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Design and Evaluation of a Novel Technology for Ambulatory Monitoring of Bruxism Events

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***Abstract*—Bruxism is a widespread phenomenon whose diagnosis is usually made from non reliable, self-evaluation of the patient on one hand, and clinical signs whose absence does not mean absence of bruxism on the other hand. Different methods have been used in research setting for the assessment of bruxism such as portable electromyography but currently there exists no reliable method for the diagnosis of bruxism at home. In this paper, the hardware and software architecture of a complete ambulatory system, enabling long term monitoring of bruxism by measuring clenching/grinding forces of the patient is presented. The results of the tests conducted in vitro to evaluate the sensor's response are also presented. In vivo tests exhibited good correlation with an electromyography of the masseter muscle. With a maximum thickness of 2 mm, the discomfort for the patient is reduced and corresponds nearly to the usual thickness of an occlusal splint. This inductively rechargeable instrumented splint enables a long-term use over different periods and clenching/grinding data can be retrieved locally or transmitted wirelessly via WiFi, on a secured server, for further analysis.**

***Index Terms*—bruxism, instrumented splint, wearable sensors.**

I. Introduction

BRUXISM is a diurnal or nocturnal oral parafunction corresponding to involuntary rhythmic or spasmodic nonfunctional clenching and/or grinding of the teeth [1]–[3]. Although bruxism is a widespread phenomenon, it remains poorly understood in many points, especially about its etiology and neurophysiological mechanisms. It seems that bruxism is largely influenced by psychological factors such as stress and anxiety [4], [5]. Data on the prevalence of bruxism are quite variable because they are essentially based on a self-evaluation of the patients [6], [7]. In adults, the prevalence of clenching during the awakening is estimated from 20 to 50% and the prevalence of sleep bruxism around 10% [8], [9]. Bruxism is a disorder of major concern to dentists because of its possible consequences on the different components of the masticatory system [10]. Excessive occlusal forces can be responsible for dental restoration and/or hard dental tissue breakdown (wear, cracks) and cause temporomandibular disorders [11]. However, tooth clenching or tooth grinding must be differentiated because their consequences on the teeth, and for temporomandibular joint (TMJ) and masticatory muscles, are not identical. Tooth grinding irremediably leads to the wear of natural or prosthetic teeth. On natural teeth, wear has several possible consequences such as hypersensitivity to cold and hot, pulpitis, pulp necrosis, fractures, loss of masticatory efficiency, loss of vertical dimension, aesthetic problems. Tooth clenching doesn't cause tooth wear but has many deleterious consequences particularly on the TMJ (disc displacement or degenerative lesions) and on masticatory muscles (especially masseters) including hypertrophy, myalgia and tension headache [12].

Currently, there exists no reliable method for the diagnosis of bruxism at home [13], [14]. The diagnosis is usually made from self-evaluation of the patient and clinical signs such as grinding noises during sleeping, muscle tension and jaw morning stiffness, headache and signs of dental wear. However, these different signs are not always present (especially in case of clenching), so that their absence does not necessarily indicates absence of bruxism. In 80% of cases, bruxism causes no nocturnal noises, and is not always accompanied by muscular pain or hypertrophy of the masseters [15]. Similarly, dental wear is absent in the majority of cases (tooth clenching) and is not specific to bruxism [16]. For example, it can be the consequence of a chemical erosion resulting from the frequent ingestion of sodas or vomiting. Different methods have been developed for the assessment of bruxism [10]. Among them, polysomnographic (PSG) recordings provide the most suitable research diagnostic criteria for sleep bruxism but the technical problems (electrode placement, variation of the skin resistance level) and the fact that the technique is time-consuming and cost-intensive do not allow for routine use in large clinical studies [2],

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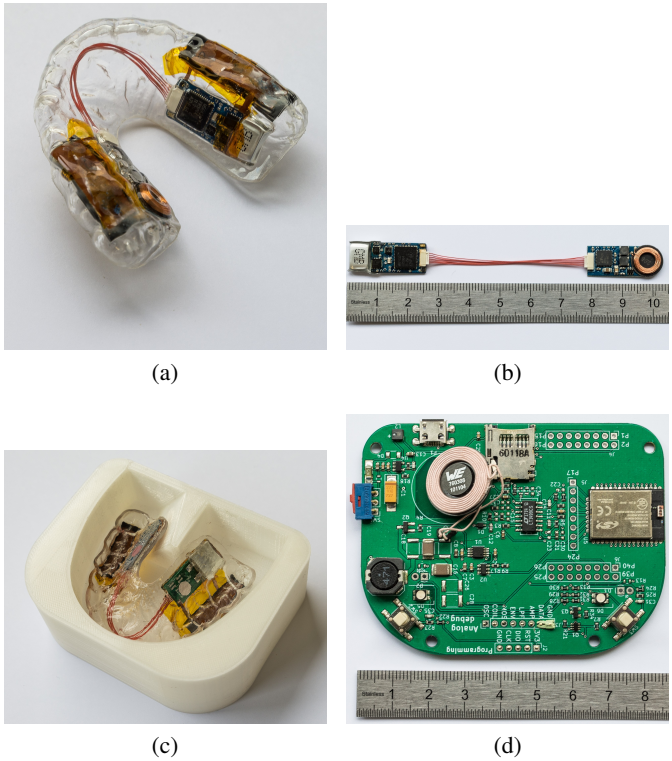
[3]. Portable electromyography (EMG) devices, which allow the recording of EMG activity of masticatory muscles during sleep in the habitual environment, reduce costs and limit patient discomfort, representing an acceptable instrument in the research setting. Such EMG recordings have been the most frequent source for detailed information about sleep-associated oral motor disorders, the masseter muscle being the preferred site for EMG recording [17]. However, similar technical problems prevent their use in ambulatory patients. In several studies, bite force recorders were developed to precisely measure dental forces exerted by the patient, but these devices are not relevant to measure bruxism as they are not suitable for ambulatory use [18], [19]. Some researchers tried to improve this aspect by instrumenting oral splints but presented bulky devices not suitable to be used by the patient without discomfort [20]–[24]. Furthermore, because these devices aimed to measure bite force in real time, they were using radio-frequency inside the patient oral cavity to transmit real-time data. Although having a good autonomy they did not exist with the possibility to charge the device to extend its life and therefore measure bruxism over a long period.

In this paper, we present a complete ambulatory system enabling long term monitoring of bruxism by measuring clenching/grinding forces of the patient. Thickness of the occlusal splint is one of the main source of discomfort for the patients [25]. With a maximum thickness of 2 mm, which corresponds nearly to the usual thickness of an occlusal splint, we expect this instrumented splint not to cause additional discomfort. A long-term use over different periods is possible because the device is rechargeable; data are transmitted through the inductive link to a charging base only when the instrumented splint is charging and can be retrieved locally or transmitted wirelessly via WiFi, on a secured server, for further analysis. In a first part, we present the hardware and software architecture of this new technology; and in a second part, we report the results of the test conducted in vitro to evaluate the sensors response as well as in vivo tests where the measured data from the instrumented splint have been compared to an EMG record of the masseter muscle.

II. Material and Methods

A. System overview

Our system designed for the monitoring of bruxism is composed of two separate devices. The first one is an instrumented occlusal splint, as illustrated on Fig. 1a, in which are encapsulated two piezoresistive sensing elements as well as two miniature electronic circuit boards (25 mm x 10 mm) and battery. The circuit boards are linked together with a 6 contacts cable. The second device is a charging base (Fig. 1c) whose shape is made for placing the occlusal splint. Two pellets sensitive to humidity are also inserted at each side of the splint, near the electronic components in order to check the sealing of the system. The occlusal splint is formed by two thermoformable plastic foils with a thickness of 1 mm (DURAN®, SCHEU-DENTAL GmbH) encapsulating sensors and electronics. This material is dedicated to the manufacturing of occlusal splints with a biocompatibility approved according to DIN 10993 and EN ISO 7405 standards. If humidity is present inside the splint (due to penetration of saliva for example), then the white color of the pellet change to red. The base comprises an electronic circuit board (85 mm x 65 mm) which wirelessly both charge the splint's battery and transfer the recorded data.



(a) (b) (c) (d)

Figure 1. System overview : Instrumented splint (a) and the charging base (c) with their respective electronic circuits (b) and (d) [26]

The system is intended to be used as follow: the instrumented splint is worn at night by the patient and clenching/grinding signals are sampled and stored in the internal memory of the device. In the morning, the splint is placed on the charging base and a magnetic field is generated by the base to charge the battery of the system by induction. Data are transmitted by the splint using LSK modulation over the inductive link carrier

at 19200 bps. The original bitstream is retrieved by an analogic demodulation circuit in the charging base and data are stored either locally on an SD card or transmitted to a secure server via WiFi depending on the chosen configuration.

B. Instrumented occlusal splint

1) Hardware: The global electronic architecture of the instrumented splint is shown on Fig. 2. Components were selected to minimize both size and power consumption. The MSP430FR5964 (Texas Instrument, Inc.) is a low-power, mixed-signal microcontroller unit (MCU). It offers low power consumption (118 μA in active mode and 500 nA in standby), an embedded 256kB FRAM memory and a 12 bits ADC in a small 7.15 mm x 7.15 mm x 1 mm QFN package.

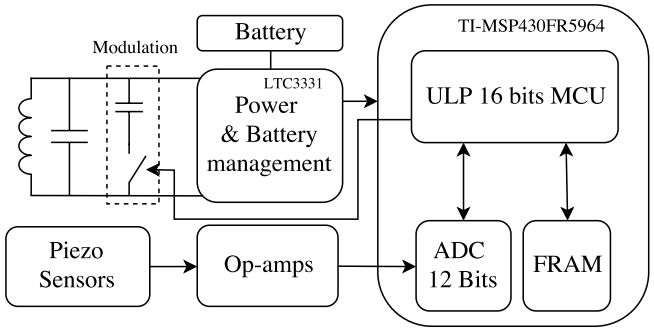


Figure 2. Electronic architecture overview of the instrumented splint

2) Sensors: The sensors are composed of carbon black filled polyethylene (ET331080, GoodFellow) whose resistance decrease with the force applied. Conversely, sensors conductance offers a better linearity than the resistance. In the splint, four layers of 0.08 mm thick have been inserted between two copper clad laminated polyimide electrodes. A characterization of the electric resistance and conductance variations depending on the force applied is presented on Fig. 9 in section III-B.

Therefore, sensors are interfaced with the microcontroller using an operational amplifier circuit in a non-inverting amplifier configuration as depicted in Fig. 3. It enables the use of the operational amplifier with a single supply and the expression of the output voltage (given in equation 1) is a function of the conductance of the sensor, where V_{ADC} is the output voltage of the circuit, $R_{digipot}$ is the resistance of a digital potentiometer controlled by the MCU to form a programmable gain amplifier, R_{piezo} is the variable resistance of the sensor and V_{in} is a reference voltage.

$$V_{ADC} = (1 + \frac{R_{digipot}}{R_{piezo}}) \cdot Vin \qquad (1)$$

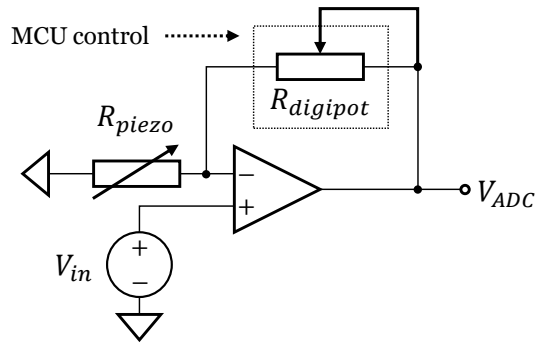


Figure 3. Sensors interfacing chain

Several studies have shown that physiologic and morphological variables such as age, gender or craniofacial morphology can affect the maximum bite force value exerted by the patient [27]. Therefore studying an absolute force value reduces the measurement range for patients with a low maximal bite force. Studies reported in literature after 2000 show an average value of 534 N [28]. Thus the measurement chain has been designed accordingly and the sensors tested at 500 N. Furthermore, because a pressure molding machine is used in the fabrication process of the instrumented splint, the sensors are preloaded by this encapsulation process and the applied load depends on many parameters such as the height of the plaster model or the shape of the patient's teeth. Therefore, to use the maximum of the microcontroller ADC range, two digital potentiometers in a rheostat configuration are used as feedback resistors enabling adjustment of the measurement range regardless of the strength of the patient's maximum tightness or the preload applied during the manufacture of the splint. The maximal force consciously exerted by the patient is set to 80% of the full scale and the exact ADC value of this force is recorded to subsequently express the clamping forces as a percentage of this maximum value and not as an absolute measurement. Consequently, the protocol for using the instrumented splint includes a calibration phase for the first use where the patient is required to exert its maximum conscious force on the splint.

3) Power & communication: The instrumented splint is powered by a small (10.5 mm x 10.5 mm x 3.1 mm) 12 mAh rechargeable lithium-ion battery. Inductive charging is used to charge the battery thus enabling the encapsulation of the entire electronic circuit in a splint. When the splint is charging, an alternating magnetic field generated by the charging base is converted into an AC voltage by a parallel LC resonant circuit. The LTC3331 integrated circuit (Analog Devices, Inc.) manages the transition between the two power sources (induction

or battery). This circuit includes a voltage rectifier, a buck and a boost converter. It enables an autonomous power path management for battery charging and system powering by ensuring a smooth transition from an inductive powering state to a battery powered state. The instrumented splint communicates with the charging base through the inductive link by means of capacitive modulation technique : two transistors periodically switch two capacitors across the resonant parallel tank. Messages are sent by the embedded microcontroller at 19200 bps using an UART-like format. The splint receives periodic acknowledgement messages from the charging base, as described in section II-C2, to ensure a good synchronization of the communication state machine.

4) Embedded MCU software: The sate machine of the embedded MCU software is given figure 4. Firstly a calibration is performed during the first usage to adjust the measurement range and record the maximum value consciously exerted by the patient. Afterwards the splint can be used by the patient, and the output voltage from the sensor conditioning chain is sampled at 2 samples per second as soon as the splint is removed from the charging base. ADC values are stored in the embedded, non-volatile FRAM memory until either this memory is filled, or the instrumented splint is placed on the charging base. Data are transmitted while the splint is charging and a measurement cycle can start again only when the memory of the splint has been completely transferred to the base. Attention has been paid to minimize power consumption when the system is used: the microcontroller is kept in a low power mode (LPM3) between measurements and is only periodically awakened in an active state for a very short time (14 μs) required to sample the voltage from the analog measurement chain.

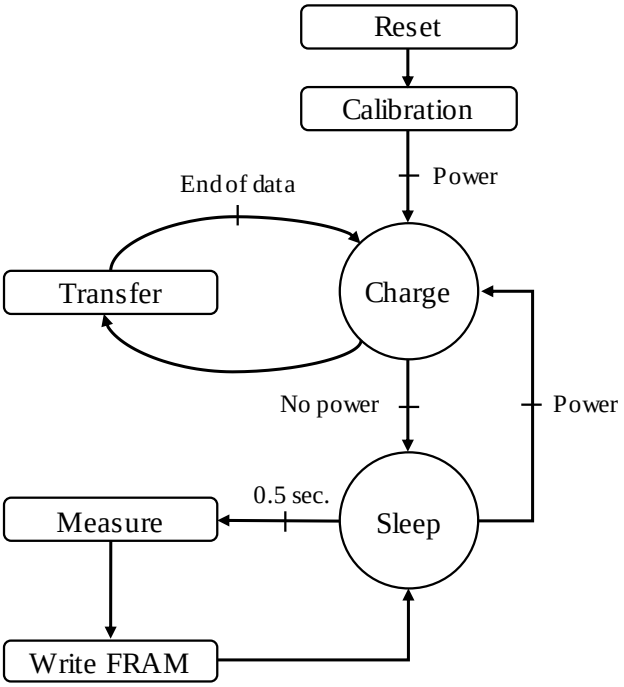


Figure 4. State machine of the embedded system

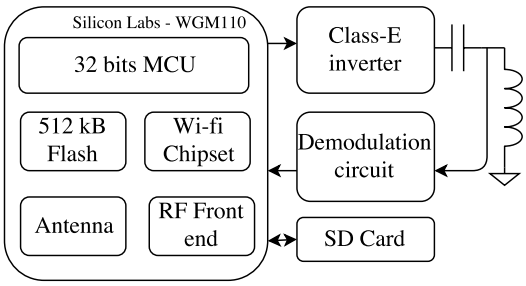


Figure 5. Electronic architecture overview of the charging base

C. Charging base

1) Hardware: The electronic architecture of the charging base (Fig. 5) is built around a WGM110 (Silicon Laboratories) WiFi module. This module includes a 32-bit MCU as well as a fully integrated 2.4 GHz 802.11 b/g/n radio and antenna. A class-E inverter is used as a coil driver to implement a resonant inductive link for wireless power transfer to the instrumented splint. Data transfered by the splint via backscatter modulation through this inductive link is demodulated using an analogic demodulation circuit and data are stored on an SD-Card. If data transmission to a server is required, the charging base can be connected to internet using the WGM110 embedded WiFi radio. The data are then forwarded to the server using HTTP queries. The board is powered from a standard commercial 230 V_{AC} - 5 V_{DC} converter with a micro-USB connector.

2) Power: An alternating electromagnetic field is generated by the charging base to power and charge the instrumented splint. A class-E oscillator (Fig. 6) generates an alternating current in an inductor producing the magnetic field. The class-E topology of the inverter enables zero voltage switching (ZVS) of the transistor used and thus reduces losses and heat in the switching elements. By periodically disabling the class-E inverter, an on-off shift keying (OOK) modulation is implemented to transmit occasional status messages for the synchronization of the communication between the splint and the charging base. Two main standards does exist for wireless power transfers (Wireless Power Consortium and AirFuel Alliance). Those protocols use either backscatter modulation or Bluetooth Low Energy (BLE) to transmit messages from the power receiver to the power transmitter in order to regulate the power transmitted to the load [29]. In order to minimize size, back-

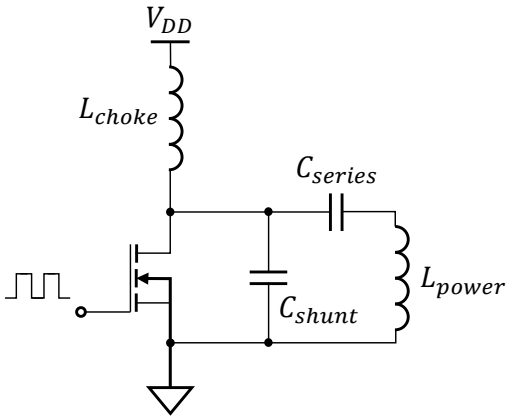


Figure 6. Class-E oscillator topology

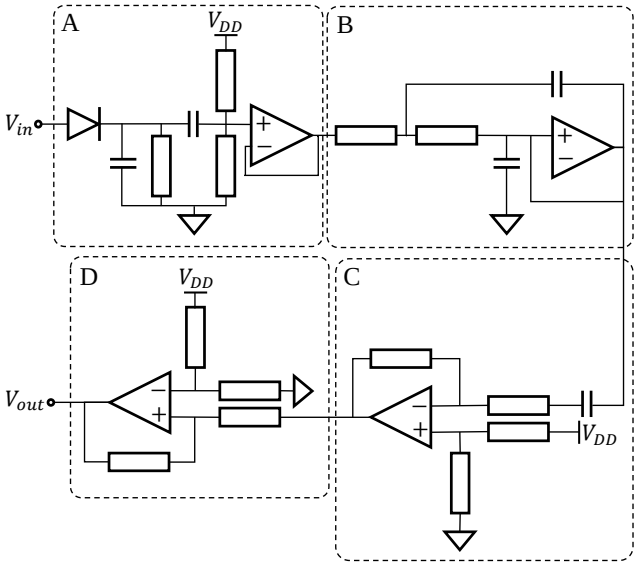


Figure 7. Wireless transmitter power carrier demodulator architecture. A : Enveloppe detector, B: 2nd order Sallen-Key LPF, C: Inverting amplifier, D: schmitt trigger

scatter modulation has also been chosen in our device to transmit messages from the splint to the charging base. But the need for transmitting the acquired signals led us to use proprietary messages instead of the QI standard. Therefore, transmitted power levels has been adjusted to get enough output power at the receiver side under worst case coupling conditions and to avoid exceeding the rated current of the transmitter coil in the best case coupling condition. Futhermore the LTC3331 integrated circuit used in the instrumented splint has an input protective shunt.

3) Communication: As shown on Fig. 7, messages received from the splint are firstly demodulated using an envelope detector. Once the communication signal is extracted from the carrier, the DC part is removed and the signal is filtered, amplified and passed through a Schmitt trigger to retrieve the original bitstream.

4) MCU software: The main role of the software embedded into the charging base is to ensure that data are properly received and stored on the correct media (SD card or server). Additionally, the software implements detection and communication with the splint:

1) Firstly the program periodically activates the inductive link in order to ”ping” the splint and wait for a possible response;
2) Then a proprietary communication protocol enables the synchronization between the gutter and the base as well as the transfer of measurements.
3) Additionally, the OOK modulation used by the base enables the transmission of short status messages to the splint in a very punctual way; the reception of status messages coming from the splint makes possible to know if it is still on the charging base and detect a possible removal. They also indicates whether the splint has data to be unloaded and the indication of its battery level;
4) Finally, if the transmission of data to a server is required, the recharging base can be connected to the internet using WGM110 embedded WiFi stack. The data are then forwarded to the server using HTTP queries.

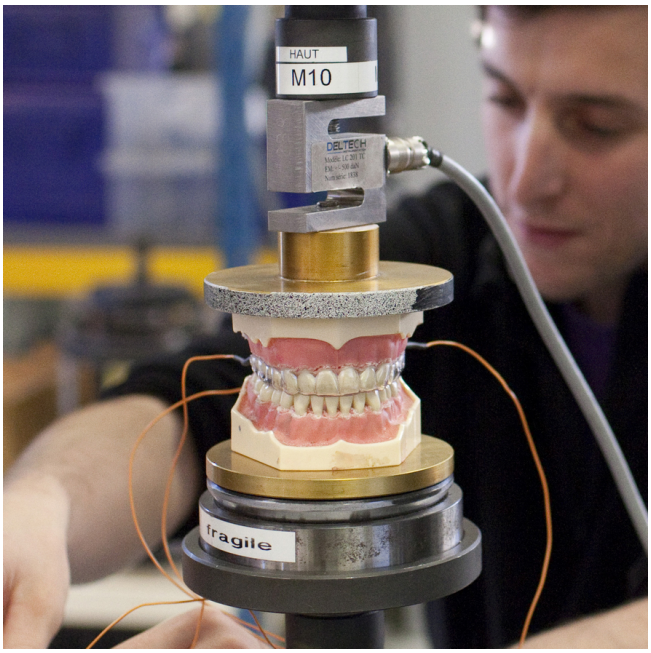


Figure 8. Overview of the experiment for in vitro characterization of the sensing system

III. Results

A. Power and communications

Current consumption measurements were performed using a 2400 SourceMeter (formerly Keithley Instruments, now Tektronix inc.) for the two operating modes of the splint (away from the base). In the normal measurement mode, the average current consumption is 80 μA and increases up to 127 μA during the calibration mode. Together with the 12 mAh battery, the system can be used during 150 hours without placing the splint on the base. However, because of the sampling rate of 4 samples per second which represent 8 bytes to be written in FRAM, the measurement period of the splint is limited to 8 hours until the memory is filled, whereupon the measurements are stopped and the system remains in a idle state until it is placed on the charging base to transfer data.

B. In vitro evaluation of the measurement method

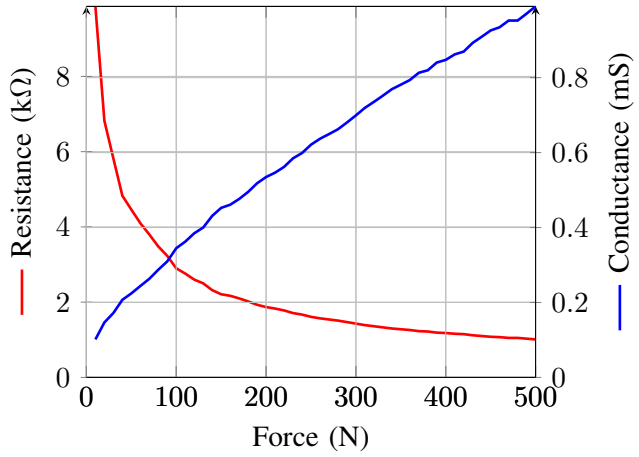


Figure 9. Resistance-force and conductance-force characteristic of the ET331080 piezoresistive film

The sensors and the signal-acquisition chain were evaluated using a Z Mart Pro compression machine (Zwick Roell). The sensor material, an ET331080 piezoresisitive film (GoodFellow), was encapsulated in an occlusal splint composed of two thermoformable plastic foil. The first foil was heated at 220 °C and deposed on a physical model using a pressure molding machine (Ministar S, Scheu Dental). The sensor was then positioned on each molar area of the splint, the second foil is deposed, and finally the excess material was trimmed away.

Firstly, the electric resistance of the sensors was directly measured when varying the applied force between 0 and 500 N. The resistance-force and conductance-force characteristics of the piezoresistive films are shown on Fig. 9.

According to the interfacing circuit described in Section II-B2, the sensors were connected to an external, non-inverting amplifier circuit using a TLV2464 operational amplifier (Texas Instruments), in order to obtain a voltage which varies only with the change in resistance of the sensors, depending on the force applied (see Equation 1). Additionally, a flat aluminum stirrup was positioned on top of the splint containing the model in order to allow a uniform pressure distribution 8. During

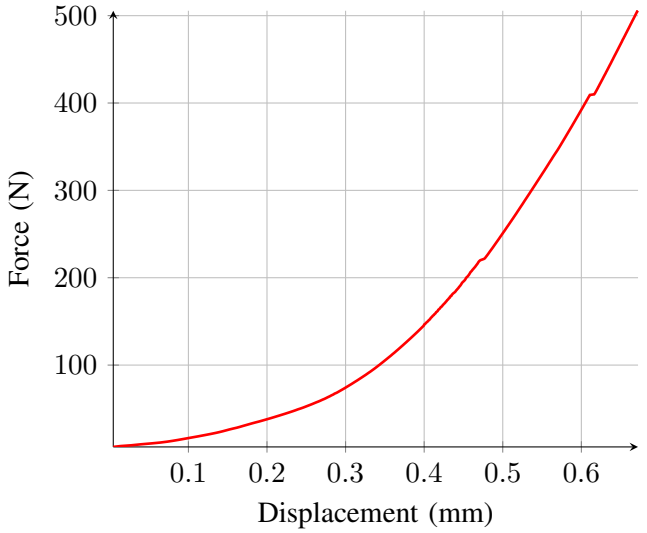


Figure 10. Force vs. displacement profile applied to the splint during in vitro characterization

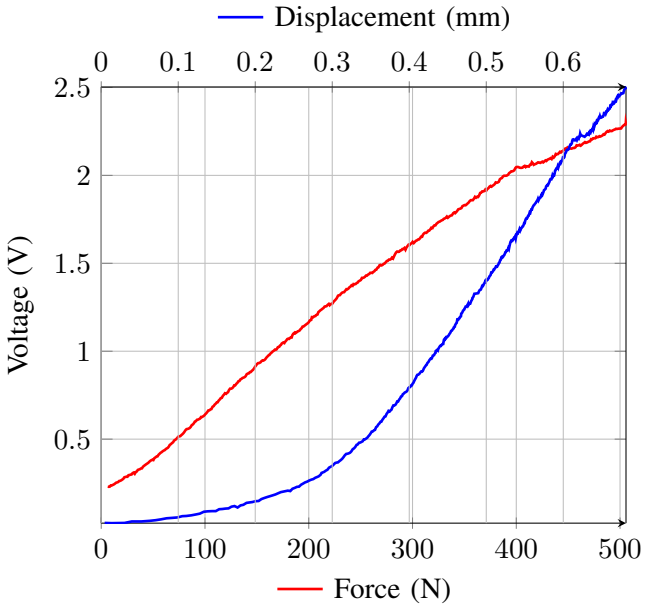


Figure 11. Output voltage as function of the displacement and the force applied

the tests, forces were applied from 0 to 500 N on the device at a rate of 1 N/s. The force - displacement curve applied during this test by the compression machine is shown on Fig. 10. Simultaneously, the output voltage of the acquisition chain was sampled at 1 sps with a portable data logger (OM-DAQPRO-5300, Omega) and is represented on Fig. 11 together with the force and displacement applied. Finally, rapid cycles of pressure variation were applied in order to characterize both the response time of the system, and additionally no particular residual effects of the high pressures applied on the splint.

The repeatability of the splint has been studied through rapid loading-unloading cycles. The splint was inserted in the physical model placed on the same compression machine. The output signal was recorded using data logger at a rate of one sample per second. Five cycles have been applied where the force ranged from 50 to 250N, each cycle lasting about 1 minute. The maximal relative difference has been evaluated to 4.57%. The output value for the maximal force (250N) slightly increased with the number of cycles indicating a viscoelastic trend of the splint under rapid solicitations.

C. In vivo evaluation

1) Preliminary results: Preliminary in vivo data were obtained with an instrumented splint which has been worn by a voluntary subject (male, 59 years old). If humidity is present inside the splint due to penetration of saliva, then the white color of the pellet changes to red. The subject has been told to successively operate clenching, grinding and tapping. The splint was then placed back on the charging base and data were collected on a microSD flash memory card. The signals obtained are plotted on Fig. 12 on which the different phases are mentioned. Repeated measurements following this procedure have enabled to establish consistent repeatability of the measures. However, quantitative indicators could not be computed as it is very difficult for a subject to replicate exactly the same force applied during each trials.

Clenching, tapping and grinding events can be identified according to the following criteria:

- Clenching: Left and right signals increase and decrease synchronously, and the average duration of the event is comprised between 3 and 8 seconds [30];
- Tapping: Left and right signals increase and decrease synchronously, and the average duration of the event is shorter than 3 seconds;
- Grinding: Left and right signals increase and decrease alternatively.

2) Comparison with electromyography: In addition to the preliminary signals obtained and to confirm the ability of the instrumented splint to surrogate polysomnography for the diagnosis of bruxism, the signal measured by the instrumented splint were compared to the EMG signals recorded from the masseter muscles. A PowerLab 26T bioamplifier (ADInstruments) was used to assess the surface EMG activity of the masseter muscle while wearing the instrumented splint and performing a simple sequence of dental clenching. Fig. 13 clearly shows the relationship between the clenching data from the instrumented splint and those measured using the bioamplifier.

3) Test over a complete night: Finally, the voluntary subject has worn the device during one night to test robustness and autonomy of the device. Figure 14 illustrates data recorded over more than 7 hours, which represents the duration of the entire night, thus demonstrating the ability of the sensor to monitor continuously clenching forces during the night.

IV. Conclusion

In this paper we presented a new technology for the monitoring of bruxism out of hospital. This technology is composed of a rechargeable instrumented occlusal splint and a connected charging base. We demonstrated its capability to collect clenching/grinding data. While the masseter's EMG is widely used in research settings to get information about sleep-associated oral motor disorders, this measurement method is uncomfortable for the patient and necessitate to spend nights within an hospital. Thus we believe that our technology could be used as a surrogate of the masseter's EMG, avoiding technical problems such as electrode placement, and providing an easy and cost effective solution for the monitoring of bruxism at home. In comparison with existing systems, the presented instrumented occlusal splint has the advantage of being able to differentiate clenching events from grinding events, due to the precise measurement of intensity and duration of events on left and right side independently. Also, the system can be used during more than one entire night, can charged without any wire and does not use any RF communication within the mouth, which makes it more convenient and comfortable to use compared to devices cited in introduction; especially with the fact that, given the additional internal electronics, the final thickness of the occlusal splint remains close to 2 mm. It is expected that the lifetime of the instrumented splint exceeds two years with a daily usage as it depends on the thermoformable plastic foils used for the encapsulation. As such, this duration is given by clinical practice with ordinary occlusal splint made of equivalent materials. The current

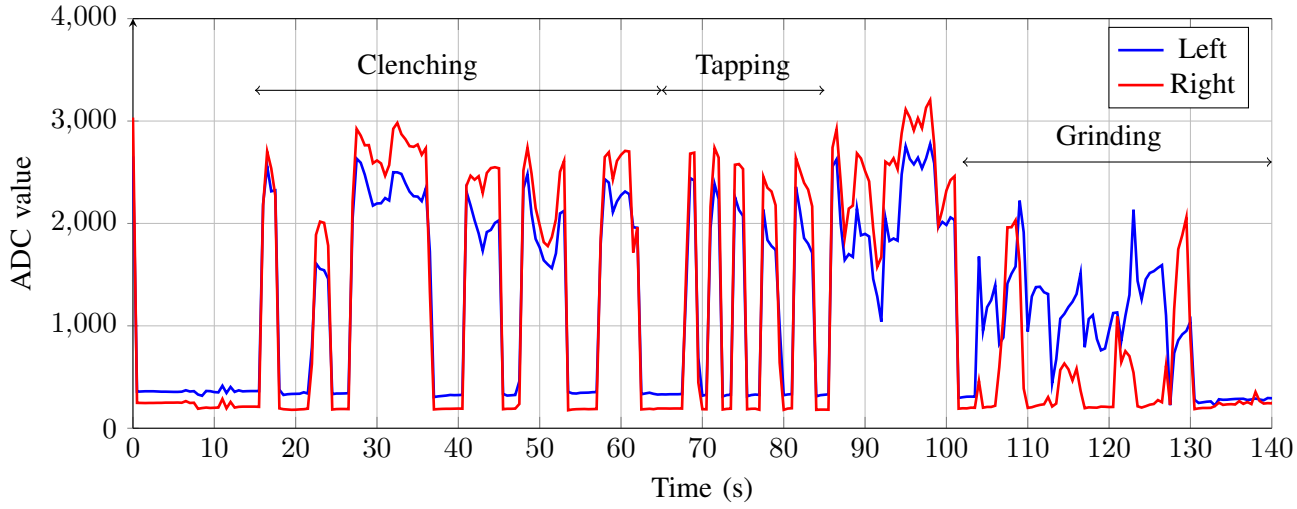


Figure 12. Example of clenching, grinding and tapping signals obtained with the instrumented splint

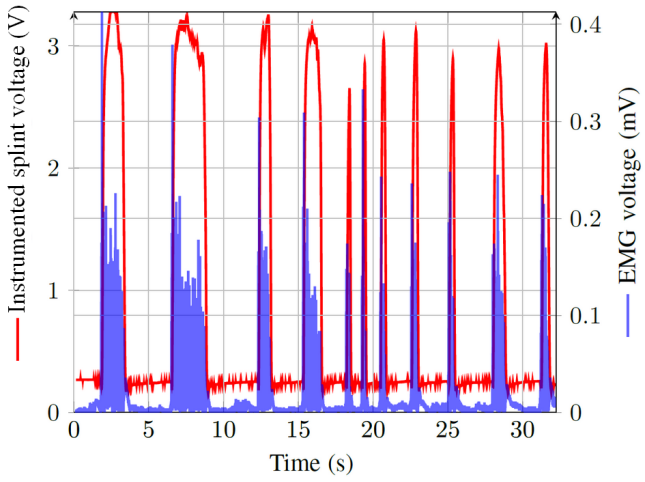


Figure 13. Masseter EMG (rectified) and splint signal

gold standard test for the diagnosis of bruxism remains the polysomnography, therefore future studies will include comparative measurements of polysomnography and signals obtained with the instrumented splint to demonstrate the relevance of this measurement technique for the diagnosis of bruxism events, as well as comfort, repeatability and maximum lifetime of the sensor. This will also include tests to prove the ability of the system to be used in real life conditions for periods greater than a week and evaluate its compliance as well as the ease of use for the patients. When more data will have been collected, it will be possible to define thresholds for the magnitude and frequency of bruxism events and thus enable their classification in terms of severity. We believe that this device will overcome the current lack of tools preventing from running studies at large scale for the analysis of bruxism. Indeed, the use of the system could be promising, whether as a research tool for studying bruxism and its relationship with the sleep cycles and the sleep disorders (sleep apneas) or as a medical device for the ambulatory diagnosis of bruxism. First recordings show that it is possible to record the bruxism events during several nights and to measure different parameters such as the number of bruxism events, their duration, their intensity and to characterize their shape and their distribution along the night.

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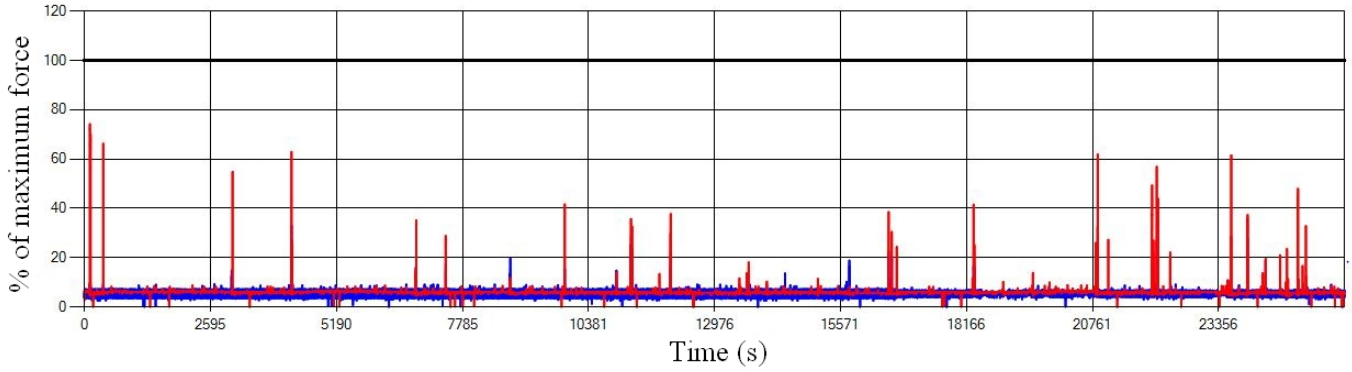

Figure 14. Illustration of a signal acquired during one entire night. Observed peaks correspond to bruxism events.

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