Reliability and Validity of Instrumentation Used to Record Nocturnal Clenching and/or Grinding

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Nocturnal clenching and grinding can be recorded with a portable electromyograph unit and a standard cassette tape recorder, which registers the clenching episodes on a cassette tape. The information can then be coded by a new instrument, called a Pulse Identifier, that subsequently transfers the data to a polygraph chart recorder. This study evaluated the reliability and validity of the Pulse Identifier when interfaced with other instruments that measure nocturnal clenching/grinding. A known number of clenching incidents over a baseline period of time were evaluated by three "blind" scorers. The results demonstrated an interscorer reliability coefficient of 0.99 and a validity coefficient of 0.99.
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Clenching and/or grinding behavior that occurs during sleep has been quantified in the sleep laboratory with stand-alone electromyograph (EMG) instruments[1–3] and in the natural environment with portable EMG recording devices.[4–19] The portable EMG recording device was first developed and utilized by Solberg and Rugh[19] to evaluate nocturnal clenching/grinding behavior in the home environment rather than in the more artificial setting of the sleep laboratory. The unit senses EMG-measured muscle activity from bipolar electrodes placed over one of the patient's cheeks. This instrument records EMG activity from a field of masticatory muscles, since surface electrodes are employed.

Threshold Variable

Portable EMG-threshold recording units quantify masticatory muscle activity in several different data forms. The EMG data collected from clenching patients is often recorded as either the number of times the patient exceeds a preset microvolt threshold or the cumulative EMG activity above a preset microvolt threshold.[4–25] Generally, the sensitivity level is set so that recording of muscle activity is done above a preset threshold to avoid recording normal, nonparafunctional muscle activity, ie, smiling, swallowing, and speaking. The microvolt thresholds that have been used in these clenching/grinding studies vary greatly: thresholds of 20 μV,[6–9,12,15–18] 30 μV,[10] and 100 μV[13,14] have been used by some researchers, while others have not specified the threshold used.[5,11,19]

Equipment Variables

Rugh and Schwitzgebel[26] investigated the equipment-related variability factors associated with EMG biofeedback devices and find a wide variation in electrical testing of 11 commercially available EMG biofeedback devices. The variability of the equipment was determined to be due to lack of equipment standardization rather than poor manufacturing or design. Burgar and Rugh[25] emphasize the need for standardization of the equipment-related variables used in the data collection process. These authors suggest standardization of factors such as input impedance, minimal detectable signal (peak-to-peak, μV), band width, center frequency, 60-Hz suppression (dB), electrode characteristics, noise, common-mode rejection ratio, filter characteristics, time constant, battery life, and feedback signal. The Food and Drug Administration has classified these instruments as Category II types of instrumentation. This equipment category requires standardization of the above-listed variables; however, these standards have not been established. This lack of standardization for equipment that monitors clenching/grinding makes comparisons between studies difficult.

Types of Portable EMG Recording Instruments

Some portable EMG recording units are designed to record muscle activity once a preset threshold has been exceeded and these units can be used as data recorders, treatment devices, or a combination of both. Generally, this type of equipment can be adapted to a form of biofeedback treatment in which an aural or other type of feedback signal alerts the patient that the preset threshold has been exceeded.[4,11–15,17,19,21–24,27] Other portable EMG units have been designed to electronically record the amount of EMG activity above a preset threshold as an integration function,[21,28] which is a factor computed by the equipment as a calculation of the area beneath a rectified sine wave. This is a different form of data than the previously described suprathreshold per unit time data. Many studies have also been completed with this type of integrated EMG data as a measure of masticatory muscle activity in which the instrument is not utilized as a treatment device.[6–10,12,16,18] Both types of EMG data in the studies cited, generally, have been collected over a 10- to 14-day period and both types represent a composite of the total amount of EMG activity accumulated during this time.[15]

Portable EMG Suprathreshold Biofeedback Units

Dowdell et al[22] use a portable EMG biofeedback unit interfaced with a tape recorder for biofeedback treatment as well as recording the dependent variable for data collection. A tone generator is triggered by the suprathreshold clenching/grinding event with the feedback delivered through an earphone or speaker, and the patient is then aroused from sleep by the tone generated. Many other investigations have utilized this configuration to record EMG-measured clenching/grinding incidents and durations on a portable cassette recorder.[11,13,14,19]

Suprathreshold Biofeedback Data Quantification

In the past, the taped information has been translated into data by counting the number of audible on/off demarcations when the tape recording was played back through an earphone in the laboratory. Each audible on/off demarcation on the tape represented one EMG-measured clenching/grinding incident, and the length of tape used represented the duration of clenching/grinding activity above the 20-μV threshold per sleep period. An obvious disadvantage of this scoring system is the problem of variability introduced by scorers who may hear and count the taped demarcations differently.

The recorded information provides the researcher/clinician with a cumulative recording of the number of clenching/grinding incidents for each night of sleep during the baseline period. The patient keeps a written record of the length of time that the portable EMG unit is set to record sleep-related nocturnal clenching/grinding activity and also tape records the day and time at the beginning and end of each sleep period to mark each recording session. This allows the investigator to determine the average number of clenching/grinding incidents that are occurring per hour per sleep period. The number of seconds of clenching/grinding activity per sleep period also allows calculation of EMG-measured clenching/grinding activity per hour of recording time.

The Pulse Identifier

Clenching/grinding activity that has been recorded on a tape recorder can be quantified by a research laboratory technician listening to the number of audible signals on the tape. The new Pulse Identifier (Fig 1) was developed by Zaharkin[20] in 1982 to enable the reliable transfer

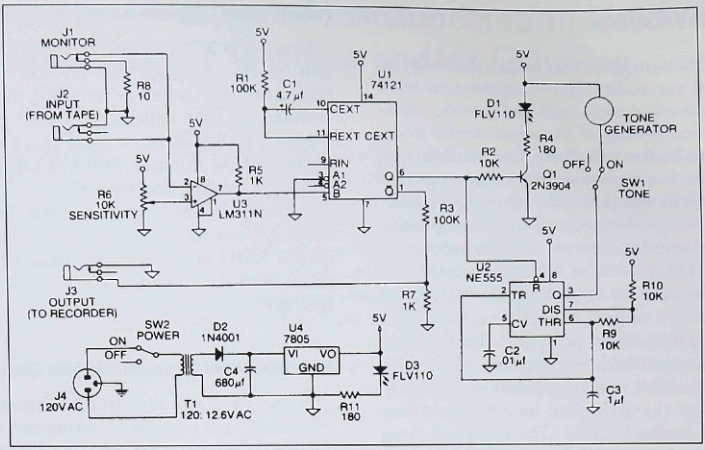

Fig 1 Schematic diagram of the Pulse Identifier. All resistors are in ohms; D1 and D3 any standard LED; T1 = Radio Shack #273–1365; device isolated, jacks 1 to 3 wired to accommodate other instruments.

of the recorded clenching/grinding activity from a cassette recorder tape to a standard polygraph. With the aid of this instrument, the technician can record the amount and type of clenching/grinding behavior on a hard copy. One EMG-measured clenching/grinding incident produces a standard vertical change from the baseline horizontal path by the chart recorder. The Pulse Identifier instrument enables the investigator to quantify the amount of clenching/grinding activity, ie, frequency and duration, more easily and demonstrate the type of parafunctional behavior, ie, tooth grinding vs clenching. Tooth grinding produces a series of vertical line demarcations with short horizontal recorded lines before the pen recorder returns to baseline, while a tooth clench produces only one vertical line demarcation with a long horizontal recorded line before the pen recorder returns to baseline.

Purpose

Reliability of an instrument has been described as the accuracy, precision, or consistency of measurements by an operator in using an instrument or test or the error factors or variance of the evaluator in using the instrument as a proportion of the total amount of variance in the measurement process. Validation is "1. The process in which the degree of validity of a measuring instrument is determined. 2. The process of establishing the objective proof of a proposition, measuring instrument, etc. . . . A test's ability to predict performances other than performance on itself, that is, a test's correlation with a factor, life-situation performance, clinical category placement, etc."[29] This experiment attempted to evaluate the scorer's use of the instrument to establish a type of validity called concurrent validity, which has been defined as "a measure by demonstrating a high correlation between your new measure and an established measure."[30]

In an extensive review of the literature, Lund and Widmer[31] point out that many treatment methods have been documented as successes as treatment modalities, but most of the cited studies do not have reliability nor validity documentation of the instruments that were used to support their results. The intent of this study was to evaluate reliability and validity of multiple scorers using a portable EMG recording device with a tape recorder and a Pulse Identifier in combination with a standard polygraph to assess simulated clenching activity. Mohl[32] and several others[33–40] emphasize the need for the evaluation of diagnostic and therapeutic equipment to meet these criteria.

Materials and Methods

The investigator served as a mock patient to record a known number of clenching incidents with the portable EMG unit and its accompanying tape recorder. Three experimental scorers independently assessed the tape-recorded mock data. The experimental scorers were experienced with the assessment procedure but were unaware of the frequency and duration of clenching activity prerecorded by the mock patient.

Equipment

A portable modified BF-100 EMG unit was used to obtain the number of clenching incidents per recording session. This instrument had essentially the same electronic configuration and function as the instrument developed by Solberg and Rugh.[19] A standard, portable cassette tape recorder (Model No CTR-56, Realistic) was used to record the tone generated by the portable EMG unit. This instrument coupled with the portable EMG unit provided the simulated 10-day trials to be discussed below.

The experimental instrument being assessed in this investigation, the Pulse Identifier, was interfaced with the portable cassette tape recorder and the polygraph instrument. This instrument enabled the conversion of audible tone signals into a vertical displacement of the pen on the polygraph chart recorder.

The signal that passed from the portable cassette tape recorder through the Pulse Identifier was converted to a paper copy with a Grass polygraph (Model 7, Grass Instrument, Quincy, MA), and a preamplifier and amplifier (Models 7PA and 7DA, both Grass Instrument) were used to amplify the signal. A chart recorder speed of 1/4 cm/sec was employed through the data assessment period for all scorers.

Procedure

The bipolar electrodes of a portable modified BF-100 electromyograph were affixed to the experimental (mock) patient as if to a "real" patient.[11] The dates and times of each trial were verbally introduced on the tape to identify the beginning and ending of the trial. The masseter area electrode placement was not considered a variable because these were placed once at the beginning of the experiment and were not removed until all experimental trials were completed. The experimental patient then clenched a randomly, predetermined number of times for each trial. Each clenching incident was introduced by the experimental subject through a strong suprathreshold clench (> 20 μV) of approximately 1 second in duration. Ten trials with a known number of clenching incidents per trial were recorded to simulate a typical clenching patient data collection baseline of 10 days. These entries represented a typical recording with verbal information that would be given by an actual patient for each day.

The experimental subject was one of the investigators and the specific number of clenching incidents for each trial was known only to that individual. The specific number of clenching incidents to be introduced was determined from a table of random numbers. The investigator entered the appropriate verbal labelling, eg, "night no. 1 begins" and "night no. 1 ends," before and after the prescribed number of clenching incidents.

The three experimental scorers had no knowledge of the number of clenching incidents per trial. The information on the cassette tape was transferred from a tape recorder through the Pulse Identifier to the chart recorder. The charted hard copy of clenching incidents was evaluated by the three independent scorers. They quantified the number of clenching incidents but not their duration for each of the 10 trials. An example of the hard copy that was used by the scorers to assess the amount of simulated-clenching incidents can be seen in Fig 2.

This experiment was designed to investigate the ability of three scorers to quantify a known amount of simulated-clenching data in 10 trials by using a test-retest research design. This type of experimental design enabled the investigators to calculate reliability and validity coefficients.[41] Each scorer's enumeration of clenching incidents was compared to each of the other scorer's findings to determine the interscorer reliability of the scoring technique. Once the reliability was established, the results of each scorer were then compared to known standard values for each trial to determine the validity of the instruments and the scoring technique.

Results

Reliability was determined by calculating an intraclass correlation coefficient, r_I, according to the following formula:

$$r_I = \frac{\hat{\sigma}^2_D}{\hat{\sigma}^2_D + \hat{\sigma}^2_E}$$

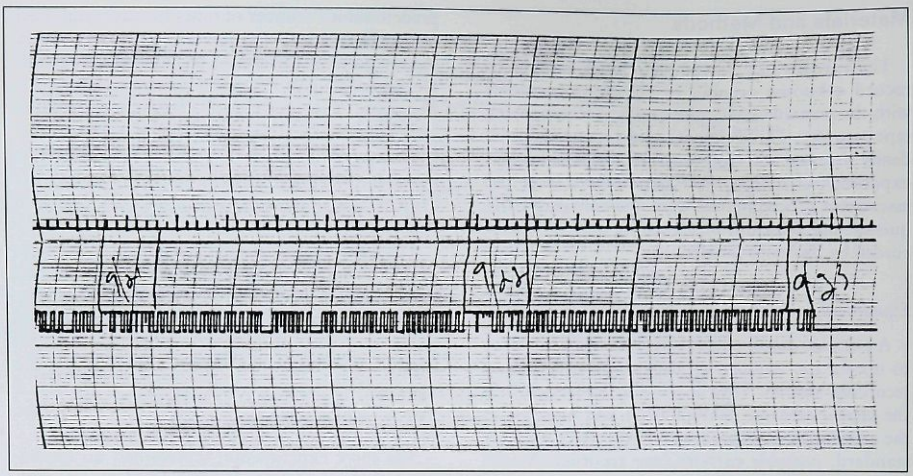

Fig 2 Example of hard copy generated by the Pulse Identifier.

where

$$\hat{\sigma}^2_E = \text{mean square error}$$

and

$$\hat{\sigma}^2_D = \frac{\text{mean square DAY} - \text{mean square error}}{3}$$

This coefficient is the mean square term (variance) for days minus the mean square error term divided by three scorers to yield an average variance for a scorer. This average scorer variance factor divided by the same average scorer variance plus the mean square error yielded a reliability coefficient. The analysis of variance numbers used in the calculations can be seen in Table 1. The interjudge reliability coefficient was high ($r = .99$, $P < .001$). This statistic demonstrates a measure of how closely each scorer's assessment of the data correlates with each of the other scorers for all 10 trials.

A more specific reliability coefficient has also been calculated as a covariance factor between scorers 1 and 2, 1 and 3, and 2 and 3. The calculation of this reliability coefficient between scorers 1 and 2 can be seen in the following example:

$$\hat{\sigma}_{12} = S^2_{12} = \frac{\Sigma\,(x-\bar{x})\,(y-\bar{y})}{n-1}$$

Table 1 ANOVA Values

	df	SS	MS	F
Model	11	27733	2521	3455.5
Error	18	13.1	0.73	
Corrected Total	29	27746		
Day	9	27732	3081	4223.3
Evaluator	2	0.87	0.43	

where

$$r_{12} = \frac{S_{12}}{\sqrt{S^2_x S^2_y}}$$

and

x = scorer no. 1
y = scorer no. 2
n = 10 trials

These coefficients were .99 ($P < .001$) for the comparison of each scorer with each other scorer.

The validity of the scorers was determined by a correlation of the known values with the average values of the three scorers for each trial. The validity coefficient of the three scorers demonstrated the closeness of these scorers to the known values for all 10 trials. This coefficient was also high for all three scorers ($r = .99$, $P < .001$). The raw data of the experiment can be seen in Table 2.

Discussion

The present study has demonstrated the Pulse Identifier in combination with a Grass polygraph, a portable EMG device, and a tape recorder to be a set of instruments that provides reliable and valid quantification of recorded simulated-clenching data. A potential weakness in this study may be that the simulated-clenching data might not adequately reproduce the nocturnal clenching activity of patients. A normal subject was used to provide known numbers of simulated-clenching incidents in order to calculate validity coefficients. Clenching patients were not used because that type of patient investigation would only allow for an assessment of reliability without a knowledge of the actual frequency and intensity of the clenching behavior. Parafunctional tooth grinding, a common nocturnal, parafunctional activity in bruxing patients, was not investigated in this study.

The Pulse Identifier instrument enabled the evaluators to accurately quantify the data by converting the taped EMG-related data generated by clenching into an easily scored hard copy. This instrument enables the evaluator to assess the duration of bruxing behavior but does not provide a measure of amplitude. In addition, chart recorder paper speed can be easily increased to more effectively distinguish the number of clenching episodes. Though not usually necessary, purposefully increasing paper speed could be of value when very rapid bursts of grinding activity occur in close succession. The instrumentation allows the accurate scoring of any EMG data of this type.

The ability of an evaluator to use an instrument to accurately assess the clenching activity, ie, validity, is crucial to further experimental work with this instrument in the assessment of the behavioral activity of interest in investigations or treatment. Reliability is also crucial to experimental investigations in this area, because multiple evaluators need to be able to use the equipment consistently in multiple trials to compare themselves and other evaluators. The experimental documentation of the evaluator's error factor in using experimental equipment is an important assessment because it helps substantiate the experimental data resulting from the equipment's use. This equipment combination was subsequently utilized by Pierce and Gale[15] in the same laboratory for a clinical study of clenching/grinding in patients. Those investigators were able to more confidently measure the intended parameters based upon the assessment of equipment/scorer errors reported in this study.

The process of demonstrating equipment measurement error through reliability and validity assessment prior to employment in actual experiments is a standard procedure in many areas of scientific investigation and should be encouraged in all temporomandibular disorder and orofacial pain investigations in which instrumentation is used. One way that this particular methodology could be better validated in future investigations might be to include the use of the BF-100 EMG recording unit in a sleep laboratory where quantification of actual clenching behavior can be observed with more sophisticated EMG equipment and visual verification.[41]

Table 2 Raw Data of the Actual and Researcher-Estimated Values for 10 Trials

Day	Actual Value	Evaluator no. 1	Evaluator no. 2	Evaluator no. 3
1	23	30	29	27
2	5	8	9	9
3	14	18	18	18
4	38	50	51	49
5	97	102	102	100
6	11	11	11	11
7	43	46	46	47
8	93	96	94	95
9	49	47	48	48
10	37	36	37	37

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Resumen

La Fiabilidad y Validez de los Instrumentos Utilizados para Registrar el Apretamiento y el Crujido Nocturno

El apretamiento y el crujido de los dientes pueden ser registrados con una unidad electromiográfica portatil y una grabadora standard. Esta registra los episodios de apretamiento en un cassette y la información es codificada por un nuevo instrumento, el Identificador de Pulso, el cual subsecuentemente transfiere la información a una grabadora de gráficaspolígrafo. Este estudio evaluó la fiabilidad y validez del Identificador de Pulso cuando está interfasado con otros instrumentos que miden el apretamiento/crujido nocturno. Tres registradores "ciegos" evaluaron un número conocido de incidentes de apretamiento sobre un período basal. Los resultados mostraron un coeficiente de fiabilidad de 0.99 entre los registradores, y un coeficiente de validez de 0.99.

Zusammenfassung

Zuverlässigkeit und Validität von Geräten zur Aufzeichung von nächtlichem Zähnepressen und -knirschen

Nächtliches Zähnepressen und -knirschen kann mit einem Elektromyographen in Verbindung mit einem üblichen Cassettenrecorder aufgezeichnet werden. Dieser speichert die Pressepisoden auf Magnetband, von wo die Information an de "Pulse Identifier" gelangt und von diesem codiert wird. Die Daten werden sodann an einen Plotter weitergegeben. Diese Studie ermittelte die Zuverlässigkeit und die Validität des "Pulse Identifiers" in Verbindung mit weiteren Instrumenten zur Aufzeichnung von nächtlichem Pressen und Knirschen. Eine bekannte Zahl von Pressepisoden wurde von 3 Zählern erfasst. Die Resultate zeigten einen Zuverlässigkeitskoeffizienten von 0.99 und einen Validitätskoeffizienten von 0.99.