Temporalis Muscle Activity Comparison

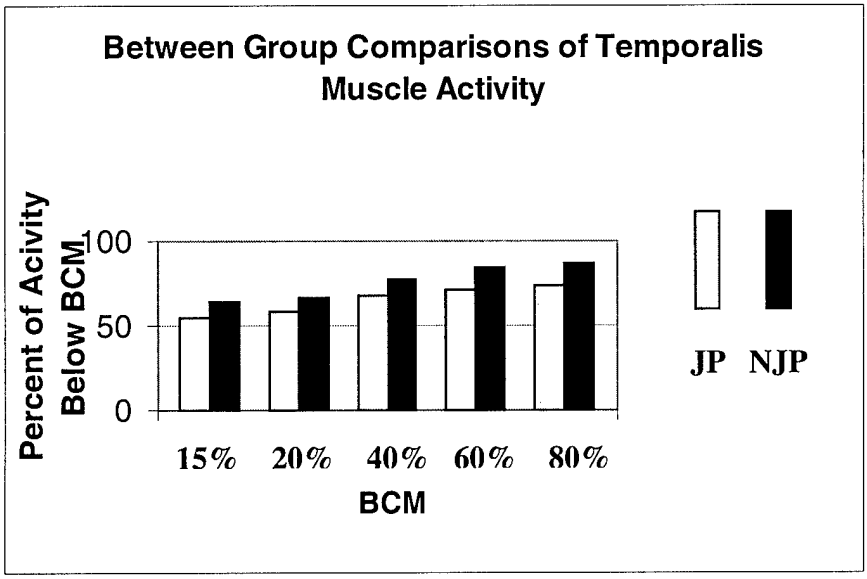

Figure 2. Group Masseter Muscle Activity Comparison

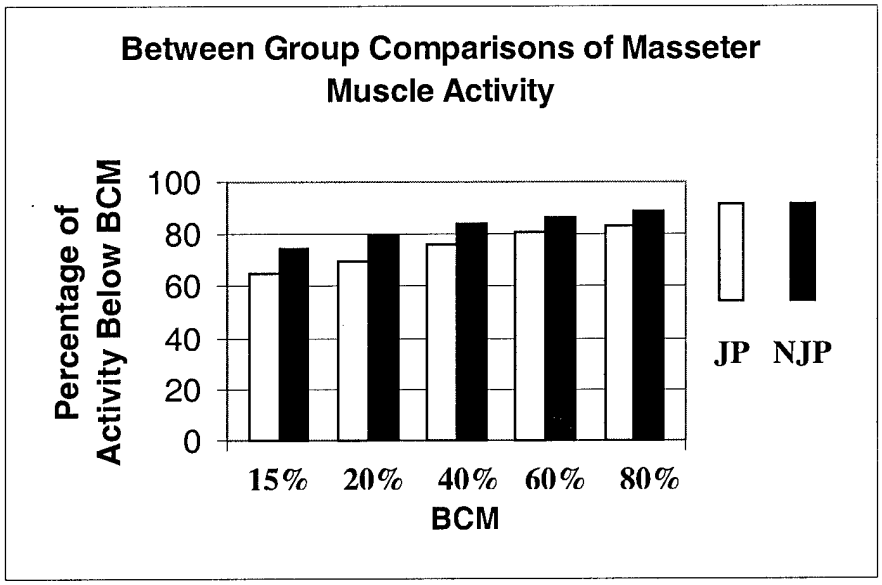

Table 4a. Average T < 15% by group.

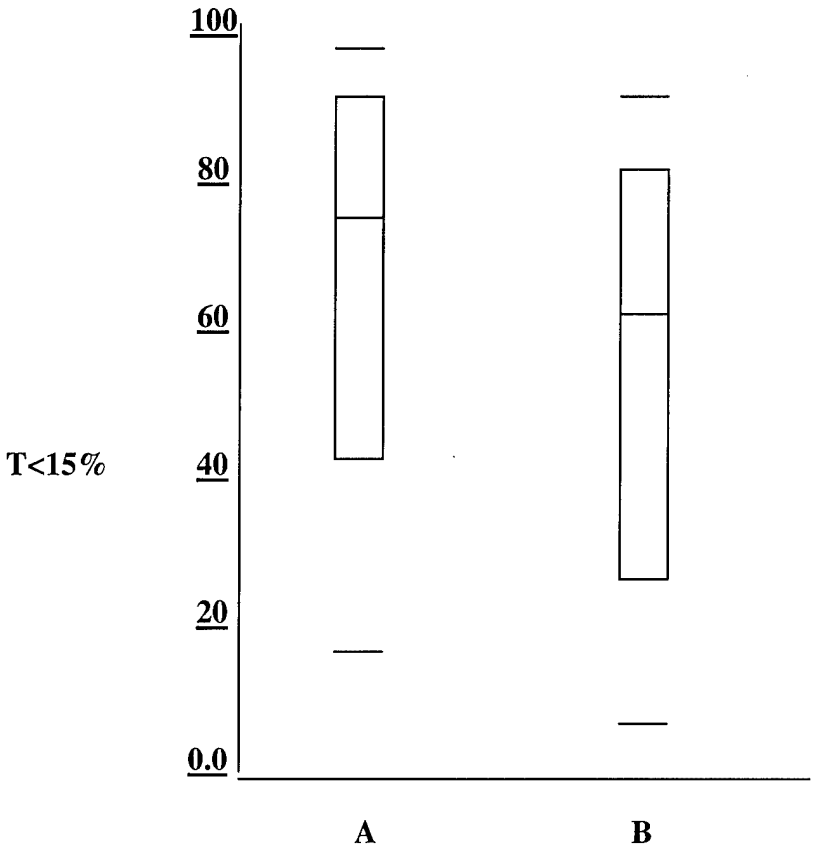

Table 4b. Average M < 15% by group.

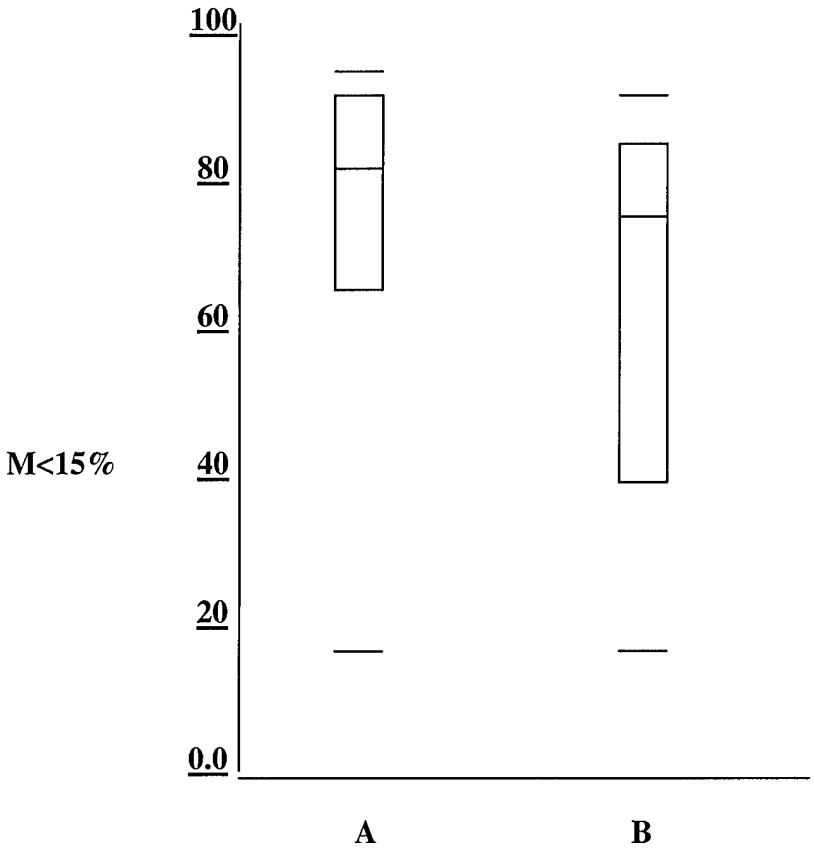

Table 5. Group Comparisons at Each Percent Level

	15% T	15% M	20% T	20% M	40% T	40% M	60% T	60% M	80% T	80% M
JP	54.8	64.9	58.6	69.6	67.6	76.0	71.3	80.8	73.6	83.2
NJP	63.8	74.5	66.9	79.2	77.7	84.5	84.0	86.6	86.6	88.5
JPvsNJP P-value	0.49	0.42	0.52	0.42	0.34	0.42	0.17	0.53	0.12	0.51

4.6. Adverse Events

Adverse events are rarely encountered in electromyography investigations. Literature review and discussions with local EMG experts elicited the possibility of a skin rash as the major risk factor consequent to electrode pad placement. The exclusion criteria as well as the IRB-approved consent form addressed and screened subjects for previous cutaneous local irritations and allergies following electrode pad placement, adhesive tapes and/or band-aids. Of the twenty subjects accepted for participation, none reported a positive history for cutaneous lesions or allergies consequential to adhesives, nor did any subject experience an adverse event secondary to electrode pad placement during this study. No adverse events were reported from any of the 20 patients during or following the study.

4.6.1. Sleep Interference

Though sleep quantity or quality was not initially established as an outcome measure, each participant was subjectively questioned as to interference with sleep secondary to equipment set-up and utilization. Of the twenty subjects, four stated that the leads had a significant deleterious effect upon sleep. Three of the four patients experiencing sleep disturbance, per their own account, reported the interruption to be for the first few days, while the fourth subject reported encountering sleep difficulty throughout the ten-night study period.

4.6.2. Computer Novice, JP Subject #4

One individual, subject #4 of the JP group, had never used a computer prior to this study. Following study completion this subject reported that the provided initial EMG and computer system orientation, along with the written instructions, were sufficient with no problems experienced during the study period. Upon data review, this subject possessed the greatest amount of data being removed from evaluation. It is unknown if this resulted from lack of computer familiarity.

5. Discussion

The patients were predominately female, 16 were female and 4 were male. This is characteristic of a TMJ and Orofacial Pain clinical environment in that the majority of patients are female.

Despite the small sample size in this preliminary investigation, statistical analysis reveals that an increased sample size would not appropriately address the problem of distinguishing between the JP and NJP groups based on nocturnal muscle activity. Specifically, this study design resulted in excessive intra-group variability and extensive inter-group overlap. This removes the possibility of clinical relevance in that, based on the current design and data, it would not be possible to reliably categorize an individual to one group or the other when viewing only the nocturnal muscle activity.

One might expect that voluntary clenching force by persons experiencing waking jaw pain would be reduced relative to persons without jaw pain. This was not demonstrated in this sample population, as there was no significant difference in initial BCM recordings between the JP and NJP groups.

The errors of electrode disconnection presented additional difficulties in identifying functional activities. Following a complete disconnect, the data recordings of muscle activity were persistent repeating numbers and therefore a disconnection was easily recognizable by means of the EMG graphing software. A more difficult situation presented with prolonged

periods of extremely high recordings. Subsequent hardware and software developer consultations concluded that the most plausible explanation was an incomplete disconnect. Prefabricated electrode pads for study use were pre-gelled with a center sensor and conducting medium to detect the muscle electrical activity surrounded by the pad and adhesive. It is conceivable that, though the pad remained adhered to the skin, the sensor could lose intimate contact with the skin and insufficiently conduct electrical muscle activity to the recording apparatus. These areas could not be masked from calculation, as to the authors' knowledge, no standard exists as to the intensity level and duration at which an individual may sustain nocturnal muscle activity relative to a BCM. Therefore it could not be determined from the present study whether a prolonged high intensity recording was the result of excessive parafunction or apparatus error. In light of these occurrences, analyses continued under the unverifiable assumption that each group encountered roughly equal incomplete disconnect episodes. Although functional muscle activity times were not affected by the excessive recordings, the effect upon total measured muscle activity, if any, is uncertain.

5.1. Study Significance

In clinical practice morning jaw pain is frequently diagnosed as resulting from nocturnal bruxism, though there appears to be no literature describing continuous recordings of orofacial muscle activity comparing morning jaw pain subjects with healthy control subjects. Previous investigations attempted to establish baseline thresholds as well as determine parameters to further classify the inclusion criteria for data collection. This study attempted

data recording at one-second intervals, regardless of intensity or duration, over the entire sleep cycle in the subject's home environment. The goal was to use the mean of three conscious maximum clenching levels (BCM) as a baseline for which to compare the collected data. Computer software measured the duration of temporalis and masseter muscle EMG activity below various intensity levels labeled as a percent of the BCM (i.e. 15%, 20%, 40%, 60%, and 80%).

The literature is equivocal about a standard EMG amplitude threshold levels and a bruxism event definition. With no consensus available considerable variation in experimental design and data recording protocols creates confusion in interpreting or comparing diverse investigations. This preliminary study chose a level of 15% of the BCM based on the unpublished data by Acosta and Schulte, which found functional masseter and temporalis muscle activity to be 1.7% to 11.9% of the BCM and parafunction activity 27.6% to 81.9%. In this particular investigation untrained healthy individuals with no jaw pain were asked to perform the various functional and parafunctional activities while seated in an upright position in a standard dental chair. The present study baseline was selected to be 15%, a level between the functional and parafunctional levels of muscle activity. A threshold of 40% BCM has been used in an investigation by Okeson (26). Below 40% was selected by the authors based on previous studies in which swallowing activity occurred at less than 30% of maximum clenching effort. With known differences between diurnal and nocturnal orofacial musculature activity levels and patterns, we considered additional amplitude levels (i.e. 20%,

60% and 80%). Despite investigating further levels relative to BCM, significant differences between JP and NJP subjects were not identified.

5.2. Clinical Relevance

Present clinical treatment protocols for morning jaw pain are directed at etiology as of yet, not definitively identified by scientific investigation. Explicitly recognized etiologies for the morning jaw pain may enhance or alter current treatment regimens to more satisfying methods of patient pain management. In addition, future scientific investigations seeking superior management strategies using known etiologies would ultimately be more effective. Methods to identify differences in muscle activity levels between morning jaw pain subjects and those individuals without morning jaw pain may perhaps help in developing outcome measures comparing effectiveness of the existing treatments and pharmaceuticals. Also, known etiologies may assist researchers to identify risk factors and preventive modalities rather than relying on present measures addressing resultant disorders, namely, pain.

5.3. Study Methodology

This study was a clinical investigation comparing temporalis and contralateral masseter muscle EMG activity of a morning jaw pain group with that of a control, no morning jaw pain, group. Blinding of the investigating providers was unnecessary as no bias could be introduced during data collection or data evaluation. Data collection was accomplished via the previously described EMG device, EMG amplifier and personal notebook computer apparatus. Secondly, the acquired data then was imported directly into analyzing software.

Graphs and data summaries were displayed by the EMG software program including recording start date and time, recording ending date and time, mean temporalis and masseter BCM, total recorded time, recorded time minus the selected 30-minute compensated sleep latency period and temporalis and masseter muscle activity below the BCM (Appendix 1). Statistical analyses comparing JP and NJP BCM, age, sex, sleep duration and the levels of activity below 15%, 20%, 40%, 60% and 80% were performed as previously described.

5.4. Study Limitations

This study was a preliminary investigation, and therefore, due to the limited number of subjects the results must be viewed with caution. The interesting trend was that at each investigated level the NJP subjects maintained a greater duration of masseter and temporalis muscle activity in the functional range as defined by this study. However, the intergroup mean proximity, intergroup overlap and intragroup variability of duration below a particular fraction of BCM, precludes simply increasing the study sample size to obtain results with statistical or clinical relevance.

The present study design has inherent weaknesses that may have contributed to the extensive intragroup variability and intergroup overlap. One, acquiring a BCM entails that, under directions of the provider, an individual clench to a maximum effort. Evaluating nocturnal EMG data, subjects frequently and markedly exceeded conscious voluntary clenching levels, that is, the BCM. A conscious voluntary clenching level is possibly flawed as a tool for assessing nocturnal masticatory musculature EMG activity. Proprioception, as well as

learned behaviors and unknown factors, may inhibit clenching forces in the conscious subject, yet unconsciously physiologic controls may be reduced or completely inactive. Secondly, though past researchers found anatomical variances, such as subcutaneous adiposity, gender and age, not to have a statistically significant effect upon validity of masticatory muscle EMG recordings, their cumulative effect, plus possible voluntary clenching measure errors, may create enough noise variation as to remove the chance of obtaining significant and relevant findings.

5.4.1 Instructions for Sleep Duration

Shortcomings encountered during the study period deserve mention and some recommendations for improvement. First of all, at the initial clinical evaluation no information was ascertained concerning the subjects' present sleep patterns or typical sleep duration, nor were subjects directed to a required minimum sleep period for data validity. Obtaining initial sleep information and establishing loose guidelines may have enabled assessment of sleep interference secondary to equipment usage. Also, sleep diary appraisal could highlight differences, should they exist, between initial sleep patterns and latter nights possibly identifying an equipment adjustment period.

Subjects were directed to close the computer software program as soon as waking followed by removing the electrode pads. One subject volunteered that on one occasion during the night the electrode pads were removed due to sleep interference followed by the subject returning to sleep. Future EMG investigations should be more explicit with directions that the

subject must continue data recordings through the entire sleep period and not remove the electrodes and return to sleep. It is not known whether this occurred in additional subjects or had a significant effect on total muscle activity time recorded.

5.4.2. Instructions for Consecutive Night Recordings

Another shortcoming recognized after initiation of the study was that subjects were not directed to perform the study through 10 consecutive nights. Nine of the twenty subjects did not participate in a consecutive fashion, 5 in the JP group and 4 NJP subjects. Of the 9 persons with interrupted recording periods, 2 JP and 3 NJP subjects experienced 2 recording interruptions for a total of 14 disruptions over the course of this study. It is not known how this may have affected the study results. Future study directions should clearly define that subjects must be able to perform the data collection for 10 consecutive nights.

5.4.3. System Improvements

A major disadvantage encountered with the present study was system disconnect. As previously described (3.5.1. *Acquired Data*) multiple occurrences of incomplete and complete disconnections occurred during the study period. Deletion of 13 of the 200 nights of EMG data was the result. The authors suspect that the electrode pads and the connection at the EMG and computer PC Card Port interface were the weakest links. One subject did report difficulty securing electrode pads from a package previously opened by a preceding subject. Upon obtaining an electrode pad from a previously unopened package the problem was resolved and the pad adhered throughout the night. We are unaware of literature reporting

such events with the electrode pads. Prior to further use of the electrode pads these events should be reviewed with the manufacturer. Possible solutions include exchanging the present electrode pads with those from another manufacturer and/or have the pads packaged as single –use instead of multi-packaging. Another possibility is a technique used by some researchers that have technicians travel to the subjects home each night to cleanse and prepare the subject's skin and place the electrode pads each night. The advantage of this protocol is the adherence to stringent standards for pad placement as well as reproducibility in site selection each night. A significant disadvantage is the cost involved with the technician's salary and travel expenses as well as time involvement that would have increased the cost of the study by an estimated 50 to 75%.

5.5. Future Research

Per the recommendations stated above improvements and protocol design changes should be implemented prior to re-attempting this study. The shortcomings of pad design and subject use of the system warrants review along with possible enhancement of the notebook computer PC card port and EMG interface. Consistent with other studies, the findings here suggest that the extensive variability and lack of consensus regarding baseline measurements may perhaps be best served by the identification of new parameters to evaluate nocturnal bruxism.

In addition, future investigators should identify possible sources of variability. Eliminating these confounders may allow differences between the JP and NJP groups to be identified,

should they be present. Possible sources for variability include pad placement. The preparation and pad site should be improved to reduce the occurrence of disconnections. As stated, the PC port connection needs improvement to prevent disconnections at this point. Advantages over the present system may be gained by using a device that eliminates the wires to the electrodes and tension that may be caused by the patient movement while sleeping. Modern receptors and wireless systems may be possible with the EMG design.

6. Conclusions

In the present preliminary investigation no significant differences were identified with respect to age, sex, BCM and sleep recording duration between the JP and NJP groups. Nor was a significant difference present between the two groups in the percent of sleep time each spent below 15%, 20%, 40%, 60% and 80% of the BCM. Extensive variability and overlap among the two groups preclude using the present study design even with greater subject numbers.

Through future research employing improved study designs and advanced measuring devices, findings may reveal, as this study suggests, that a morning jaw pain group's nocturnal muscle activity levels are not significantly different than a control group without morning jaw pain. This may then indicate a factor other than nocturnal muscle activity responsible for morning jaw pain. Additional risk factors would necessitate investigation to identify why particular individuals are susceptible to developing morning jaw pain while others with similar or greater nocturnal muscle activity appear to be immune to morning jaw pain.

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8. Appendix 1. Subject Data Tables

8.1. JP Subject Number 1 (T-BCM = 182.8, M-BCM = 198.1)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	39.0	16.6	39.1	98.9	39.3	99.5	39.4	99.6	39.4	99.6
2	89.0	99.1	89.0	99.3	89.0	99.9	89.0	99.9	89.9	99.9
3	15.0	99.7	15.0	99.8	15.0	99.9	15.0	99.9	15.0	99.9
4	7.6	98.6	7.6	98.7	7.7	98.7	7.8	98.8	7.8	98.8
5	15.2	99.8	15.2	99.9	15.2	100	15.2	100	15.3	100
6	8.9	65.1	20.1	82	75	82.0	90.3	82.0	93.3	82.0
7	39.6	39.7	44.1	40.8	44.7	44.4	44.7	44.8	44.8	44.8
8*										
9	16.9	15.4	17.0	17.4	34.4	18.9	40.5	20.9	66.6	20.9
10	18.0	84.6	18.0	84.7	22.1	97.6	31.6	99.8	33.9	99.8

* Entire night voided – electrodes or system disconnect

8.2. JP Subject Number 2 (T-BCM = 72.9, M-BCM = 72.4)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	10.5	1.9	39.3	2.0	99.1	2.0	99.5	2.1	99.8	7.5
2	0.7	3.3	35.5	3.8	67.1	36.5	79.0	52.9	79.1	78.9
3	2.8	35.4	4.4	35.5	21.3	35.7	25.1	40.5	28.0	44.6
4	23.0	0.0	36.0	0.0	57.6	10.7	62.4	17.5	67.3	39.1
5	0.2	0.1	13.6	0.3	24.7	2.4	54.6	2.7	60.6	13.3
6*										
7	3.6	0.2	14.7	0.5	95.2	3.8	95.8	19.5	96.9	29.7
8	12.0	11.8	33.0	19.4	64.2	44.3	80.5	64.8	84.7	67.2
9	8.5	72.8	12.0	72.8	26.1	72.9	30.5	73.0	35.9	73.1
10	0.2	5.8	0.4	6.5	23.3	26.6	50.4	62.9	57.2	87.4

* Entire night voided – electrodes or system disconnect

8.3. JP Subject Number 3 (T-BCM = 155.5, M-BCM = 173.9)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	88.0	92.3	91.2	94.0	95.3	98.0	98.2	99.6	99.5	99.7
2	96.9	99.8	97.8	99.9	99.9	100	100	100	100	100
3	68.3	99.9	69.7	100	87.3	100	97.9	100	99.5	100
4	64.6	86.5	65.4	99.0	65.5	99.1	65.6	99.2	65.6	99.4
5	3.0	24.1	3.1	41.6	3.3	76.1	3.3	89.9	3.3	98.3
6	1.3	55.1	2.7	56.3	4.6	62.2	8.9	68.2	9.8	78.8
7	97.3	99.7	97.3	99.7	97.4	99.9	98.1	100	98.2	100
8	53.5	40.9	56.4	54.1	76.5	86.8	82.3	95.7	84.7	96.0
9	15.0	92.1	15.0	97.0	15.0	97.3	15.1	97.3	15.1	97.4
10	97.9	99.0	98.8	99.1	99.5	99.4	99.7	100	99.7	100

8.4. JP Subject Number 4 (T-BCM = 163.2, M-BCM = 184.9)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	95.7	69.5	97.3	70.4	98.6	71.0	99.3	84.3	99.3	85.6
2	77.1	76.9	78.0	78.3	92.8	84.0	99.0	93.0	99.7	96.6
3*										
4	92.8	89.7	93.0	92.0	93.7	99.1	99.7	99.7	99.7	99.7
5	71.8	71.6	91.8	72.8	99.1	80.9	100	99.7	100	100
6*										
7*										
8	99.6	99.8	99.8	99.9	100	100	100	100	100	100
9	37.6	59.5	37.7	83.8	80.5	94.8	90.4	99.4	96.4	99.5
10	96.3	94.1	97.7	97.5	98.5	98.7	99.2	99.5	99.8	99.5

* Entire night voided – electrodes or system disconnect

8.5. JP Subject Number 5 (T-BCM = 128.4, M-BCM = 137.7)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	86.9	99.4	87.2	99.6	87.6	99.9	87.7	100	87.7	100
2	96.1	99.2	96.3	99.5	96.7	99.9	96.9	100	97.0	100
3	99.5	99.8	99.6	99.9	99.9	100	100	100	100	100
4	99.2	98.5	99.5	99.4	99.9	99.9	100	100	100	100
5	99.2	99.4	99.4	99.6	99.8	99.9	99.9	100	100	100
6	99.1	99.7	99.4	99.8	99.9	100	100	100	100	100
7	99.4	99.5	99.6	99.7	100	99.9	100	100	100	100
8	99.4	99.7	99.6	99.8	99.9	100	99.9	100	100	100
9	3.4	3.6	3.4	4.5	8.5	34.8	24.2	75.5	60.7	94.7
10	99.0	99.5	99.3	99.7	99.8	99.9	100	100	100	100

8.6. JP Subject Number 6 (T-BCM = 147.8, M-BCM = 177.8)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	91.0	93.5	91.3	95.4	96.8	96.1	97.6	97.5	97.9	97.8
2*										
3	73.9	64.1	75.9	65.7	77.1	66.6	80.1	68.8	80.1	69.6
4	9.8	94.7	10.3	98.0	10.8	99.1	10.8	99.2	10.8	99.2
5	55.9	55.9	56.0	56.0	56.1	56.1	56.1	56.1	56.1	56.1
6	98.9	98.8	99.4	99.4	99.9	99.9	100	100	100	100
7	99.8	99.9	99.8	99.9	100	100	100	100	100	100
8	36.7	88.2	36.8	94.3	36.8	100	36.8	100	36.8	100
9	99.6	99.8	99.7	99.9	99.9	100	100	100	100	100
10	56.5	54.2	60.5	73.0	72.6	75.9	76.9	77.5	77.0	77.7

* Entire night voided – electrodes or system disconnect

8.7. JP Subject Number 7 (T-BCM = 192.8, M-BCM = 201.6)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	43.7	83.9	43.8	84.2	43.9	84.4	43.9	84.4	43.9	84.4
2	0.3	12.2	7.4	13.9	38.6	35.9	46.5	52.8	47.4	59.4
3	2.3	42.2	3.4	53.8	34.7	65.9	46.4	67.2	61.5	68.2
4	14.0	50.9	14.1	73.7	50.9	83.1	55.8	92.4	65.6	93.3
5	16.2	36.1	24.6	36.2	24.7	37.9	47.1	45.2	53.7	52.9
6	24.2	25.4	25.6	26.3	26.9	41.8	47.3	50.8	58.1	51.4
7	31.8	24.6	32.1	28.5	53.1	30.4	54.4	32.8	61.2	46.0
8	13.6	17.4	18.6	18.5	36.1	55.3	50.3	82.0	59.1	91.3
9	17.6	17.6	17.6	17.6	23.9	34.7	34.7	34.7	34.7	34.9
10	13.0	6.5	23.0	15.7	23.8	15.7	24.1	66.1	24.2	70.1

8.8. JP Subject Number 8 (T-BCM = 81.2, M-BCM = 79.5)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	92.0	97.1	98.0	97.7	98.9	98.6	98.9	98.8	99.0	98.9
2	99.1	99.1	99.4	99.4	99.8	99.7	99.8	99.9	99.9	99.9
3	78.9	64.7	89.4	66.4	99.7	77.2	99.8	92.1	100	97.9
4	71.4	82.4	79.6	82.6	91.0	83.7	91.2	85.1	92.9	85.2
5	75.2	99.0	75.4	99.3	75.6	99.7	75.7	99.8	75.8	99.9
6	83.8	99.3	99.2	99.5	99.9	99.9	99.9	99.9	100	100
7	69.7	98.9	71.2	99.2	99.4	99.7	99.7	99.9	99.8	99.9
8	98.7	98.8	99.1	99.2	99.7	99.7	99.8	99.8	99.9	99.9
9	99.2	99.3	99.4	99.5	99.8	99.8	99.8	99.8	99.9	99.9
10	14.1	99.2	14.1	99.5	14.1	99.9	14.1	100	14.1	100

8.9. JP Subject Number 9 (T-BCM = 182.4, M-BCM = 216.4)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	98.1	98.2	98.3	98.4	98.6	98.6	98.6	98.6	98.6	98.6
2*										
3	96.8	0.5	96.9	0.6	97.5	50.2	97.9	70.1	97.9	77.2
4	97.9	98.3	98.1	98.5	98.3	98.5	98.4	98.6	98.4	98.6
5	99.5	99.7	99.6	99.8	99.8	100	99.9	100	99.9	100
6	48.5	4.8	92.9	33.6	99.8	100	100	100	100	100
7	99.6	89.4	99.8	99.8	100	100	100	100	100	100
8	17.6	37.4	59.1	94.8	99.6	99.8	99.8	99.9	99.8	99.9
9	90.0	88.3	97.2	89.4	98.2	98.3	98.3	98.3	98.3	98.3
10	99.8	99.8	99.9	99.9	100	100	100	100	100	100

* Entire night voided – electrodes or system disconnect

8.10. JP Subject Number 10 (T-BCM = 92.5, M-BCM = 62.5)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	21.1	41.2	25.6	41.3	39.6	41.4	41.4	41.5	41.5	41.5
2	48.0	33.1	48.2	38.2	48.4	47.6	62.6	48.7	63.5	50.3
3	67.8	68.5	69.3	69.2	70.9	70.3	71.1	70.8	71.2	71.0
4	3.5	42.5	3.5	43.5	3.5	44.6	3.5	44.8	3.5	44.9
5	36.9	43.4	37.0	43.6	69.1	54.3	87.8	81.0	88.6	94.4
6	0.0	7.6	0.0	35.7	0.0	40.9	0.0	41.1	0.0	41.2
7	36.3	36.2	36.4	36.4	36.6	36.7	36.7	36.8	53.1	38.3
8	45.4	55.4	53.9	56.1	58.0	57.0	59.2	57.4	59.2	57.5
9	34.2	26.5	34.6	28.8	37.3	36.1	39.9	37.4	42.3	38.0
10	43.4	44.2	43.6	44.3	51.0	69.6	61.9	93.6	77.7	96.6

8.11. NJP Subject Number 1 (T-BCM = 72.2, M-BCM = 88.2)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	99.0	25.3	99.4	34.6	99.8	47.6	99.9	50.8	100	51.3
2	74.2	99.7	90.5	99.9	99.6	100	99.8	100	99.9	100
3	56.6	99.6	59.1	99.8	65.3	100	69.5	100	82.1	100
4	73.5	99.6	79.8	99.7	90.2	99.8	90.3	99.8	90.3	99.8
5	90.3	89.9	96.1	94.7	97.2	97.0	97.2	97.1	97.2	97.1
6	38.9	43.1	43.0	47.5	51.7	56.0	56.6	62.3	60.1	73.7
7	77.9	99.1	88.2	99.8	99.7	99.9	99.9	100	100	100
8	89.5	81.6	93.9	87.8	99.6	90.2	99.9	90.3	99.9	90.3
9	96.5	77.4	97.1	79.3	97.4	80.0	97.6	80.1	97.9	80.3
10	88.8	41.4	99.4	44.8	99.8	53.1	99.9	53.3	99.9	53.3

8.12. NJP Subject Number 2 (T-BCM = 114.8, M-BCM = 126.2)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	32.6	66.7	47.1	66.8	85.6	70.2	96.8	96.3	100	100
2*	94.4	92.7	36.3	35.6	37.1	35.6	37.2	35.6	37.8	35.6
3	0.7	99.9	0.7	100	84.6	100	93.8	100	100	100
4	99.5	98.8	99.7	99.1	99.9	99.8	100	100	100	100
5	99.3	99.8	99.5	99.9	100	100	100	100	100	100
6**										
7	74.0	99.6	82.9	99.8	95.3	100	99.9	100	99.9	100
8*	99.5	99.8	28.9	29.0	29.0	29.0	29.0	29.0	29.0	29.0
9	99.7	99.9	99.7	99.9	99.8	100	99.9	100	99.9	100
10	98.6	99.3	99.2	99.7	100	100	100	100	100	100

* Masked area secondary to disconnect

** Masked area secondary to disconnect – insufficient minutes remained & night voided

8.13. NJP Subject Number 3 (T-BCM = 115.1, M-BCM = 132.9)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	19.3	46.7	23.4	49.3	30.8	64.1	37.8	72.3	49.0	75.3
2	67.1	33.4	99.8	54.9	100	100	100	100	100	100
3	94.1	0.0	94.8	0.0	95.1	0.0	95.2	0.0	95.2	0.0
4	53.2	31.3	86.1	31.7	99.9	32.9	100	33.5	100	33.9
5	86.7	52.1	99.8	66.6	99.8	99.9	100	100	100	100
6	86.8	90.0	99.5	98.5	99.9	99.9	100	100	100	100
7	55.5	51.7	59.8	55.8	81.4	85.0	95.9	98.6	99.9	100
8	0.0	17.1	0.5	60.0	64.9	99.7	88.8	99.9	99.9	100
9	38.6	81.4	63.9	97.6	97.2	99.9	97.3	99.9	97.4	100
10	2.0	99.2	3.9	99.5	27.5	99.9	75.8	100	96.4	100

8.14. NJP Subject Number 4 (T-BCM = 176.0, M-BCM = 145.7)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	65.5	53.0	69.8	70.2	94.0	100	100	100	100	100
2	95.9	90.6	96.2	96.4	98.0	99.9	99.5	100	100	100
3	96.0	95.3	96.2	95.8	97.5	96.4	97.6	96.4	98.2	96.4
4*										
5	90.5	90.6	91.7	91.0	91.9	91.9	99.6	91.9	100	91.9
6	90.7	79.5	93.9	84.4	97.3	99.6	99.6	99.9	100	100
7	98.8	99.3	98.9	99.5	99.6	99.8	100	100	100	100
8**										
9	92.5	67.5	93.3	84.0	96.6	98.6	99.9	99.6	100	100
10	88.6	87.1	90.2	89.9	93.3	100	98.2	100	99.7	100

* Night voided secondary to disconnect

** Masked area secondary to disconnect – insufficient minutes remained & night voided

8.15. NJP Subject Number 5 (T-BCM = 100.2, M-BCM = 64.4)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	85.0	84.0	90.6	86.5	100	93.6	100	96.2	100	99.9
2	81.8	0.0	92.8	53.3	99.8	99.8	100	100	100	100
3	99.8	99.5	99.9	99.7	100	99.9	100	100	100	100
4	23.4	99.3	40.3	99.6	53.2	99.9	91.9	99.9	100	100
5*	98.6	99.6	98.9	99.9	99.2	100	99.2	100	99.2	100
6	3.4	99.6	15.2	99.7	66.7	99.9	88.4	100	92.1	100
7	99.8	65.1	99.9	95.4	100	96.1	100	98.5	100	98.8
8	97.4	94.9	97.5	96.5	97.6	97.6	99.8	99.9	100	99.9
9*	0.0	0.0	0.0	0.0	81.5	46	92.8	62.2	98.5	99.7
10	84.5	83.8	89.9	86.2	100	92.6	100	95.2	100	100

* Masked areas secondary to disconnect

8.16. NJP Subject Number 6 (T-BCM = 120.6, M-BCM = 82.3)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	98.0	99.5	99.8	99.7	99.4	100	100	100	100	100
2	99.6	99.4	99.7	99.7	100	100	100	100	100	100
3	99.1	95.0	99.5	99.5	100	99.9	100	100	100	100
4	99.2	99.2	99.5	99.5	99.8	99.8	99.9	99.9	99.9	99.9
5	99.5	97.1	99.7	98.2	100	99.3	100	99.7	100	99.9
6	84.5	97.9	84.6	98.3	84.8	99.2	84.9	99.7	84.9	99.9
7	98.9	99.6	98.9	99.8	99.1	99.9	99.1	100	99.2	100
8	100	97.9	100	98.3	100	99.3	100	99.7	100	99.9
9	99.1	73.1	99.3	98.0	99.8	99.4	100	99.8	100	99.9
10*										

* No recording – software program not accessed correctly

8.17. NJP Subject Number 7 (T-BCM = 196.2, M-BCM = 109.8)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	98.7	99.1	98.8	99.2	98.9	99.2	99.0	99.3	99.2	99.3
2*										
3	99.8	99.4	99.8	99.5	100	99.7	100	99.8	100	99.9
4	98.2	98.5	98.4	98.6	100	99.8	100	99.9	100	100
5*										
6	57.2	58.4	57.2	59.2	59.4	60.0	59.7	60.2	60.0	61.8
7	91.4	97.8	91.4	98.6	99.9	99.9	100	100	100	100
8	97.4	99.4	99.4	99.5	100	99.5	100	99.8	100	100
9	93.1	83.5	94.3	93.9	98.2	94.4	100	95.4	100	100
10	100	99.9	100	100	100	100	100	100	100	100

*Masked areas secondary to disconnect – insufficient minutes remained & nights voided

8.18. NJP Subject Number 8 (T-BCM = 57.2, M-BCM = 79.4)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	37.4	0.0	45.4	0.0	86.9	4.5	99.0	35.9	99.6	76.4
2	0.0	0.0	0.0	0.0	12.8	0.0	60.6	0.0	85.9	0.0
3	79.2	41.4	84.7	41.6	98.1	42.6	99.8	43.3	99.9	43.6
4	0.0	0.0	0.0	5.5	23.5	47.8	52.8	70.7	71.9	78.9
5*	0.0	0.5	0.0	0.5	0.0	0.5	0.0	21.7	0.0	75.6
6	0.0	35.8	0.0	52.4	0.1	65.5	1.0	85.4	2.4	92.2
7	0.0	36.0	0.0	59.7	0.0	96.3	0.0	99.1	0.0	100
8	10.5	11.9	13.2	11.9	24.6	12.0	35.1	12.0	44.8	12.0
9	0.0	0.0	18.6	0.0	76.2	0.0	97.3	0.0	99.2	0.0
10	0.0	0.0	1.5	0.0	19.1	0.0	54.9	0.0	76.1	0.0

*Masked area secondary to disconnect

8.19. NJP Subject Number 9 (T-BCM = 60.5, M-BCM = 77.2)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	98.4	99.6	98.9	99.7	99.6	100	99.9	100	100	100
2	0.5	0.5	0.5	92.1	89.0	92.8	92.5	92.9	93.1	93.0
3	0.0	96.6	0.0	99.6	0.0	96.6	83.1	96.6	86.8	96.6
4	0.0	99.6	0.0	99.7	9.2	99.9	9.7	99.9	11.7	99.9
5	13.1	0.0	31.0	97.5	68.8	97.5	92.5	99.9	99.8	100
6	43.6	83.6	73.5	86.0	90.4	88.5	99.9	93.8	100	99.9
7	2.5	99.6	2.9	99.7	18.3	100	42.2	100	51.8	100
8	0.0	99.4	0.6	99.6	24.4	99.9	52.2	100	74.2	100
9	1.1	99.4	7.7	99.6	43.8	99.9	60.8	100	90.5	100
10	44.8	99.5	54.1	99.7	74.6	99.9	77.5	100	89.7	100

8.20. NJP Subject Number 10 (T-BCM = 144.6, M-BCM = 189.4)

Night	T<15%	M<15%	T<20%	M<20%	T<40%	M<40%	T<60%	M<60%	T<80%	M<80%
1	99.5	99.9	99.5	99.9	99.6	100	99.6	100	99.6	100
2	90.5	90.1	90.5	90.3	90.5	90.5	90.5	90.5	90.5	90.7
3	94.2	71.6	97.0	94.8	97.8	97.8	97.8	97.8	97.8	97.9
4	17.6	99.9	35.5	99.9	57.6	100	91.4	100	95.7	100
5	98.0	98.2	98.1	98.3	98.5	98.5	99.3	99.4	99.6	99.6
6	96.9	97.0	96.9	97.0	97.0	97.0	97.0	99.2	97.0	100
7	19.4	99.5	58.2	99.8	67.3	99.9	67.4	99.9	67.4	100
8	0.0	99.1	0.0	99.1	0.0	99.1	0.0	99.1	0.0	99.1
9	0.0	99.8	0.0	99.9	4.1	100	4.1	100	4.1	100
10	0.0	56.1	0.0	56.2	0.0	57.1	0.0	59.3	0.0	60.6

9. Appendix 2. Copy of Consent Form

Consent Form

SURFACE ELECTROMYOGRAPHIC EVALUATION OF NOCTURNAL BRUXISM

You are invited to participate in a research study of nocturnal bruxism (clenching, bracing, gnashing and/or grinding of the teeth while sleeping). You must be able to read and write English. You have been chosen because of one of the following reasons:

1. You are healthy and have all of your teeth.
2. You have a history of nocturnal bruxism.

We ask that you read this form and ask any questions you may have before agreeing to be in this study.

Dr. Randall J. McDaniel and Dr. John K. Schulte are conducting this study at the University of Minnesota, division of TMJ and Orofacial Pain. The purpose of the study is to measure the levels of nocturnal bruxism by using an electromyographic system to record jaw muscle activity.

Sleep clenching, bracing, gnashing and/or grinding of the teeth can have serious negative effects on the teeth, gums, jaw muscles, and jaw joints. These activities may contribute to headaches, jaw muscle pain, jaw joint pain, jaw arthritis, and/or earaches.

If you agree to be in this study, we would ask you to do the following:

1. You would receive a clinical TMJ examination at the University of Minnesota TMJ and Orofacial Pain Clinic. This exam will evaluate the muscles of your head and neck, the jaw joint and the inside of your mouth. This will take about 2 hours.

2. You would be thoroughly trained to set-up and use the equipment for the study.
3. You would take home the equipment and use it for ten (10) nights while sleeping. During these ten (10) nights you will place two (2) small adhesive pads to the skin over jaw muscles, which is similar to applying a small circular Band-Aid to your skin. These pads are attached to long cords that plug into the electromyographic (EMG) device, which then plugs into a notebook computer. You will be instructed to the simple use of these devices. The electrodes will transmit information to the EMG instrument and this information will be stored in the computer. All of this data will be collected in your natural sleeping environment. This instrument should not disturb your sleep. Similar studies support this statement.
4. You would return all the equipment with the stored data the day following the tenth (10^{th}) night of the data collection.
5. Upon returning the equipment, you would receive another short interview and exam. This will take about 2 hours.
6. Following this, no further information or tasks would be required from you.

You will be paid $25.00 if you complete 3 nights of the study. You will receive an additional $25.00 for completing six (6) nights of the study and an additional $50 for completing all ten (10) nights data collection.

3 nights completed = $25.00 total compensation

6 nights completed = $50.00 total compensation

10 nights completed = $100.00 total compensation

There is no other direct benefit to you for being in this study.

This study has minimal risks and these are as follows:

1. There is a slight chance of having some discomfort when removing the electrode pads from the skin of the face, such as that of removing a Band-Aid.

2. There is a risk of irritation to the skin underlying the electrode pad. This could be from the adhesive or from the pad being on the skin for ten (10) nights.

Participants of this study will not be held financially responsible for failure, breakage and/or damage to any of the equipment and/or devices utilized in the home portion of data collection.

If being in this study harms you, we will provide or arrange care as needed. We do not have funds to pay for such care, however. Payment will be your responsibility, or that of your Health Insurance Company (or Medicaid, etc).

The records of this study will be kept private. If the results of this study are published, we will not include any information that will make it possible to identify an individual. The investigators of this study and representatives of Bioresearch Associates Inc (manufacturer of the EMG apparatus and computer software) may review your record.

Participation in this study is completely voluntary. You are under no pressure to be in the study. Your decision whether or not to participate will not affect your current or future relations with the University of Minnesota. If you do participate, you are free to withdraw at any time without affecting those relationships. To receive the monetary compensation you must complete the number of nights of data collection as outlined above.

3 nights completed = $25.00 total compensation
6 nights completed = $50.00 total compensation
10 nights completed = $100.00 total compensation

If during the course of this study, there are significant new findings discovered which might influence your willingness to continue, the researchers will inform you of those developments.

The researchers performing this study are Dr. Randall J. McDaniel and Dr. John K. Schulte. You may ask any questions you have now and if there are questions later you may contact Dr. McDaniel at the University of Minnesota TMJ and Orofacial Pain Clinic at: (612) 626-0140 or by pager at any time during the study (612) 579-8469. Dr. John K. Schulte is the advisor for the study and can be contacted at (612) 625-7954. If you have any questions or concerns regarding the conduct of this study and would like to talk to someone other than the researchers, you may call Dr. James Fricton, Director of TMJ and Orofacial Pain Clinic, University of Minnesota, at (612) 624-3130.

You will be given a copy of this form to keep for your personal records.

Statement of Consent:

I have read the above information. I have asked any questions I had, and I have gotten answers. I agree to be in this study.

Name: _____

Signature: _____ Date: _____

Witness:

Name: _____

Signature: _____ Date: _____

Principal Investigator:

Name: Dr. Randall J. McDaniel

Signature: _____ Date: _____

10. Appendix 3. Copy of Patient Instructions

INSTRUCTIONS FOR JAW STUDY

1. Please read all instructions carefully before using the study equipment.

2. **DO NOT AT ANY TIME:**
   a. Open any other computer program, other than the sleep study program.
   b. Remove the PC Card.
   c. Use the computer with the battery power (use the wall plug each time)
   d. Use the computer for any purpose, other than that authorized for the study.
   e. Use the computer or EMG system without the power surge.
   f. Allow any other person to operate or use any of the study equipment.
   g. Have food or drink near the equipment.
   h. Allow children access to the equipment.
   i. Use the equipment other than for its intended purpose.
   j. Alter the sleep program in any way.
   k. Add or delete any programs from this system.

3. For questions/problems during the study contact Dr. McDaniel at pager:
   (612) 579-8469

4. When all 10 nights of the study have been completed, please carefully place all the equipment in the case and return it safely at your final evaluation.

5. All items are labeled with 2 letters. Single black letter designations are for connection portions, for example: Connect label "A" to Label "A"(this is for the computer power cord and the receptacle port on the back of the computer). Also items and connectors are labeled with "this side up".

5. The power surge protector (labeled "PS") must be plugged into a grounded electrical 3-prong plug wall outlet. If a 3-prong grounded electrical outlet is not available use the adapter (labeled "XX") and use the screw on the wall plate to secure the metal

ground portion at the bottom of the adapter, then plug the power surge into the adapter.

Equipment set-up procedure

Step 1:

Place the notebook computer (label "NC") in a safe location next to your bed (such as on a nightstand). Connect the computer power source ("CP") to the computer (label "A" to label "A").

Step 2:

Connect the computer power source ("CP") into the power surge protector ("PS"), by connecting label "B" to label "B".

Step 3:

Connect the EMG Device ("ED") to the computer ("NC") on the left side at the PC Card port, by connecting label "C" to label "C". Note the connector labeled "this side up". Ensure that the "ED" cord is not stretched tightly as this is a weak connection and any strain on the connection will cause a separation.

Step 4:

Connect the amplifier ("AM") to the EMG Device ("ED"), by connecting label "D" to label "D" and noting "this side up" label.

Step 5:

Connect the EMG power source ("EP") to the EMG Device ("ED"), by connecting label "E" to label "E".

Step 6:

Connect the EMG power source ("EP") to the power surge protector ("PS"), by connecting label "F" to label "F".

Step 7:

Connect the power surge protector ("PS") into your grounded electrical wall outlet and make sure the power surge protector is in the "on" position. The red light should be illuminated. If it is not illuminated, turn on the power surge protector with switch labeled "G".

Step 8:

Open the notebook computer ("NC") by releasing the latches (labeled "H") on the left and right top edges of the computer. Pull the latches forward at the same time and lift the top of the computer open.

Step 9:

Switch-on the notebook computer by pressing the oval shaped, on-off button located at the top of the keyboard, labeled "J". The button only need be pressed for one second and released. The computer will take 1- 2 minutes to boot-up.

Step 10:

Take the bottle of Isopropyl Alcohol and one cotton ball to a mirror. Please do not open the Alcohol (or any other liquids/foods/drinks) near any of the study equipment. Cleanse a wide area of the face and neck where the electrode pads will be placed (see diagram below).

This will be your _____ cheek.
This will be your _____ neck
This will be your _____ temple

Allow 1 – 2 minutes for these areas to dry before placing the electrode pads.

Step 11:

Peel the backing from a 2-tab electrode pad and place it over the appropriate cheek as previously directed and per the diagram below. The tabs must be aligned vertically (one on top of the other – NOT side-by-side). The pads are located in the box labeled "Electrode pads".

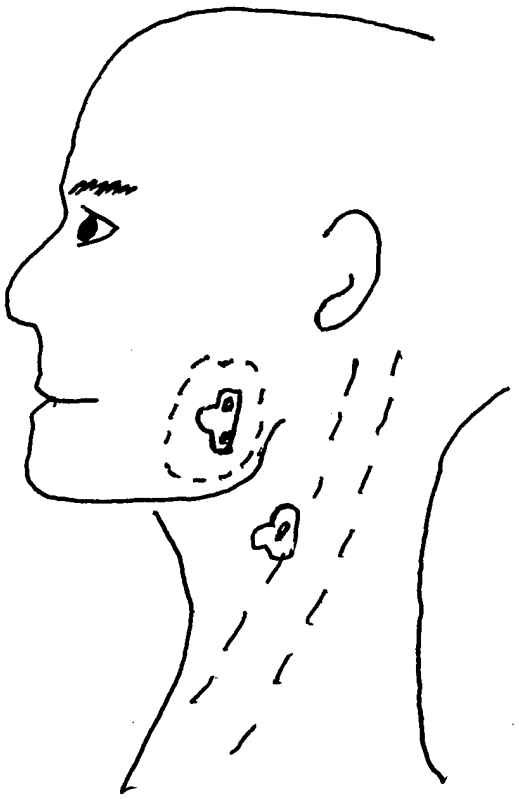
Step 12:

Peel the backing from a 2-tab electrode pad and place it over the appropriate temple as previously directed and per the diagram below. The tabs must be aligned vertically (one on top of the other – NOT side-by-side).

Step 13

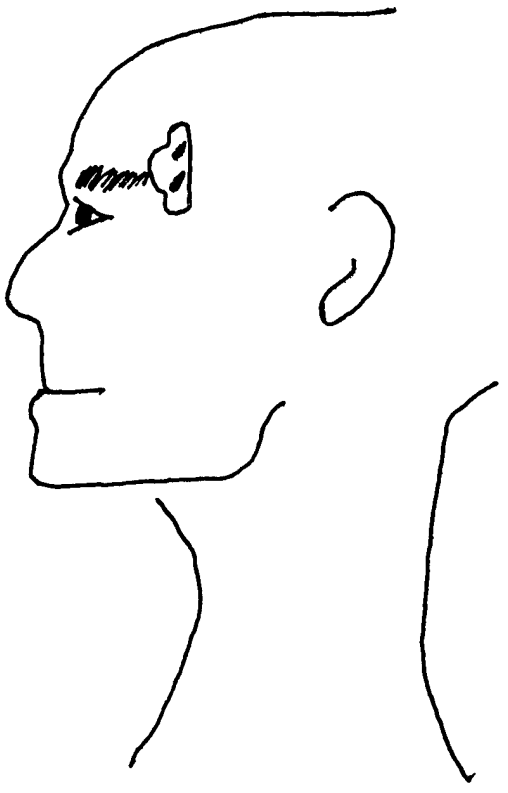
Peel the backing from a 1-tab electrode pad and place it over the appropriate neck region as previously directed and per the diagram below.

To place the cheek pad:
Bite firmly and feel the firmest portion of the muscle and the pad should be placed over this area in the vertical plane.



The neck pad should be on the same side as the cheek pad. Place the single tab pad on the front surface of and middle (top to bottom) of the muscle that goes from behind the ear to the sternum. You can feel this muscle when you tense the neck.

The temple pad:
Place one finger at the corner of the eye. The pad should be just behind this finger with the middle of the pad at the level of the eyebrow.



Step 14:

There are 2 EMG leads ("EL") with the equipment set-up. One of the leads has 2 snaps and the other has 3 snaps. Take the "3-snap" lead and connect 2 of the snaps (any 2) to the cheek electrode pad tabs. Connect the remaining snap to the single neck electrode pad tab.

Next take the "2-snap" lead and connect the snaps to the temple electrode pad tabs.

Step 15:

Connect the leads to the Amplifier ("AM").

Connect the "3-snap" lead (it is the cheek and neck side) to the Amplifier ("AM") port: _____.

Connect the "2-snap" lead (it is the temple side) to the Amplifier ("AM") port: _____.

Step 16:

The notebook computer should now be at the icon screen. Access the EMG program by double clicking the Icon:

EMG Sleep Monitor.lnk

The "EMG Sleep Monitor" window will open and it should list your name and which recording number is ready. Click-on "NEXT" to continue. It will then prompt you to "Prepare skin and place pads", which you have already done, so click-on "NEXT". It then states to "Connect the amplifier to the computer" and you have done this, click-on "NEXT". It asks to "Connect the leads to the pads". You have done so, click-on "NEXT". Now it states "Connect the leads to the amplifier", this has been done, click-on "NEXT". The window now reads "Recording..." Do not make any changes at this point. Close the computer top until it clicks closed.

Step 17:

Place the amplifier under your pillow with the lead wires hanging down the sides of you face.
NOTE: When you remove the Amplifier the following morning the box will be very warm.

NOW REST AND SLEEP !

If at any time during the night you need to get out of bed you must detach the lead snaps from the electrode pad tabs on the cheek, neck and temple areas. DO NOT disconnect the leads from the amplifier. When you return to bed reconnect the snaps as previously performed. You do not need to make any changes on the notebook computer.

If at any time during the night you find a lead or snap disconnected, please reconnect it at that time. When you wake in the morning make a note that a lead came loose during the night (or that you had to disconnect the leads) and record which night this happened. Bring this with you to the final evaluation. This does not disqualify you from the study nor does it invalidate the data. We will simply delete this portion of the data.

Morning shut-down:

Step 1:

When you wake each morning you will need to shut down the computer first.

NOTE: DO NOT DISCONNECT THE LEADS FROM THE FACE AND NECK UNTIL AFTER YOU HAVE SHUT-DOWN THE COMPUTER.

Open the computer top as previously directed. The screen will be dark; this is the active screen saver. Touch the "space bar" or slide a finger across the "touch mouse pad" once and the "Sleep EMG" window will reappear.

Step 2:

Click-on the "STOP" button and the window will momentarily read "Done!", then the program will close and the icon window will be present.

Step 3:

Now shut down the notebook computer by clicking the "Start" button in the lower left corner of the window screen. Now click "Shut Down..." A window will appear and the box "Shut Down" should be checked, if it is not, do so at this time. Now click the "OK" box. The computer will shut down.

Step 4:

Close the notebook computer top until it locks closed.

Step 5:

Now you may disconnect the leads by releasing the snaps from the face and neck pads.

Step 6:

Remove the electrode pads just as you would remove an adhesive bandage. Clean the adhesive from the pad areas with the alcohol and a cotton ball.

There is no need to disassemble the equipment until all 10 nights of the study have been completed, unless it is unsafe to leave the equipment in the set-up position for the following night.

If it remains connected for the next night:

1. Switch-on the computer as previously directed.
2. Prepare the face and neck as previously described.
3. Place the electrode pads.
4. Connect the leads.
5. Access the program and start as before.

At study completion:

Once all 10 nights of the study have been completed, disassemble the equipment and return it safely and neatly to the carrying bag. Store safely until you return with **ALL** of the equipment for your final evaluation.