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Technical procedure

A newly developed ultraminiature wearable electromyogram system useful for analyses of masseteric activity during the whole day

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ABSTRACT

Purpose: We describe the characteristics of a new data-logger-type ultraminiature electromyogram (EMG) system (FLA-500-SD) and methods used for recording and we show its potential in clinical applications by presenting an example of a clinical case.
Method: FLA contains electrodes, an amplifier, 12-bit analog-to-digital (A/D) converter at a sampling frequency of 1 kHz, 16-bit CPU, a 3.7-V coin-shaped lithium battery, and a micro SD card. The size of FLA is $37.0 \times 23.5 \times 8.6$ mm, and its weight is 6 g (9 g with a battery inserted). The device is wearable and patients can attach the device and operate it by themselves in daily life. Data recorded in the micro SD card are transferred to a personal computer and analyzed.
Although the device is ultraminiature and wearable, it has the capacity for recording a precise and clear masseteric surface electromyogram that is not inferior to that recorded by conventional stationary-type EMG recording systems.
Conclusions: To our knowledge, the device is the smallest and lightest device with capacity for the longest consecutive measuring time as a data-logger-type electromyograph with built-in electrodes and memory. The device is useful for analyses of masseteric activity during the whole day. In the future, it is expected that applications of the device will expanded to observation, evaluation and diagnosis of normal or abnormal gnathic functions, e.g., assessment of sleep and awake bruxism and observation of the chewing state in daily life.

1. Introduction

Bruxism is a repetitive jaw-muscle activity characterized by clenching or grinding of the teeth and/or by bracing or thrusting of the mandible [1]. Bruxism is a possible risk factor of various ailments and disorders in the stomatognathic system [2,3]. Assessment, treatment and management of bruxism are important in dentistry [4,5]. Assessment of sleep bruxism (SB) in ordinary clinical practice has been based on clinical findings such as teeth wear and interviews about tooth-grinding noise. However, an interview about teeth grinding noise is not necessarily objective, and the validity of clinical findings such as tooth wear for making a definite diagnosis of SB has not been proven [6]. Polysomnography with simultaneous audio-visual recording (PSG-AV) is currently the gold standard for assessment of SB [7]. It was suggested that 'possible' sleep or awake bruxism should be based on self-report, by means of questionnaires and/or the anamnestic part of a clinical examination. 'Probable' sleep or awake bruxism should be based on self-report plus the inspection part of a clinical examination. 'Definite' sleep bruxism should be based on self-report, a clinical examination, and a polysomnographic recording, preferably along with audio/video recordings [1]. However, PSG-AV has not become a routine clinical examination for diagnosis of SB due to its complexity, high cost, and burden and inconvenience for the patient. Bruxism has two distinct circadian manifestations: it can occur during sleep (indicated as sleep bruxism) or during wakefulness (indicated as awake bruxism) [1]. The necessity of a method for adequate assessment of awake bruxism has been

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pointed out. For a grading of 'definite' awake bruxism, self-report, clinical examination and an electromyographic recording are needed [1]. Thus a reliable and convenient method for assessment using a wearable device is needed.

The development of small integrated circuits (ICs) and small lithium batteries due to technological advancements has enabled miniature electromyogram (EMG) devices to be manufactured [8–11]. In cooperation with Harada Electronic Industry Ltd., Japan, we have developed an ultraminiature telemetric-type bruxism measurement system, BMS-601 (BMS), in which electrodes and an amplifier are directly connected [8]. Although the measurement sensitivity of BMS was very high [12], some linear-spike artifact signals that were thought to be arising from a communication error in the telemetric process were sometimes observed [13]. In addition, the telemetric system needed a receiver unit, which was inconvenient to wear or carry during the day. We therefore developed a data-logger-type EMG measurement system with built-in electrodes and memory [10]. This device was not telemetric and did not need a receiver unit. However, it was impossible for patients to handle the power on/off switch, change the battery and retrieve recorded data from the device by themselves in their home.

In the next step with the cooperation of Furusawa Lab Appliance Co., Japan, we developed another data-logger-type ultraminiature EMG system (FLA-500-SD) for clinical use. In this article, we describe the characteristics of the latest data-logger-type ultraminiature EMG system and the method for recording using the device and we show its potential for clinical application by presenting an example of a clinical case.

2. Materials and methods

2.1. Structure of the device

FLA contains electrodes, an amplifier, 12-bit analog-to-digital (A/D) converter at a sampling frequency of 1 kHz, 16-bit CPU, a 3.7-V coin-shaped lithium battery, and a micro SD card. The size of FLA is 37.0 × 23.5 × 8.6 mm, and its weight is 6 g (9 g with a battery inserted) (Figs. 1 and 2). The surface sizes of the bipolar measuring electrodes are 6 mm in diameter, and the distance between the centers of the electrodes is 24 mm. A reference electrode with the same size as that of the electrodes is positioned at the middle position between the two measuring electrodes. Gain of the amplifier is 256 times.

2.2. Measuring procedure

2.2.1. Preparation for recording

After charging, a lithium battery is inserted into the body of FLA. A micro SD card is inserted into a slot in the body of FLA. The switch of FLA is turned on and blinking of a small LED lamp indicates the start of recording.

2.2.2. Attaching FLA

The skin surface is cleaned with alcohol gauze, and then the device is attached to the skin surface with dedicated double-sided adhesive tape (Fig. 3A). During nocturnal use, stronger fixation by adhesive tape over the body of device is recommended. If patients need some camouflage for daytime use, the device can be covered with gauze as if it is covering a wound on the face (Fig. 3B).

2.2.3. Recording data

Prior to recording data during the targeted period, recording data during some calibration movements such as maximum clenching, tapping, swallowing and coughing is performed. Then patients start their usual daily lifetime activity without restraint. The device should be removed before faces washing and taking a bath. When the recording has finished, the device is removed and the power switch is turned off. The micro SD card is transferred from the body of FLA to a personal computer.

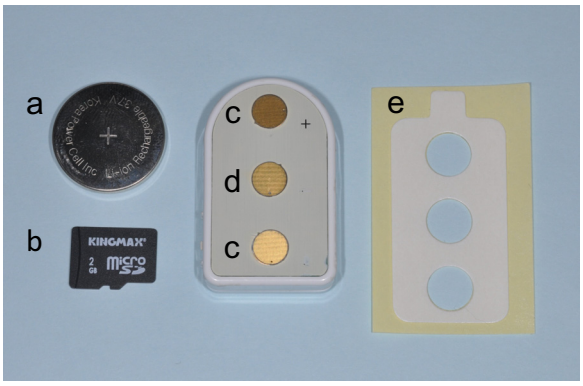

Fig. 1. Components of FLA-500-SD.
a: Coin-shaped lithium battery, b: micro SD card, c: measuring electrode, d: reference electrode, e: double-sided adhesive tape.

2.3. Data analyses

Data can be recorded in raw binary format at a sampling frequency of 1 kHz for 24 consecutive hours. The data can be converted to text (comma-separated values: CSV) data or EDF (European Data Format) data file. Owing to the capacity for conversion of the data format, the data obtained by FLA can be analyzed by various software programs.

EDF is a format for exchange and storage of multichannel biological and physical signals, e.g., polysomnographic data. The format is simple and flexible, and the volume of data is reduced and much easier to use than text format when handling a large volume data. Therefore, various kinds of commercial software and software made by the user can be flexibly used.

3. Difference from conventional methods

For conventional EMG measurement, skin preparation, i.e., scrubbing skin with a substance such as abrasive gel, and intermediation of a paste or gel pad that is electrically conductive between an electrode and the underlying skin are needed because high contact resistance between an electrode and the underlying skin causes a poor signal-to-noise ratio (S/N ratio). Recently, active electrodes, in which a preamplifier is embedded and connected to a measuring electrode, have been used for EMG measurement. The structure of an active electrode provides higher impedance of the measuring electrodes, i.e., close to skin impedance, and reduces contact resistance between the measuring electrodes and the underlying skin. Since active electrode structure is used in the new EMG device, recording can be performed with the electrodes in direct contact with the underlying skin without using conductive paste or a gel pad. The process of abrading skin can also be omitted. Patients can handle the power on/off switch, change the battery and retrieve recorded data (micro SD card) by themselves at home. To our knowledge, the device is the smallest and lightest device with the capacity for the longest consecutive measuring time as a data-logger-type electromyograph with built-in electrodes and memory.

4. Effect of performance

The following performance was approved by the ethical committee of Hokkaido University Hospital (No. 010-0303), and informed consent was obtained from the patient.

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