Low-Power Wireless System to Monitor Tongue Strength Against the Palate

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***Abstract*—The study of the tongue - especially the analysis of its strength against teeth and palate - provides important information on health conditions or treatment outcomes. In this work, an easy-to-use intra-oral device was designed and fabricated to monitor position and strength of the tongue in real-time, without using cables or tubes. The proposed intra-oral device is based on tailored-made capacitive flexible force sensors. Measured data are collected and transmitted via Bluetooth Low Energy (BLE) to a custom-made iOS application. The proposed fabrication process offers a custom-fit device made of materials and components commonly used in dentistry, ensuring biocompatibility. A preliminary device evaluation shows positive results in terms of battery duration and quality of the measured data also after its immersion in water. The 50-mAh battery allows the proposed system to be used for multiple rehabilitation sessions before recharging it. The non-linear behavior and the hysteresis of the capacitive sensors allow to detect five levels from 0 N to 1.11 N of applied force against the palate.**

***Index Terms*— Capacitive sensors, flexible printed circuits, intra-oral device, low-power system, wireless implanted device.**

I. Introduction

THE study of the mouth- especially the analysis of teeth, pH and tongue strength - provides important information on health conditions or treatment outcomes. For example, a change in pH of the saliva can cause a dental decay, or a wrong use of the tongue could compromise the teeth growth and placement, and the rest position of the tongue can affect the stance of a person. Several studies have tried to understand the mechanisms inside the mouth, for example detecting pH variation during mastication [1], the tongue position and its parallelism against the palatal arch [2], or if the connection between the orthodontic braces and tooth is lost [3]. Furthermore, the tongue is important during speech, mastication, swallowing, and breathing. The analysis of its strength against teeth and palate can help the clinicians to better understand the aetiology of a series of apparently separated conditions, such as dysphagia, sleep apnea or protrusive and retrusive malocclusions [4], but also it is very useful to monitor the rehabilitation progress for recovering the functionality of the tongue in different pathologies [5].

Nowadays, there is a lack in protocols and devices to evaluate and monitor tongue movements and strength in real time. Tongue monitoring is currently performed via visual inspection of the tongue movements with the mouth open or by using a series of very expensive and complex medical equipment. Video-Fluorography (VF) is recognized as a “gold-standard” in clinical practice. This technique requires patient cooperation, the ingestion of a contrast dye and the exposition to ionizing radiations, and for these reasons, this expensive machinery is inadequate for long-lasting sessions. Other techniques, such as magnetic resonance imaging (MRI), ultrasonography and fiberoptic endoscopic evaluation of swallowing (FEES) are less precise than VF, but they are still considered invasive because the interaction with the patient increases his stress level, making the test less comfortable. Since they are expensive and bulky, the aforementioned techniques are intended for hospital and clinic settings. Intraoral devices – sensorized devices worn inside the mouth - could be a viable solution to overcome the limitations of these techniques. For example, the intraoral devices are used outside hospitals and clinics to improve the quality of life of quadriplegic people in daily life. For example, in [6] an intraoral device is designed to drive a wheelchair by detecting tongue movements, while in [7] the intraoral device is used for tongue tracking and in [8] for gesture recognitions.

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A series of laboratory studies [9]–[12] proposed new intraoral devices that measure the tongue strength inside the mouth, and only few expensive commercial devices are available today, such as IOPI [13] and SwallowSTRONG [14]. All these devices consist in disposable sensing elements directly inserted into the mouth and attached to a handheld electronic board. Signal cables or plastic tubes connect the intraoral device (inside the mouth) and the readout unit (outside the oral cavity), but this solution can significantly hinder tongue movements affecting the measurement results. Furthermore, the size of the currently available devices often affects comfort and usage [9], [10]. Finally, sensors drift due to temperature changes - affecting the measurement of the tongue pressure - was not often fully studied or the use of non-toxic materials was not considered as a strict requirement [11].

This work proposes an innovative intra-oral device that uses tailored-made capacitive flexible force sensors to measure force and position of the tongue and transmits real-time data to a readout unit wirelessly. The design choices (layout, components, materials, etc.), obtained thanks to a rigorous experimental design activity, allowed respecting the strict constraints including size, power, biocompatibility, cost and comfort. With respect to the state-of-art, the proposed device integrates electronics and sensors on the same Flexible Printed Circuit (FPC) Board, eliminating cables between the intraoral device and the readout unit. FPC technology is very attractive for fabricating wearable sensors and smart devices in many fields, such as healthcare, because it allows building low-cost and high-volume electronics that can be easily adapted to nonplanar areas such as human body, as reported in [15]–[18]. To enhance waterproofness and ease-to-use, the circuit boards are enclosed inside two custom-fitted and non-toxic oral appliances. The readout unit, a tailored-made iOS application, adds the advantages of the touch-screen user interfaces and of the popularity of smartphones and tablets. The fabrication process was studied in every step: the intraoral device was designed and fabricated with certified non-toxic materials to be user-friendly, low-power and shaped on the palate, limiting its influence on the physiological behavior of the tongue. Experimental results related to the sensors response under the applied forces and under temperature changes were obtained by using experimental setups that simulate different conditions inside the mouth, and waterproofness tests were performed to verify the operation of the device inside the mouth.

II. System Design and Fabrication

The proposed system, shown in Fig. 1, is composed of two distinct parts: 1) intra-oral device and 2) a readout unit (tablet). The entire system was designed to allow easy fabrication process, affordable overall price, easy adaptability to most of the mouths, and clear data representation.

The intraoral device is physically split in three FPC boards to ensure proper fit and comfort inside the mouth: Micro Controller Unit (MCU) board, Sensor Board (SB), and Power Management (PM) board. The three boards are made on a flexible polyimide substrate, involving the standard FPC production processes. The design of the device required an

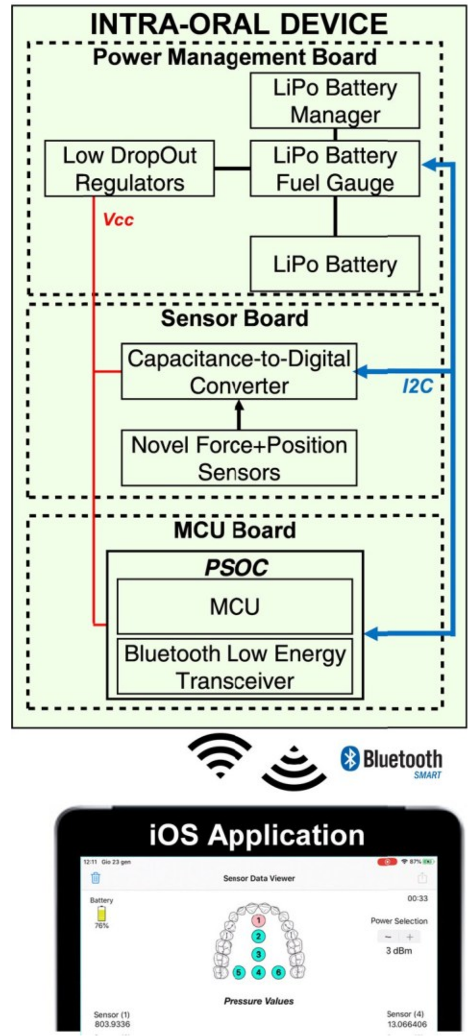

Fig. 1. Schematic representation of the developed device. It is made by three different sections, placed in three different parts of the oral cavity.

accurate research activity on the placement of the components and routing considering the geometry of the palate to reduce the invasiveness. This activity led to an optimization of the spaces and a high spatial density of the components. Furthermore, different manufacturing technologies have been considered and the possibility of using the manufacturing technology on flexible support with commercial components has allowed containing dimensions, weight, costs and invasiveness, satisfying the requirements of the application. A schematic representation of boards placing is depicted in Fig. 2 MCU (blue region) and PM (green) are located in the opposite molar-premolar areas of the maxillary vestibule, attached to the SB (orange) via a series of silicone coated wires. With respect to other solutions such as custom flexible flat cables, the use of wires allows adjusting the wire length according to the mouthguard size and it does not damage the external layers during thermoforming process. Furthermore, some preliminary tests on one healthy volunteer showed that the wired solution should not affect comfort and does not cause nausea. The SB is placed onto the palatal arch. The maximum board thickness is 170 μm. Materials and size of the boards were selected

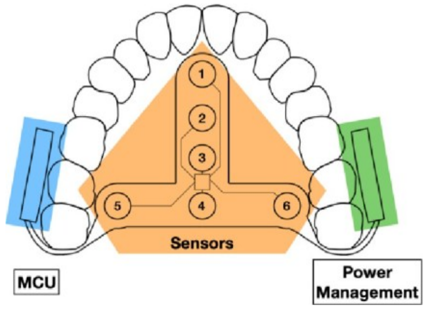

Fig. 2. Palatal view of the mouth, on which is highlighted the position of the three boards.

according to safety constraints and size limitations for the intraoral device.

The sensors are arranged in order to detect the force/position of the tongue in the most clinically relevant positions of the palate, as suggested in [19]. For this reason, as shown in Fig. 2, four sensors (1-4) are located along the medial line, and the other two (5-6) in the posterior-lateral part of the hard-palate. For the encapsulation and thus the protection of electronic boards from water, biocompatible or non-toxic materials already used in the dental field were selected. The SB is enclosed between two masks fabricated by thermo-forming Erkoflex discs (Erkodent, Germany) onto the plaster model of the subject's mouth. Erkoflex is a non-toxic material and it is based on Ethylene Vinyl-Acetate (EVA) often used in mouthguards and nightguards to protect teeth and gums during sport or sleep. To insulate the vestibular boards, the boards were inserted into a Poly Vinyl Siloxane (PVS) casing. The two molds, in which the liquid PVS is poured, were fabricated using additive manufacturing techniques. This silicone is certified as non-toxic and it is soft. The waterproofness of the device was proven by testing its performance after its immersion in water for 24 hours.

An easy-to-use custom-developed iOS application for tablet and smartphone was developed to communicate with the intraoral device via Bluetooth Low Energy (BLE), showing the real-time status and the measurements (force and position of the tongue) sent from inside the mouth.

A. SB – Sensor Board

The SB includes novel capacitive coplanar sensors designed and fabricated specifically for this application and a Capacitance-to-Digital converter (CDC) AD7147 (Analog Devices, USA).

Capacitive coplanar sensors are usually adopted in touch-sensitive interfaces of consumer electronics to replace the physical buttons and facilitate FPC fabrication process. In this application, an array of six capacitive coplanar sensors placed on a T-shaped FPC (Fig. 3) was developed to measure position and force of the tongue against the palate. The copper electrodes are spiral-shaped, with an external diameter of 8.5 mm (Fig. 3). The complete sensing element is made as a layered structure, an inner PVS sheet is placed on the electronic board, and everything is enclosed in two EVA layers (Fig. 4). The PVS is between the tongue and the board. When a force is applied to the sensing element, the thickness

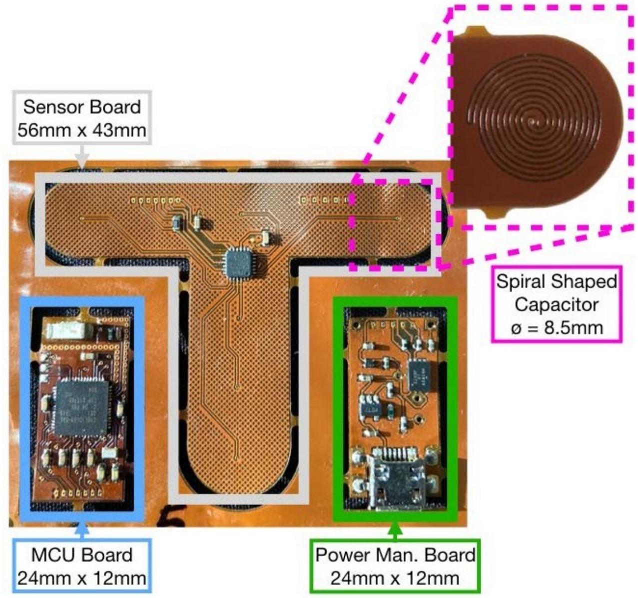

Fig. 3. Electronic boards (SB, MCU and PM) of the intraoral device with a zoom view of one capacitive coplanar sensor (on the right).

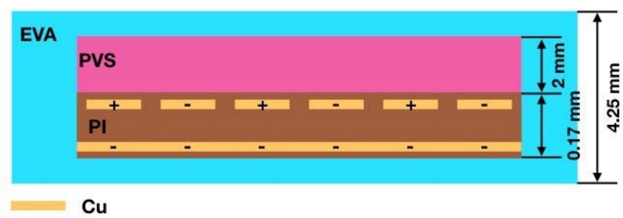

Fig. 4. Schematic section of the Sensor Board. It is made by a silicone layered structure where, at its boundaries the EVA enclosure, inside the PVS and the board. The overall thickness is 4.25 mm and it is the sum of 2 mm of the PVS, 171 μm of the board and 1+1 mm of the EVA.

of the PVS changes, causing a capacitance change. This sensor then offers a low-cost alternative to aforementioned polymer-based capacitive force sensors, reducing the fabrication process complexity using standard FPC technologies. For a deeper explanation of its working principle and shaping, refer to [20].

The AD7147 (Analog Devices, USA) excites the six sensors with a 250 kHz signal and reads the six inputs every 18 ms by a 16-bit Σ-Δ ADC converter. This CDC can work only at a voltage between 2.6 V and 3.3 V and the read capacitance value depends on this voltage value. CDC communicates with MCU via I^2C (Inter Integrated Circuit) interface. This board has an overall size of 56 mm × 43 mm and it is suitable for medium to big mouth dimensions.

B. MCU Board

CYBL10563-56LQXI (Cypress Semiconductors, USA), a Programmable Radio-on-Chip with Bluetooth Low Energy (PRoC BLE), was selected in order to satisfy a series of constrains, such as small size and low power consumption. This device includes a royalty-free BLE stack, compatible with Bluetooth 4.1. Although there are no direct evidences of negative effects of the electromagnetic fields on the human body [21]–[28], national authorities emitted some restrictions on the wireless transmission power to potentially mitigate their effect on the population. CYBL10563-56LQXI ensures a maximum transmission power of 3 dBm, and this keeps the device in the power class number 2 reducing the number of international limitations on it. Furthermore, since a standard rehabilitation session with the device will last less than 15-20 minutes, the subject wearing the proposed device is exposed to low level electromagnetic radiations for a limited duration.

The PRoC BLE communicates through 2450AT42B100 (Johanson Technology, USA), a 2.45 GHz small SMD chip antenna [29]. This chip antenna is off-the-shelf, requires a minimum printed area (8 mm × 3.86 mm) and offers reasonable performance, needing passive components for the matching network. The overall board size is 24 mm × 12 mm in order to put all the required components onto an area compatible with the vestibular area.

C. PM - Power Management Board

This board is composed of different sections and, as the MCU board, this board (24 mm × 12 mm) is placed into the opposite vestibular area of the mouth:

- Single-cell Lithium Polymers (LiPo) rechargeable battery 401515 powers the intra-oral device; the battery has a nominal voltage of 3.7 V at 50 mAh and it can supply peak currents greater than its capacity. The battery size (15 mm × 15 mm × 0.4 mm) respects the size constraints of PM board.
- MCP73831 (Microchip Technology, USA) charge management controller regulates voltage and charging current to extend battery life during battery charging. The battery is recharged via micro-USB port, positioned in the lowest part of the board. During operations inside the mouth, a USB port cap is mounted to prevent water infiltration.
- LC709203F (ON Semiconductor, USA) is a CMOS Battery Fuel Gauge and provides information about the state-of-charge of the battery. This device embeds an I^2C communication interface, and many different battery-related features. With respect to a simple Analog to Digital Converter (ADC), the voltage fluctuations (for example due to peak currents or chemical battery noise) do not affect the measurement of battery status. Its power consumption varies from 2 μA to 4.5 μA in Operation mode.
- MIC5504-3.3 Low Drop-Out (LDO) linear regulator (Microchip Technology, USA) is used to fix the supply voltage to 3.3 V. Linear regulators are highly integrated and cheaper, they drain a minimum quiescent current and they need only two capacitors as external components. PM board includes two LDOs, for powering MCU and CDC separately, to remove the CDC idle current when turned off from the overall power consumption.

Fig. 5 shows the proposed intra-oral device at the end of the fabrication process. The vestibular boards are enclosed into the purple silicone, the palatal board instead is enclosed with the transparent EVA.

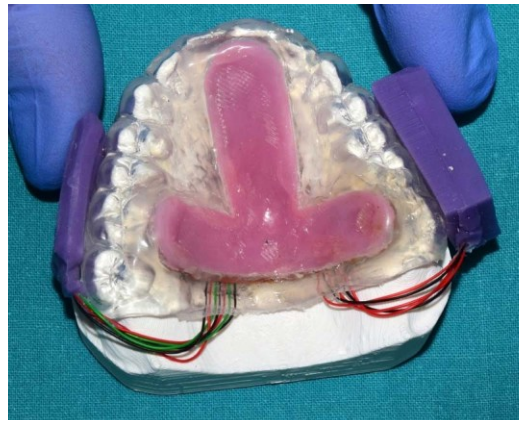

Fig. 5. The intra-oral device is composed of three elements, the two enclosed in the purple silicone are the vestibular boards, the transparent one in the middle is the palatal board.

D. iOS Application

An application for smartphones or tablets was developed in order to allow interaction with end users. Smartphone and tablets have a series of advantages: they are easy-to-use and widespread. Indeed, they have a touch screen interface, and no further developed hardware is required since most of them adopted BLE. Recent studies forecast that more than a quarter of the global population will have a smartphone in 2020 [30], thus a mobile app for monitoring the data will get our device more pervasive.

An iOS test app was written in Swift in order to show the features of the device. The screen (Fig. 6) shows a palate outline with sensors arrangement and tags (on the top), the force data (in the middle) and the bar plot which graphically shows the force value measured by the sensors (on the bottom). The user interface gives also the possibility to interact with the device to change the transmission power, to pause or resume the session and reset the device. On the top left corner, the battery level is also reported. Moving towards the telemedicine, this application allows the user to share the obtained data through the most common cloud storage services (for example Google Drive, Dropbox, iCloud, etc.), or e-mail (on the top right).

III. Preliminary System Test

A. Power Consumption Test

The device working cycle can be divided in four different power consuming phases: Advertising, Connection, Peripheral Setup and Working. During the Advertising phase, most of the peripherals are turned off, and the device transmits to the surroundings its presence every 3 seconds. In this phase, the device is mainly considered in deep sleep mode and drains the lowest power. In Connection phase, the connection between the two devices is established and the PRoC wakes up from sleep. During Peripheral Setup phase, the CDC is turned on, configured and tuned. In Working phase, the CDC works in full-power mode and drains the most power; the device carries the measurements and sends them to the readout unit.

The power consumption was calculated by measuring the current consumption of the overall intra-oral device during

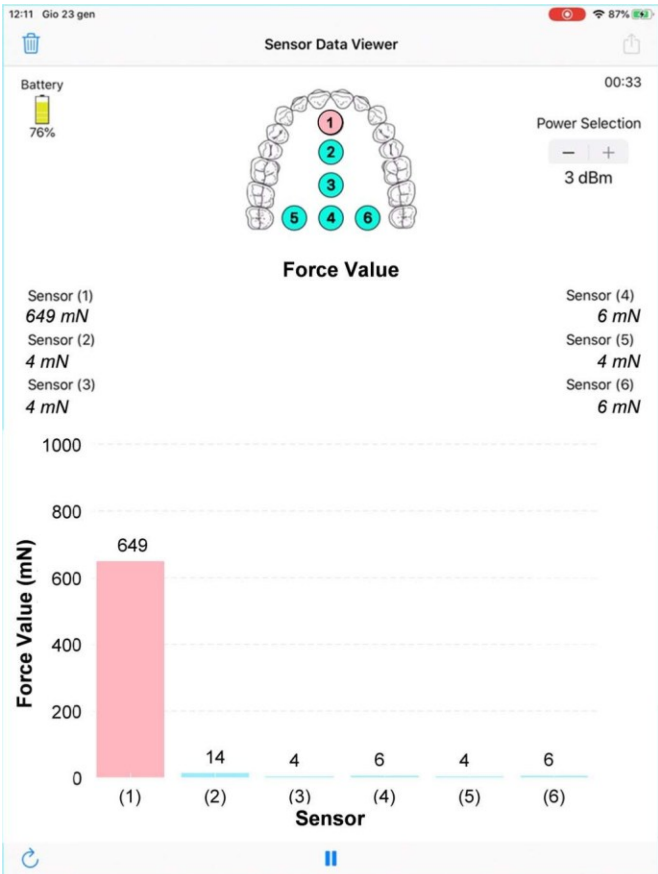

Fig. 6. App screenshot. This frame was captured during a measuring session. The most important parameters from the intra-oral device (battery level, sensors values, etc.) are shown in the screen.

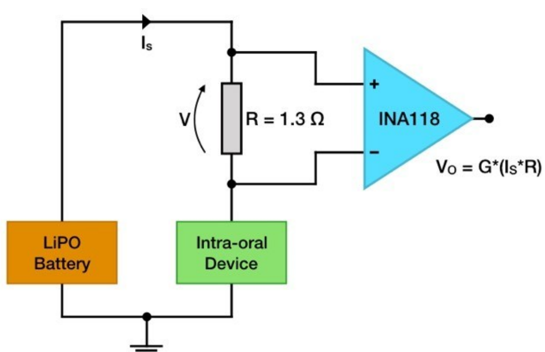

Fig. 7. Schematic representation of the custom power consumption monitor.

each phase. The detailed current drain (I_s) in every different working phase is obtained by using custom-made electronics shown in Fig. 7; INA118 (Texas Instruments, USA) is an instrumentation amplifier that measures the voltage across the small resistor R.

The resistor value is sufficiently low to not affect the behavior of the intraoral device and the output voltage (V_o) of the INA depends on the value of the absorbed current, according to Eq. 1:

$$I_S = \frac{V_O}{G \cdot R} \tag{1}$$

where G is the gain of the INA. Without the attached load, V_O was equal to 40 mV, according to the INA118 datasheet. Considering the output offset voltage and using $G = 1000$, the minimum measurable current becomes $I_{low} = 33.34\ \mu A$.

Table I reports the average power consumption, and the battery life estimation, with a battery capacity of 50 mAh. As expected, the current consumption is minimum during Advertise status and maximum during Connection status. The overall current consumption allows to use the intraoral device during several rehabilitation sessions without having to charge it.

TABLE I
POWER CONSUMPTION DURING ALL THE WORKING PHASES OF THE DEVICE

Device Status	Current Consumption	Battery Life Estimation*
Advertise	137 µA	365 h
Connection	4.5 mA	11 h
Tuning	3.95 mA	12 h 40 m
Measurement	3.91 mA	12 h 47 m

*for a Battery Capacity of 50 mAh

TABLE II
SENSOR RESPONSE AGAINST TEMPERATURE CHANGE

Sensor [#]	Temperature Coefficient [fF/°C]	Max. Hysteresis [fF]
1	7.1	13.8
2	3.6	7.0
3	3.7	7.2
4	4.9	9.7
5	7.2	14.4
6	6.6	12.9

B. Temperature Tests

The sensors output depending on temperature change was evaluated. For this purpose, an automated test in a climatic chamber (Perani UC 150/70, C.T.I. s.r.l., Italy) was arranged to record the output of the six sensors when the temperature varied from 18 °C to 43 °C (heating phase), with increasing steps of 4 °C, and vice versa (cooling phase). To maintain the contour conditions as stable as possible, the device was placed inside a hermetic box filled with silica gel, which absorbs the unwanted humidity variations, and every temperature step was kept steady for 50 minutes as reported in [31], [32].

Data shown in Fig. 8 and Table II were obtained averaging the last 5 minutes of every temperature step. The sensor drift is calculated with respect to the capacitance value of each sensor at the start of the test, when the chamber temperature was 18 °C.

Fig. 8 shows as an example the behavior of the Sensor #2. The sensor capacitance varies almost linearly with temperature. The slope of the first best-fit line is 3.6 fF/°C. In the

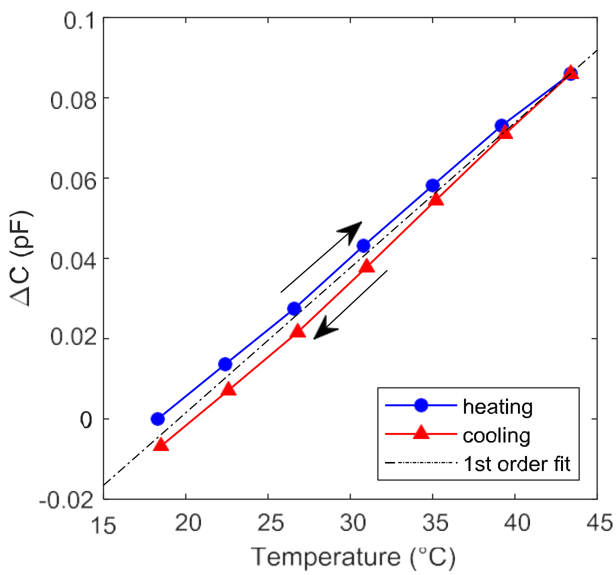

Fig. 8. Capacitance drift of Sensor #2 due to temperature change during heating and cooling phases. Every temperature step is kept for 50 minutes. These points are obtained averaging the last 5 minutes of every temperature step. The first order best-fit line is found through least squares method.

thermal cycle, there are differences in sensor response between the heating and the cooling phase resulting in hysteresis response; the maximum value of the hysteresis is 7.0 fF (at 18 °C). This effect can be explained by thermal properties of the materials that protect the board. The tests were repeated for all the sensors, aiming at obtaining compensation curves to counterbalance eventual modifications in environment conditions inside the mouth. The soft palate part of the mouthguard – where 2, 3 and 4 sensors are placed - is thicker than the teeth section (1, 5, 6) entailing a slower dependency on the temperature, as shown in Table II. The standard deviation calculated from the measurements taken in the last 5 minutes for each temperature step is lower than 2.19 fF (for all the sensors), which is negligible with respect to the capacitance drift over temperature.

C. Load/Unload Cycle Test

The effective response of the proposed capacitive coplanar sensors under an applied load was evaluated through a self-made system by applying an increasing load to every sensor (Fig. 9). An ad-hoc excitation tip, made of a conductive plastic and held firmly in alignment by a weight-support structure, focuses the load on only one sensor. Its overall weight is 10 g. Four calibrated weights (10 g, 27 g, 61 g and 110 g) were applied on each sensor, waiting 2 minutes before changing the amount of the weight. The maximum weight (110 g) was determined considering the maximum pressure of the tongue reported in the literature [10]. Every load/unload cycle was repeated 10 times for each sensor. In order to apply the force perpendicularly, the device was placed on the plastic model of the upper palate and clamped by a ball-joint clamp.

The capacitance variation of Sensor #5 (on the right side of the SB board) with respect to the applied load is shown in Fig. 10. The relationship between the sensor output and the applied load is not linear, but it can be easily approximated

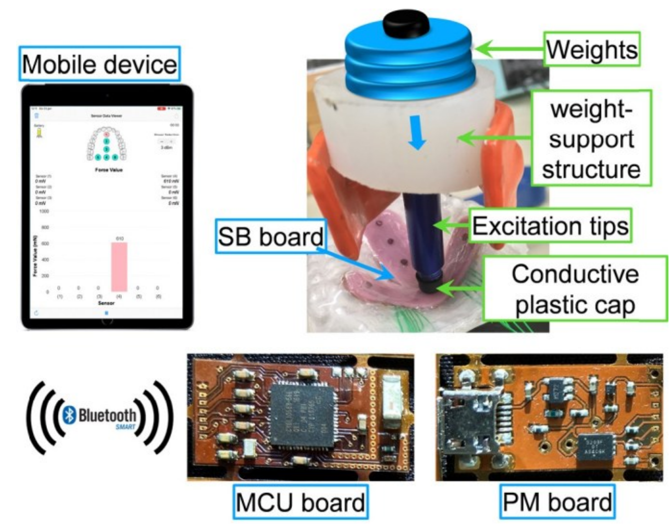

Fig. 9. Experimental setup for the characterization of the sensors against the force applied on one sensor. A weight support structure focuses the force induced by the weights (simulate the force applied by the tongue) on one single sensor. The excitation tip simulates the tongue. The MCU boards sends the measurements (in terms of capacitance) to the mobile device via Bluetooth.

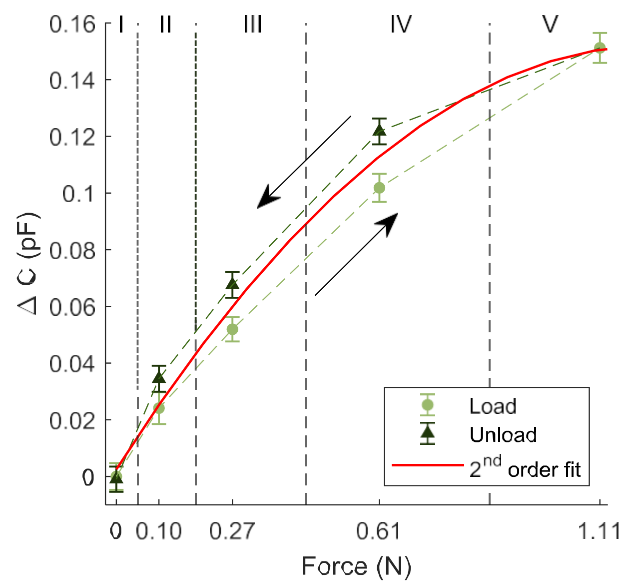

Fig. 10. Load/Unload test of Sensor #5. The capacitance change reported on y-axis was calculated with respect to the capacitance value measured with no load at the start of the test. The points represent the mean value on ten repeated measurements and error bars represent the standard deviation. The colored areas define the expected output range for each of the five levels of force (0 N, 0.1 N, 0.27 N, 0.61 N and 1.11 N).

with a second order curve (red line, R^2 = 0.973). The standard deviation calculated on 10 measurements in the same conditions is lower than 6 fF and hysteresis (maximum output difference with the same applied load) is maximum (16 fF) at 0.61 N. Considering the standard deviation and the effect of hysteresis, the sensor could be used to detect five different force-varying regions (labelled on the top): I - none, II - mid-low, III - mid, IV - mid-high and V - high load.

Similar results (summarized in Table III) were obtained for all the six sensors. Standard deviation calculated on the 10 repeated measurements is lower than 10 fF (except

TABLE III
LOAD/UNLOAD TEST RESULTS FOR THE ALL SENSORS ON THE MOUTHGUARD

Sensor #	Max. Std. Dev. (fF)	Output Span (fF/N)	Max. Hysteresis (fF)
1	10	106	28
2	2	70	11
3	5	124	23
4	4	146	22
5	6	142	16
6	34	152	55

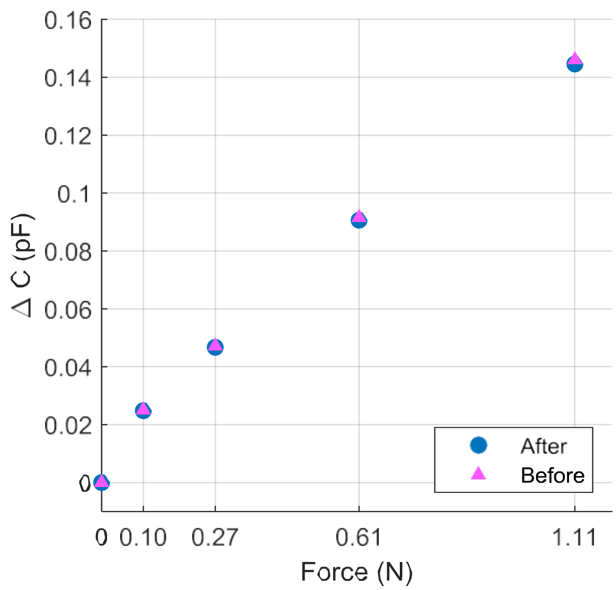

Fig. 11. Load test Before and After the insertion of the mouthguard into a water bath, in the case of Sensor #4.

for Sensor #6). As noted in temperature tests, the response of the sensor to the load application depends on its position in the mouthguard. The output span - the difference between the maximum and the minimum capacitance - of each sensor and the hysteresis vary according to the sensor position. Indeed, the thickness of the silicone materials - between the electrode and the excitation tip - is not uniform due to the production process of the mouthguard; this affects the stiffness of the dielectric material and thus the capacitive sensors response due to a different deformation of the dielectric material induced by the same applied load. The hysteresis effect can be explained by the mechanical properties of the silicone materials whose stress-strain curve typically shows hysteresis [33]. Considering standard deviation and hysteresis effects, all the sensors can detect five different force-varying regions.

Load/unload test was repeated after placing the device into a water bath for 24 hours (longer than a rehabilitation session, which lasts 15-20 minutes approximately). The results on Sensor #4 are shown in Fig. 11, as an example. The negligible differences between the two trials for all the sensors demonstrate that the device is waterproof.

IV. CONCLUSION

The wide adoption of smart devices in the medicine is improving the effectiveness of the healthcare, such as the rehabilitation process. A field not yet well treated is the case of the tongue impairments, which afflict mostly the elderly population and affect different activities, such as swallowing, speech production, and nutrition. The common point of the treating methods of these disorders is the rehabilitation, and the evaluation of the tongue functionalities is based on monitoring tongue movements and thrust strength.

The aim of this work was to develop a system composed of a low-power wireless intra-oral device, capable of measuring the position and the strength of the tongue, and a smartphone application, capable of receiving data and communicating with the intra-oral device. With respect to the measurement systems reported in the literature for tongue assessment, the proposed system allows the patients to undergo long-lasting rehabilitation programs, without the harming of x-rays, and without cables coming from inside the mouth. The proposed fabrication process offers an intra-oral custom-fit device, made of biocompatible materials commonly used in dental clinics. The electronic components are mounted on a flexible substrate, and completely isolated from the mouth by a silicone enclosure. The readout unit is an iOS App, appositely developed for this application and able to show on the screen position and applied force of the tongue, and to share the obtained data. The force applied by the tongue against the palate is measured by a series of capacitive coplanar sensors, made mixing coplanar capacitors and polymers technologies. Although the sensor response exhibits hysteresis due to the intrinsic nature of the silicone, it is possible to distinguish different levels of force; indeed, the experimental results proved that it is possible to distinguish five levels from 0 to 1.11 N, for all the six sensors. The capacitance varies linearly with temperature, but it can be balanced through a temperature sensor. The results obtained after immersion in water proved that the intra-oral device is properly insulated. The battery life ensures the usage for multiple rehabilitation sessions. Further experimental tests will be performed to evaluate the device performance: 1) sensors characterization of multiple device to evaluate the repeatability of the production process; 2) trials on healthy subjects for the evaluation of the behavior in the oral cavity, with a temperature measurement and compensation; 3) trials on unhealthy subjects. The ethics committee submission for pre-clinical validation and clinical validation for clinical trials has already begun and the approval will be granted soon.

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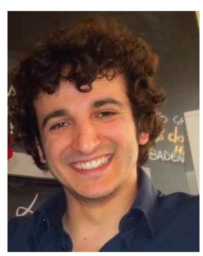

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