Measuring Inside Your Mouth! Measurement Approaches, Design Considerations, and One Example for Tongue Pressure Monitoring

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The tongue is an important muscular organ, and its interaction with the hard palate is fundamental during speech and deglutition (the act or process of swallowing). For example, typical complications of cerebrovascular diseases are speech and deglutition disorders due to limited range of motion and tongue weaknesses. Different measurement approaches of these limitations are described in the literature. The development of low-invasive measuring systems is currently considered a priority. In this paper, we describe different approaches, design considerations, and one example: a new implantable intraoral device that we developed to measure tongue pressure [1]. This paper was first submitted to the IEEE MeMeA Symposium 2014 (© 2014 IEEE, in *Proc. IEEE MeMeA*, used with permission, [1].) This new device measures tongue pressure on the hard palate directly inside the oral cavity and transmits the data via a wireless link. Since no cable links the pressure sensors inside the oral cavity and the readout unit is located outside of the mouth, this device is low invasive, which represents an important feature for this type of device. We describe a typical experimental setup to study the mechanical behavior of these devices in the laboratory and specific test protocols. The field of application of these devices is the treatment of patients with deglutition and speech disorders or with gnathological (related to the entire chewing apparatus) and dental disturbances.

Measurement Approaches

The tongue plays an important role in physiologic processes, such as respiration, mastication, deglutition, and speech production. For example, during the production of spoken language, the tongue controls airflow, allowing articulation of different sounds by interacting with the hard palate and the oral cavity. The tongue is essentially composed of muscles, which allow the tongue to assume different shapes quickly. The tongue function during deglutition is a biomechanical complex process, consisting of a series of rapid shape variations for keeping and preparing the bolus inside the oral cavity and for pushing it through the oropharynx.

Nowadays, the number of patients affected by neurologic cerebrovascular or cognitive disorders is increasing. These patients usually have problems during deglutition and articulation of sounds. Therefore, they require a rehabilitative therapy [2], [3]. Down syndrome, also known as Trisomy 21, is a congenital autosomal anomaly causing intellectual impairment, motor disorders, and dismorphologies. Deep and high palate, incomplete lip closure, hypotonic lips, fissured tongue, inaccurate and slow tongue movement, and hypodontia are some of the most common craniofacial characters observed in people with Down's syndrome. Children with Down's syndrome or children affected by open bite have to be cured through intensive and efficient therapies in their first years to improve mobility and positioning of the tongue during deglutition and speech production. Children with Down's syndrome demonstrate a forward tongue position during food deglutition. Tongue position on the presentation of food is most commonly behind the teeth, but these children put their tongue on the teeth and on or beyond the lower lip. If this behavior persists, secondary pathologies such as airway infections, retarded and decreased bite function and development of oral stereotypes occur. Therefore, these pathologies establish and impede healthy physiological development. Because of this, habitual mouth-breathing, feeding disorders, lack of mastication, prolapsed and protrusion of the tongue, lip incompetence, drooling as well as deglutition and speech disorders are problems most often recorded in disabled children with orofacial muscle dysfunction. This developmental syndrome requires early functional training of the orofacial muscles. Another physiological alteration requiring particular attention is the open bite. It is characterized by a specific misalignment between the teeth of the two dental arches in the vertical plane caused by a dental or skeletal malposition. This prevents the patient from assuming the correct intercuspal position, since each tooth of one arch occludes specific portions of two others in the opposing arch, with some exceptions.

This is an extended version of the paper presented at the IEEE International Symposium on MeMeA 2015 [1].

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Despite its significant role in several vital functions, the study of the tongue has not received great attention by anatomists, speech therapists, and physiologists due to its complexity. For example, deglutition patterns are not so easy to distinguish clinically. The recent biofunctional orofacial model is a new approach for defining normal functions and dysfunction of the oral cavity during deglutition [4]. This model allows evaluating the equilibrium of opposite forces exerted on teeth by tongue, lips and cheeks.

The measuring systems of tongue pressure against the hard palate during speech production or deglutition can be a therapeutic and diagnostic tool, since the contact between tongue and palate is essential during these vital functions. Especially, the evaluation of tongue position right after the deglutition can help to identify dysfunction of the tongue. In this particular situation, in healthy people, the tongue tip is usually on the hard palate just behind the upper teeth and is compatible with the rest position. Otherwise, in patients with tongue dysfunction, the rest position is lost immediately after the conclusion of deglutition.

The literature reports very little information about tongue pressure against the palate and associated measuring systems. Indeed, these systems have been largely ignored, although they could be useful for research in biological, diagnostic and therapeutic fields [2]. The detection of tongue contact or measurements of tongue pressure exerted on the hard palate are not easy tasks. The few proposed techniques, which differ significantly from each other, are characterized by remarkable limitations and several are invasive for the patients and complex.

Measurement Methods

The primary techniques, which have been adopted for measuring tongue pressure or contact, are described briefly.

- An X-ray technique [5] allows the detection of the contact between tongue and palate by observing only one direction. Unfortunately, radiation exposure time is an issue, and a value of contact pressure is difficult to obtain.
- Similarly, Magnetic Resonance Imaging (MRI) [6] is a medical imaging technique, and it solves the issue of X-ray single direction, allowing 3D imaging of the oral cavity. However, the image acquisition time is usually long, and it prevents the acquisition of tongue movements such as during the pronunciation of letters or words.
- Conversely, electropalatography (EPG) [7] is a technique for monitoring the tongue contact with the hard palate and consists of a custom-made artificial palate containing electrodes that are inserted in the oral cavity. It does not permit measuring the tongue pressure against the palate but only detects their contact. A commercial device generally adopted in these applications is the Iowa Oral Performance Instrument (IOPI) [8]. This instrument is designed properly to evaluate the strength and endurance of the tongue and of the lips. It is composed of a disposable standard-size tongue bulb, which is attached to an acquisition system through a tube. However, this device can be used in few applications, and it was ineffective for detecting tongue pressures during word articulation in [9].

The lack of techniques to detect and measure tongue pressure against the palate has led research institutes to implement several different techniques for research and diagnostic aims.

- In [10], the measurement of the tongue pressure on the palate is performed during swallowing. Tongue pressure and strength are compared between young and elderly subjects. The three adopted sensors are air-filled bulbs fixed to the medial palate and connected to a pressure measuring system that is external to the oral cavity, by means of a cable.
- In [11], the same method is adopted for detecting lingual dysfunctions in patients affected by dysphagia. The method is adopted for measuring the tongue pressure on the palate during deglutition, while in [3], the same device is adopted for measuring tongue pressure only during the swallowing of liquids. This solution is useful for measuring the pressure on several areas of the palatal surface, but it is an invasive solution for the patient due to the tubes, which come from the mouth to link the sensors to the measuring system.
- In [9], tongue pressure on the palate is detected during speech production in patients who have undergone surgery for the partial removal of the tongue. The pressure sensors are commercial strain gauges (Kyowa PS-2KA), and they are placed on the palate surface where the tongue should make contact.
- In [12], the same sensors have been adopted for measuring tongue pressure against the lingual surface of the lower anterior in patients wearing cervical headgear (CHG). In this case, the sensor is incorporated in a lingual flange of a custom-made intraoral appliance made of silicon rubber.
- In [13], the effect of the tongue pressure against the palate is measured and evaluated by using strain gauges (Kyowa PS-1) to define the factors related to the formation of the tongue's indentations.

The authors have found that the strain gauges are very effective because they are relatively thin (only 0.1 mm), but they require an external conditioning circuit outside the oral cavity, and the cables reduce the number of applications.

A substantial amount of research has shown several patented techniques for measuring tongue pressure against the palate, even if their specific application has not been defined yet. In [14], a measuring system based on very thin resistive sensors is described. The sensors are placed on the palate, and they communicate with the external conditioning circuit via a cable to amplify the signals and record the measurement data. In [15], a molded structure conforming to the hard palate and equipped with two sensors is proposed for measuring tongue pressure against the palate. In this case, since the molded structure protrudes from the outer lips, it can be considered invasive and not appropriate for phonetic rehabilitation activities.

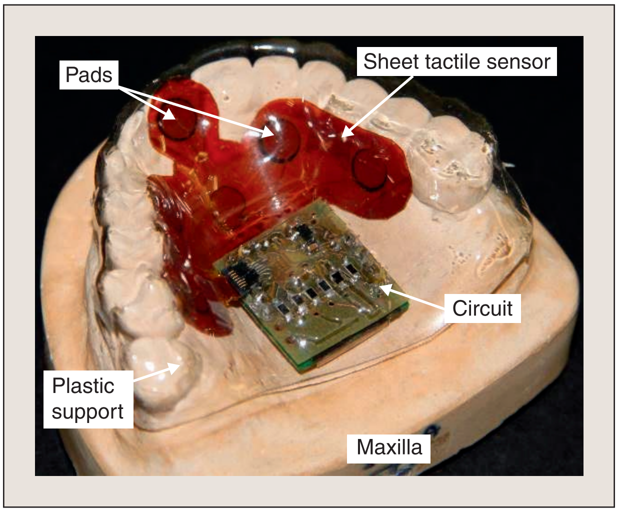

Fig. 1. Images of the tongue pressure sensor enclosed in a biocompatible plastic support and placed on a maxilla model (© 2014 IEEE, used with permission, [1].)

Videofluorography (VF) or videoendoscopy (VE) are usually used for clinical and diagnostic purposes. In fact, VF is considered the gold standard for the evaluation of the dysphagia. In [16], [17], the authors have qualitatively analyzed the coordination of tongue and mandibular movements during mastication and deglutition using VF and VE. However, since it involves radiation exposure, VF is not recommended for repetitive and prolonged applications. Therefore, in the literature, new low-invasive methods for measuring tongue contact against the hard palate have recently been studied and proposed. In [9], [18], different types of sensors have been adopted for measuring tongue pressure inside the oral cavity. These techniques are based on sensors fixed on the palate that are connected to the external conditioning circuit outside the oral cavity via cable. For example, in [19], the authors proposed a pressure sensor consisting of a palatal sheet equipped with five sensors. Unfortunately, the wired connection between the oral cavity and the readout unit placed outside can compromise speech sound articulation or deglutition. Furthermore, the patient can perceive this device as invasive due to the cables hanging from the mouth.

New Wireless Methods

Systems using wired connection between sensors inside the oral cavity and a conditioning circuit placed outside the mouth are discussed extensively in the literature, and different approaches adopting wireless communication have been proposed [20], [21]. For example, the focus of Ro *et al.* is the development of a method based on wireless telemetry to improve available methods measuring intraoral pH [22]. In other cases, wireless intraoral devices are proposed as biofeedback systems. Vuillerme *et al.*, instead, shows the architecture and the working principle of a new wireless system for fall prevention and balance control [23]. In this case, the wireless tactile device provides supplementary information related to foot sole pressure distribution. In further research, an intraoral device is adopted as actuator. In [21], a prototypical system for the interface control via wireless is described. The tongue manipulates the buttons of the intraoral device, and the commands are sent wirelessly dozens of meters away to a wireless coordinator and distributed wireless controllers. Therefore, quadriplegic patients can use this device as a wireless controller for wheelchairs, electronic devices, etc.

A New Design to Monitor Tongue Pressure

Wireless communication represents an effective solution for measuring inside the oral cavity. We developed a new wireless intraoral device that is implantable to measure tongue pressure against the palate [1]. This device permits the analysis of the fundamental characteristics and the design considerations of implantable intraoral devices.

The device has a basic architecture consisting of six pressure sensors, a conditioning electronics, and a transceiver. The sensors were fabricated by a screen printing technique using a low-temperature plastic substrate. The screen printing technique allows the fabrication of low-cost, light, flexible, and biocompatible sensors. This technique is based on the deposition of a thick film (few microns) with a single pass using a mask.

The device is composed of a matrix of screen-printed sensors fabricated on a plastic film (Fig. 1). The sheet sensor is connected to a circuit for conditioning the signals and transmitting the measurement data outside the mouth wirelessly.

Minimally Invasive and Patient Adaptable

The device can be enclosed in a plastic and biocompatible support, either partially or completely. This solution allows insulating the electronics and the battery hermetically from the intraoral environment. The support can be thermoformed to adapt to the size and shape of a patient's oral cavity to make the device less invasive. The design of the system shape is a crucial

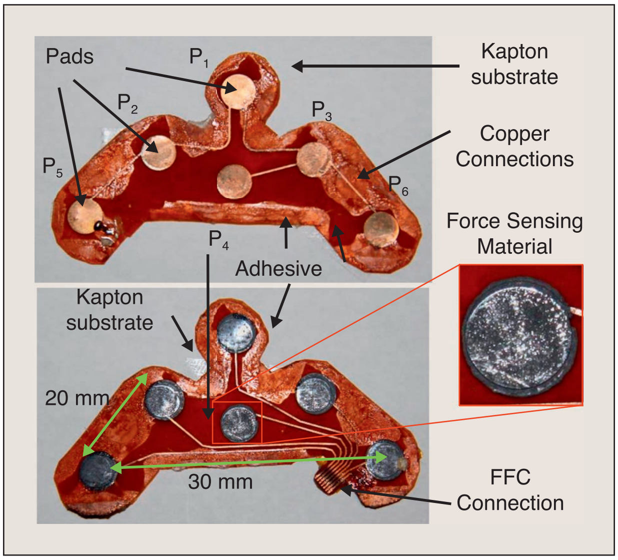

Fig. 2. Images of the two sensor layout parts and a zoom of one pad with the force sensing material deposited (© 2014 IEEE, used with permission, [1].)

aspect for adapting it to the majority of patients. Therefore, maxilla models of men, women, and children can be used as a reference for defining the geometric specifications of devices and sensors. In this design (Fig. 2), the maxilla model of an adult male was used. The pressure sensor matrix is composed of six sensors (P1to P6) arranged in specific points over the palatal surface that measure pressure exerted by the tongue against the hard palate in six points.

The position of these measuring points is based on the dental arch and on the anatomy of the selected maxilla model [19], especially on the lateral and central surface. The size of the sheet and the distance between the measuring points are shown in Fig. 2. Two measurement points (P1 and P4) are located along the midline, two (P5 and P6) are in the back-side, and two (P2 and P3) are positioned laterally. This design choice allows a very adaptable system, usable for research and diagnosis of different deglutition and speech disorders or gnathological and dental disturbances.

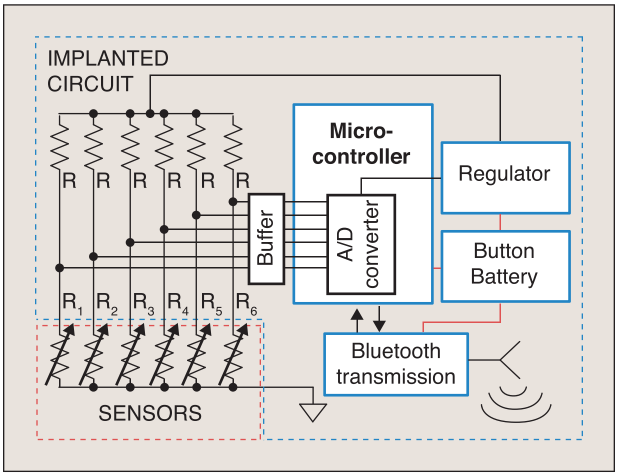

Fig. 3. Block diagram of the implanted system (© 2014 IEEE, used with permission, [1].)

Sensor Characteristics

Flat sensors represent a viable solution for less-invasive measurement. In our sensor from [1], flat sensors are used to measure static and/or dynamic forces applied on the palate through a variation of its electrical resistance. Their main advantages are low-cost per unit, little space required for installation (thicknesses below 1.25 mm) and availability in a variety of shapes and sizes. Despite these advantages, their reliable use in the pressure measurement depends on the correct calibration method first and then on compliant usage. In these sensors, a thin layer (usually a deposition of a piezoelectric composite material) is inserted between two layers of metal electrodes. The electrodes are then covered with two polyester film layers.

As illustrated in Fig. 2, the sheet on which the sensor is manufactured has a geometry that adapts to the curvature of the oral cavity. Each measuring point has a diameter of 3.2 mm and is made of two electrodes between which the layer of pressure sensitive material is interposed. The electrodes and the interconnections and are made of copper by means of a photolithographic technique that starts from two sheets of Kapton film (25 microns thick) laminated with copper (35 microns). The pressure sensitive material is deposited on the copper electrodes. This material is deposited by screen printing and cured at a low temperature of 120 °C for about half an hour. Then, an adhesive is applied to connect the two sheets so the resulting thickness of the sensor is only about 150 microns. This final thinness is considered effective to reduce discomfort in the oral cavity.

Since the copper connections and the film depositions are hermetically contained within the two sheets, only the outer layer (Kapton) is in contact with tissues, ensuring biocompatibility.

When a compression force is applied to the sensor's surface, its resistance drops due to a decrease in the resistance of the piezoresistive layer. In other words, the applied force causes a decrease in the distance between the filler particles within the matrix and then an increase in the number of conductive paths that result in a decrease in the total resistance. Since there is no adhesive between the two sensitive parts but only near the edges (Fig. 2), when a pressure is not applied, the resistance is almost infinite. Whereas, when a pressure is applied, initially there is a sudden decrease of the resistance due to the contact between the two sensitive parts, and measuring this behavior can be used for tongue-palate contact identification.

In general, the total resistance of the sensor is a function of the properties of the sensitive material, the applied force, and the induced deformation. The deformation may be considered constant for constant pressures. However, in a real situation, the voltage varies slightly with time with a constant pressure on the material. In other words, for a constant pressure, the deformation is not constant due to the creep phenomenon, and it will change with time. The reason for this is that when a constant pressure is applied, the sensitive material shows a flow behavior due to the viscoelastic properties inherent within all of these materials. The sliding of these pressure sensitive composites appears as drift in the resistance/voltage output of the sensor. Therefore, by applying a constant pressure to the sensor, the resistivity may decrease with time. For predicting the creep behavior, models have been developed based on spring-damper elements. These materials behave like an elastic solid in some cases and as a viscous fluid in the other cases; they may generally be evaluated using the viscoelastic models [24].

Simple Circuit Architecture

Simple circuit architecture of signal conditioning electronics and wireless data transmission are required. Power consumption, size, and sample rate are crucial in the design specifications.

In the proposed new design, the block diagram of the implanted system for the tongue pressure includes conditioning and transmission circuits that are driven by a low power microcontroller powered by a button battery (Fig. 3). The battery voltage is stabilized by a voltage regulator and is used as a fixed reference for the ADC and for the resistive sensors. The

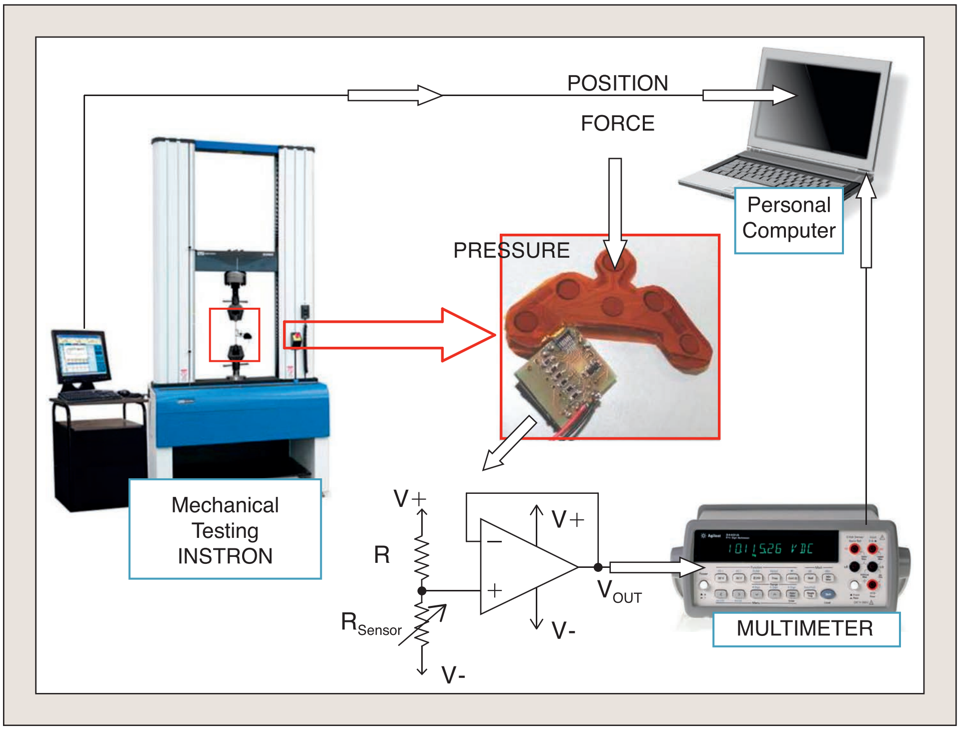

Fig. 4. Experimental setup adopted for the characterization of the sensors (© 2014 IEEE, used with permission, [1].)

◗ It is necessary to maintain a constant contact area with the sensor to ensure repeatability. In the present case, this is guaranteed by the fact that the contact area between tongue and palate is larger than the sensor area.

◗ Cycle time values must not be too high to avoid the phenomena of creep and at the same time must be sufficient to ensure the mechanical response of the sensor. Generally, in swallowing and phonetic activities, the cycle time is constant, a few seconds maximum.

For applications requiring high accuracy, calibration is required. A viable method that can be used is called "curve fitting." It is the most comprehensive calibration method for these applications. A parametric curve is calculated and considered as the nominal curve of a set of sensors, and the resulting equation is stored for future use. The parameters of the curve are determined by characterizing each individual sensor. This equation, together with the measured output signal of the sensor (resistance or voltage), is used to obtain the pressure value. If necessary, temperature compensation can also be included in the equation.

Usually during this characterization, the sensor is fixed to a support plane, and the pressure is applied by means of a tip designed ad hoc, whose diameter is approximately the same of the sensor area. This allows calculating the pressure on the sensor, by dividing by the known applied force for the sensor area. An electromechanical dynamometer is usually equipped with a load cell that is able to detect the force exerted on the sensor surface. The test system must ensure that the force is exerted along a predetermined direction with respect to the surface. The electromechanical dynamometer is usually connected to a computer that allows controlling the beam scrolling speed and the force.

Each sensor can be connected to a measuring circuit, as Fig. 4 shows [1]. In this case, the sensor is connected to a resistive divider and then to an amplifier in a voltage follower configuration. The output voltage can be measured using a digital multimeter. The tests can be performed at room temperature or in a temperature and humidity controlled chamber.

measuring principle is based on a measurement of the voltage divider, and the resistance "R" should be a value comparable with that of the sensor when it is not subject to pressure, ensuring low current.

It is important that the sampling frequency allows monitoring proper tongue behavior during deglutition or phonetic phases. The voltage values of the voltage divider acquired by a low-power microcontroller using an ADC are sent via serial communications to a transmitting module. The data are transmitted in real time to a personal computer. The circuit must be reduced in size and be positioned in an area not affected by the tongue. For applications relating to tongue pressure monitoring, an acceptable sampling frequency can be near 70 Hz. It would be better if the sampling frequency can be changed by the software, depending on the application.

How to Test?

The phase of preclinical testing allows the analysis and verification of device performance and sensor characterization before they are used directly on humans. For pressure measurements, the device must be mechanically tested to find the relationship between sensor output and pressure exerted on sensor surface. Furthermore, it is important to quantify the influence of other variables on sensors' response, such as temperature and/or humidity. Some guidelines to keep in mind during the testing phase are:

◗ It is necessary to provide a constant pressure distribution since the sensor response is very sensitive to the distribution of the applied pressure. In this design, the tongue, given its soft tissue component, allows distributing the pressure evenly.

Static Test

In the characterization procedure, it is appropriate to perform a static test to assess the extent of creep phenomenon. In this

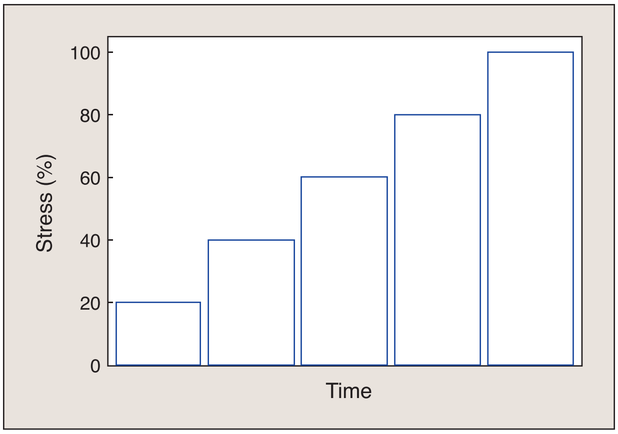

Fig. 5. A graphical representation of the static tests; different levels of stress are maintained for a time interval.

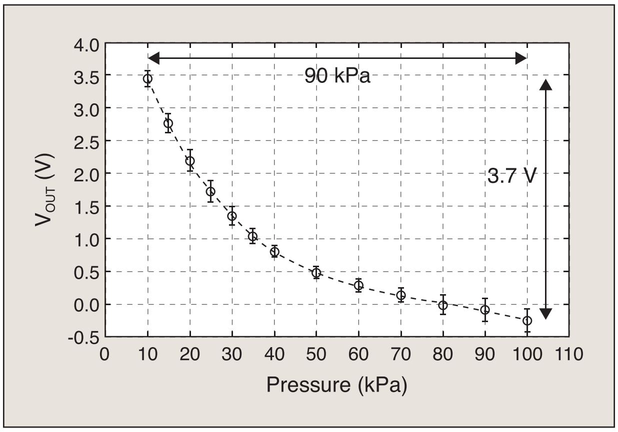

Fig. 6. Output voltages vs. pressure values up to 100 kPa for a single measurement point (mean ± 1SD). (© 2014 IEEE, used with permission, [1])

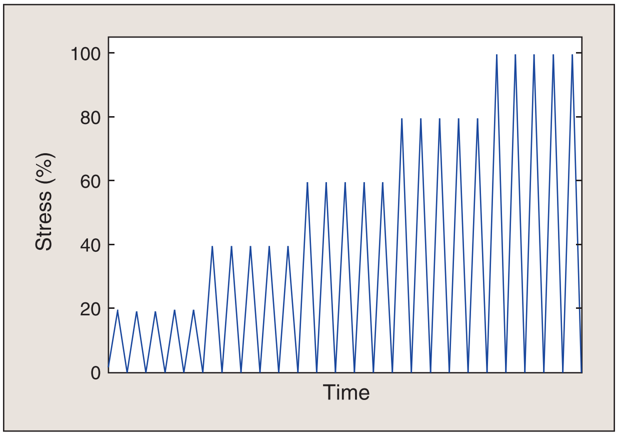

Fig. 7. Graphical representation of the dynamic test; loading–unloading cycles at various maximum levels of stress when applied on the sensor.

test, different pressure values are statically applied over each sensor, for a certain time interval (Fig. 5). Fig. 6 shows an example of the results taken from the reported design [1]. Average values and standard deviations of measured voltage values are reported for different pressure values. At high pressures, the standard deviation is greater; this phenomenon is due to the creep phenomenon.

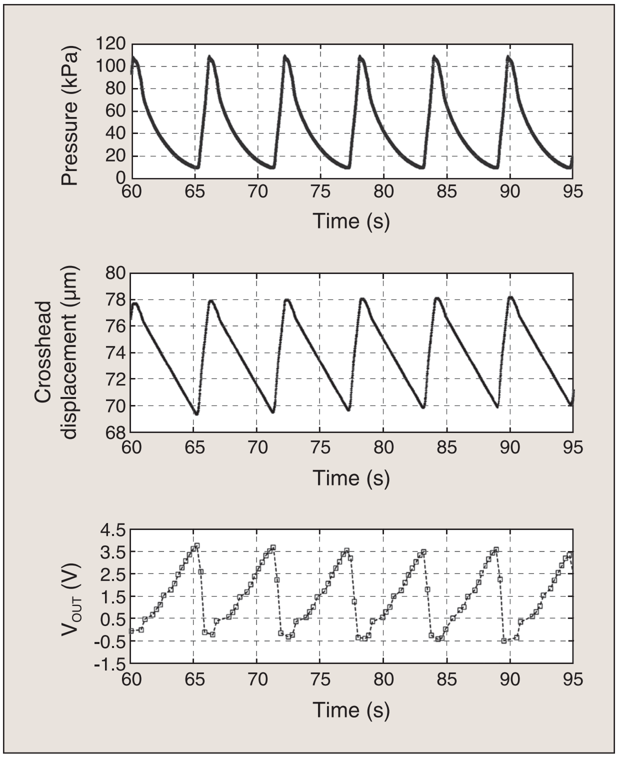

Fig. 8. An example of the applied pressure trend using (a) Pressure values, (b) Crosshead displacements, and (c) output voltages. (© 2014 IEEE, used with permission, [1])

Dynamic Test

The dynamic test consists of cycles of loading and unloading on the surface of each sensor. This test allows the assessment of any hysteresis in the sensor behavior. Samples are subjected to loading-unloading ramps to fixed load rates (Fig. 7), while at the same time, displacements, loads and sensors outputs are measured. The pressure can be applied from 0% to 100% of the full scale in a cyclic way, with the loading phase of about one second and the unloading phase of few seconds. This protocol allows testing the sensor in overload conditions.

In Fig. 8, measurement data show the applied pressure trend, and the corresponding deformations and voltages are illustrated [1]. The deformation is measured as the displacement of the force application point with respect to the point of contact with the sensor. In the literature, the maximum pressure of the tongue on the palate is 57.5 ± 15.1 kPa [25], which is about half the maximum pressure applied during this test example, whereas the minimum pressure value (for example, 10 kPa) must be chosen to ensure a constant pressure on the sensor during all cycles.

In Fig. 8, the measured values of voltage (V_{OUT}) compared to the pressure applied during six cycles are shown [1]. An increase of pressure generates a decrease of the resistance value of the sensor and consequently a decrease of the voltage value. A progressive crushing of the sensor with a consequent reduction in thickness is visible as shown by the drift of the displacement signal at slightly higher values.

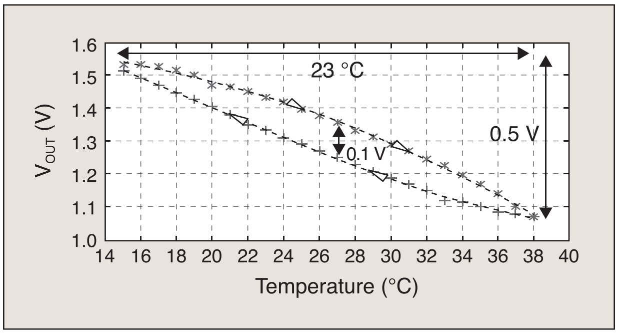

Fig. 9. Output voltage variation for a temperature cycle from 15 °C to 38 °C. (© 2014 IEEE, used with permission, [1]

Temperature Influence

In human applications, the influence of temperature on implanted sensors must be checked. During a test, the device is placed in a climatic chamber, and the sensor output is monitored as the temperature varies. As shown in Fig. 9, a temperature variation of 23 °C significantly affected the V_{OUT} and can be considered excessive for the majority of applications [1]. In fact, the oral temperature variation during the day is relatively low, since the body temperature for healthy subject generally stays between 33 and 37 °C [26].

Conclusion

The measurement of a given variable inside the oral cavity via an implantable device involves many problems as researched and reported previously. The invasiveness of the devices has been significant for the subjects. Improved devices must be small, light, made with biocompatible materials, and all electronic components must be closed in hermetic shells. Another important aspect is the ergonomics of the device and sensors; the device shape must be adapted to the anatomical configuration of the subject's mouth. The design of a custom device is definitely the best solution; however, this is in contrast with the possibility to maintain low production costs. One solution would be to design different sizes of the same device that are based on standard anatomical geometries reported in the literature so that they can be used by the majority of subjects. Another aspect relates to the sterilization of devices and sensors. In the presented case, given the low fabrication cost of the sensors, these devices are considered disposable and the hermetic shell for the electronics can be sterilized. The device must be low power and must operate for a period at least equal to the time necessary for a phonetic or swallowing rehabilitation activity or for the time necessary for clinical analysis. This involves a tradeoff between battery type (size and weight), electronic circuits, and usage time. In the future, devices that operate without batteries through power harvesting techniques or telemetry systems could further their size and increase the usage time.

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