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Wireless Unconstrained Monitoring of Intra-oral Temperature Using Thermistor and Telemeter Sealed in Mouthguard

Kenta Iitani,[1] Kanako Kishima,[2] Yuka Kasuga,[2] Kumi Yokota,[1] Hiroki Nitta,[3]
Kohki Onchi,[3] Gentaro Kawase,[3] Kouta Umezawa,[3] Koji Toma,[1,4]
Takahiro Arakawa,[1,5] Dzung Viet Dao,[6,7] and Kohji Mitsubayashi[1,3*]

[1]Department of Biomedical Devices and Instrumentation, Institute of Biomaterials and Bioengineering,
Tokyo Medical and Dental University (TMDU), 2-3-10 Kanda-Surugadai, Chiyoda-ku, Tokyo 101-0062, Japan
[2]Faculty of Dentistry, Tokyo Medical and Dental University (TMDU),
1-5-45 Yushima, Bunkyo-ku, Tokyo 113-8510, Japan
[3]Graduate School of Medical and Dental Sciences, Tokyo Medical and Dental University (TMDU),
1-5-45 Yushima, Bunkyo-ku, Tokyo 113-8510, Japan
[4]Department of Electronic Engineering, College of Engineering, Shibaura Institute of Technology,
3-7-5 Toyosu, Koto-ku, Tokyo 135-8548, Japan
[5]Department of Electric and Electronic Engineering, Tokyo University of Technology,
1404-1 Katakura, Hachioji City, Tokyo 192-0982, Japan
[6]School of Engineering and Built Environment, Griffith University,
Engineering Drive, Southport 4222, Australia
[7]Queensland Micro- and Nanotechnology Centre, Griffith University,
West Creek Road, Nathan 4111, Australia

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Monitoring body temperature has the potential to evaluate physical conditions. The oral cavity has a large accessible volume and exhibits a temperature close to the deep body temperature; the wireless monitoring of intra-oral temperature is also possible. However, devices must be small enough to not interfere with tongue movement. Here, we fabricated a mouthguard (MG) thermometer that housed a telemeter, a thermistor, and a battery on the buccal side surface of the molar and premolar of the upper jaw. The devices were sealed between two layers of MG material for waterproofing. Sealing the devices induced a longer response time to temperature changes (from 3.2 to 12.2 s), but the quantitative characteristics did not change. Rapid changes in intra-oral temperature were successfully monitored when ingesting water of various temperatures by using the MG thermometer. Moreover, a high correlation between the difference in the intra-oral and water temperatures and the intra-oral temperature change was observed. In addition, stable wireless measurement was possible during 3 h in an office with the wearer engaged in normal activities. The effects of changes in ambient temperature and the wearing of face masks on intra-oral and skin temperatures were also investigated, where an effect of ambient temperature on skin temperature but not on intra-oral temperature was observed. These results suggest that wireless temperature monitoring in the oral cavity is feasible.

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[*]Corresponding author: e-mail: m.bdi@tmd.ac.jp
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1. Introduction

Measuring body temperature is one of the most common methods to objectively determine human health status. Although body temperature is usually measured by an individual when discomfort occurs in the body, further advantages arise from continuous body temperature monitoring, such as in menstrual cycle tracking,(1) improving the diagnosis of female infertility,(2) early detection of infectious disease,(3) evaluation of circadian physiology,(4) and early clinical intervention for febrile neutropenia.(5) Therefore, many wearable thermometers have been developed to enable the continuous measurement of body temperature.(6) Han *et al.* developed battery-free wireless skin temperature and pressure sensors based on near-field communication technology.(7) Also, the Earable smart device, which monitors tympanum temperature using a thermopile IR sensor, was developed by Ota *et al.*(8)

Body temperature shows different values depending on the measurement position of the body. Although deep body temperature, which can be measured at internal organs and the brain, is medically required, it is difficult to measure non-invasively. Thus, the temperature of body cavities, such as the rectal temperature, tympanic temperature, and intra-oral temperature, which is close to deep body temperature, is measured in clinical practice. Although skin temperature is easily measured, it is sensitive to environmental disturbances such as sunlight and wind. Recently, Matsunaga *et al.* have developed a skin patch device for the real-time estimation of deep body temperature based on the zero-heat-flux method that enables the accurate estimation of deep body temperature even in windy conditions.(9) However, its applicability to extreme environments such as underwater remains questionable. Unlike the ear canal, the oral cavity has a relatively large space in which sensors and peripheral circuits can be placed. Moreover, unlike the rectum, it is not only easily accessible but can also be separated from the outside by simply closing the mouth. Therefore, the oral cavity can be considered a suitable site for the continuous measurement of body temperature.

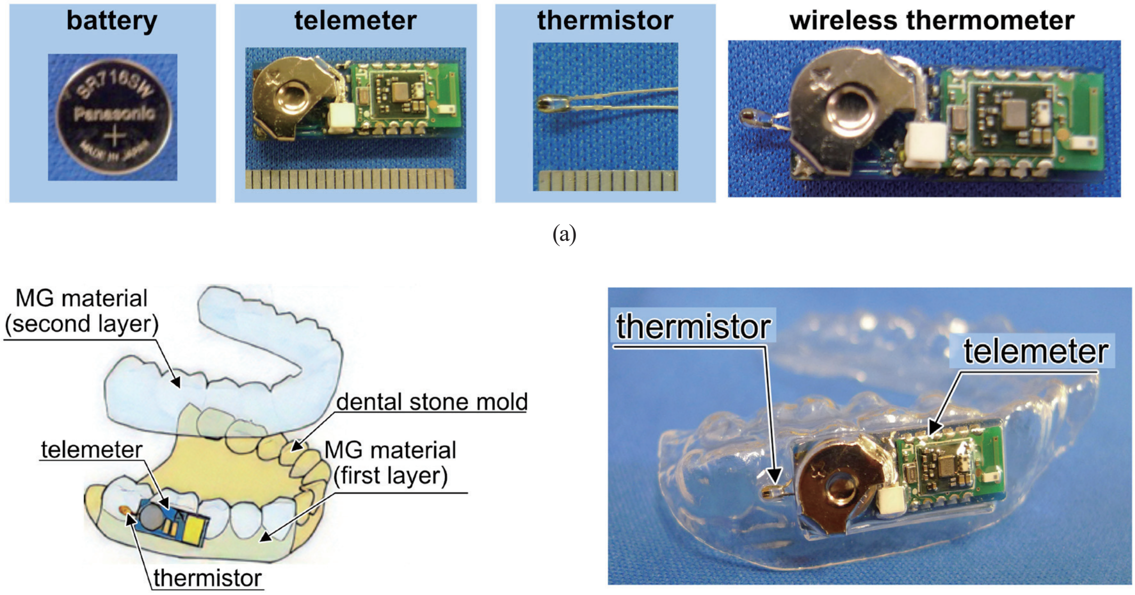
Although detailed studies have been conducted on intra-oral temperature measurement,(10,11) less research has been carried out on continuous measurement for daily monitoring. Moore *et al.* conducted an influential study in 1999 in which they installed thermocouples in an intra-oral retainer and connected them to a data logger by a signal wire that emerged from the mouth to record the intra-oral temperature every 5 s for 24 h.(12) In 2015, Choi *et al.* developed a mouthguard (MG) device for the continuous measurement of intra-oral temperature and pH with wired sensors,(13) which was updated to a wireless measurement system by Farella *et al.* in 2016.(14) The MG-type device developed by Farella *et al.* had the advantage of the simultaneous measurement of temperature and pH but was designed with measurement circuits placed on the hard palate because of its size. In this case, the movement of the tongue would be inhibited, and there was a scope for the miniaturization of the device. Very small oral temperature measurement units are used to monitor the wear time of oral appliances.(15,16) However, these devices have low time resolution (measurement every 5–15 min) because they are designed to only check the wear time.(17)

Previously, we developed an intra-oral biosensor for the continuous measurement of salivary glucose by sealing a tiny telemeter-cum-potentiostat and enzymatic biosensor inside an MG as a series of "cavitas sensors", which are our proposed format of healthcare sensors.(18,19) In this study, we fabricated an MG-type wireless thermometer that does not make the subject aware that they are wearing the sensor. First, the quantitative properties and response time of a wireless thermometer and the effect of packing the wireless thermometer with MG material on the basic properties were evaluated. The fabricated system was then used to monitor intra-oral temperature. We then performed human subject experiments to investigate the feasibility of monitoring rapid changes in intra-oral temperature, the possibility of long-term measurements, and the effects of environmental disturbances such as ambient temperature and wearing a face mask on intra-oral temperature.

2. Materials and Methods

2.1 Fabrication and characterization of MG thermometer

The wireless thermometer consisted of three main components as shown in Fig. 1(a). The button cell and telemeter were the same as those used in previous papers.(19,20) A silver oxide button cell (SR716SW, Panasonic, Japan) was selected because of the stability of the operating voltage. The telemeter based on Bluetooth Low Energy was custom built. The thermistor (Part No. 504GT-2, resistance at 25 ℃ = 500.0 kΩ ± 3%, Semitec, Japan) was selected by considering the current measurement range (0.1–3276.7 nA) and stabilized potential (+400 mV) of the telemeter to enable sensitive measurement in a normal intra-oral temperature range (36.0–38.0 ℃). These components were combined to build the wireless thermometer before



(a)

(b) (c)

Fig. 1. (Color online) (a) Components and integrated system of the wireless thermometer. (b) Schematic illustration of the MG thermometer. (c) Fabricated MG thermometer.

encapsulating it between two layers of MG material. Encapsulation was performed using a heat sealing method, the same as in the previous study of pressure sensors.(20) The following is a brief explanation of the method. First, dental stone models were made by taking dental impressions from study participants. Second, the first layer of an MG material (product name: Erkodur, material: polyethylene terephthalate glycol (PETG), thickness: 0.5 mm, Erkodent, Germany) was formed by vacuum forming in the dental stone mold. Third, the first layer was cut out to leave a base area of the wireless thermometer, and then vacuum forming was performed with the second layer of the MG material with the wireless thermometer between the two layers [Fig. 1(b)]. Finally, the wireless thermometer was securely encapsulated by heat sealing both MG layers using a hot-air gun. Figure 1(c) shows a visual image of the fabricated MG thermometer. The thermistor was placed on the buccal side surface of the second molar of the upper jaw.

In the characterization of the device, we first evaluated the response and quantitative character of the wireless thermometer before encapsulation. After that, the MG thermometer was characterized. The responses of both the wireless thermometer and the MG thermometer were acquired by changing the peripheral temperature of the devices from laboratory room temperature to a constant temperature of water in the range of 30–50 °C. The sampling rate of the wireless thermistor and the MG thermistor was set at 1 Hz. Note that the working time of the device depends on the sampling rate and communication rate. When that rate was 1 Hz, the device will stop within 6 h. The working time reached 15 h with the rate settings of 0.03 Hz. In the future, issues in the trade-off of working time and measurement rate will be solved by energy-harvesting devices, wireless powering technology, safe and high-energy cells, or biofuel cells.

2.2 Monitoring intra-oral temperature using MG thermometer

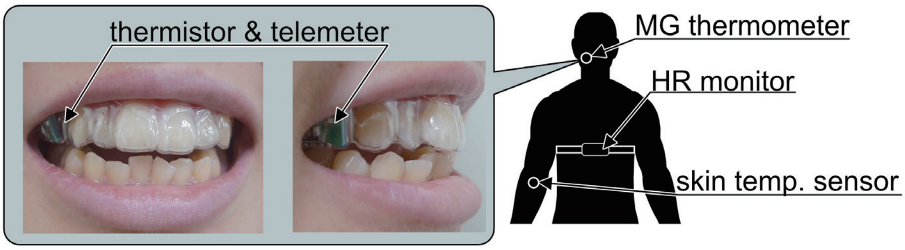
To demonstrate the feasibility of the MG thermometer, three types of human subject experiments were carried out. This study was authorized by the Institutional Review Board at Tokyo Medical and Dental University (numbers 2015-05 and D2018-054) in accordance with the latest version of the Declaration of Helsinki. Study participants were enrolled in this study after receiving explanations about the study and giving written informed consent.

The first experiment involved monitoring the dynamic changes in intra-oral temperature caused by drinking water of various temperatures (20–50 °C). Each study participant was equipped with their own MG thermometer, then seated on a chair, after which they took 30 mL of water at the time indicated by the experimenter. Then, the participant swallowed the water after 10 s of holding it in the oral cavity. The second experiment involved monitoring the intra-oral temperature during office work. In this experiment, we aimed to establish whether study participants would experience any discomfort when working while wearing the MG thermometer and whether there would be any problems with the stability of the wireless measurements over long periods. Each study participant was asked to engage in normal activities such as breathing, talking, drinking water, and so forth, while wearing the MG thermometer. Measurements were taken continuously for 3 h. In the third experiment, the MG thermometer, a skin temperature sensor (Model number GSP-6, Elitech, USA), a heart rate monitor (Model number H1, Polar, Finland), an environmental temperature and humidity sensor (GSP-6), and an axillary thermometer (Product number ET-C231P, Terumo, Japan) were used simultaneously [Fig. 2(a)] similarly to in a previous paper.(21) The experimental protocol involved wearing a non-woven mask for a predetermined period while working with the room temperature adjusted to 20 or 30 ℃, as shown in Fig. 2(b). The sampling rate of the MG thermometer in all the experiments described in this section was 1 Hz, as in the experiment described in Sect. 2.1.

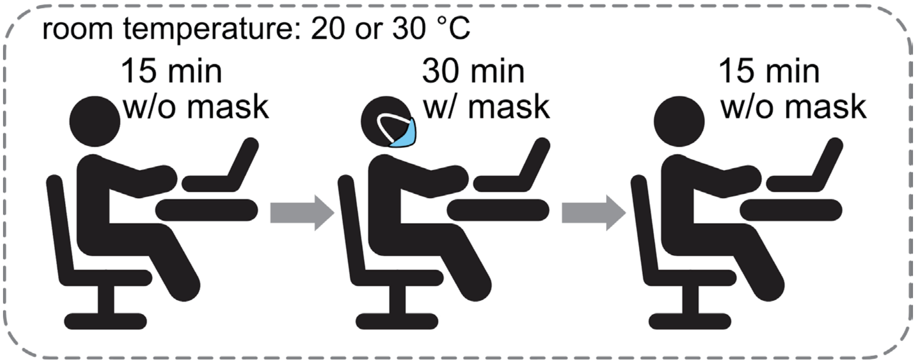
3. Results and Discussion

3.1 Basic characteristics of MG thermometer

Figure 3(a) shows the response curves of the fabricated wireless thermometer for the water of various temperatures. When the wireless thermometer was moved from air to water, the resistance of the thermistor decreased rapidly in response to the temperature change and the output current increased. The average 90% rise time ($T90_{rise}$) and 90% recovery time ($T90_{recovery}$) of the wireless thermometer were 3.2 and 13.8 s, respectively. $T90_{recovery}$ was 4.3 times longer than $T90_{rise}$, which was considered to be largely due to the difference in thermal conductivity between water and air. The output currents of the wireless thermometer at each temperature were in good agreement with the theoretical values [Fig. 3(b)]. Figure 3(c) shows the results of the same experiment as for Fig. 3(a), except with the wireless thermometer sealed inside the MG layers. Dull responses were observed for both average $T90_{rise}$ (12.2 s) and average

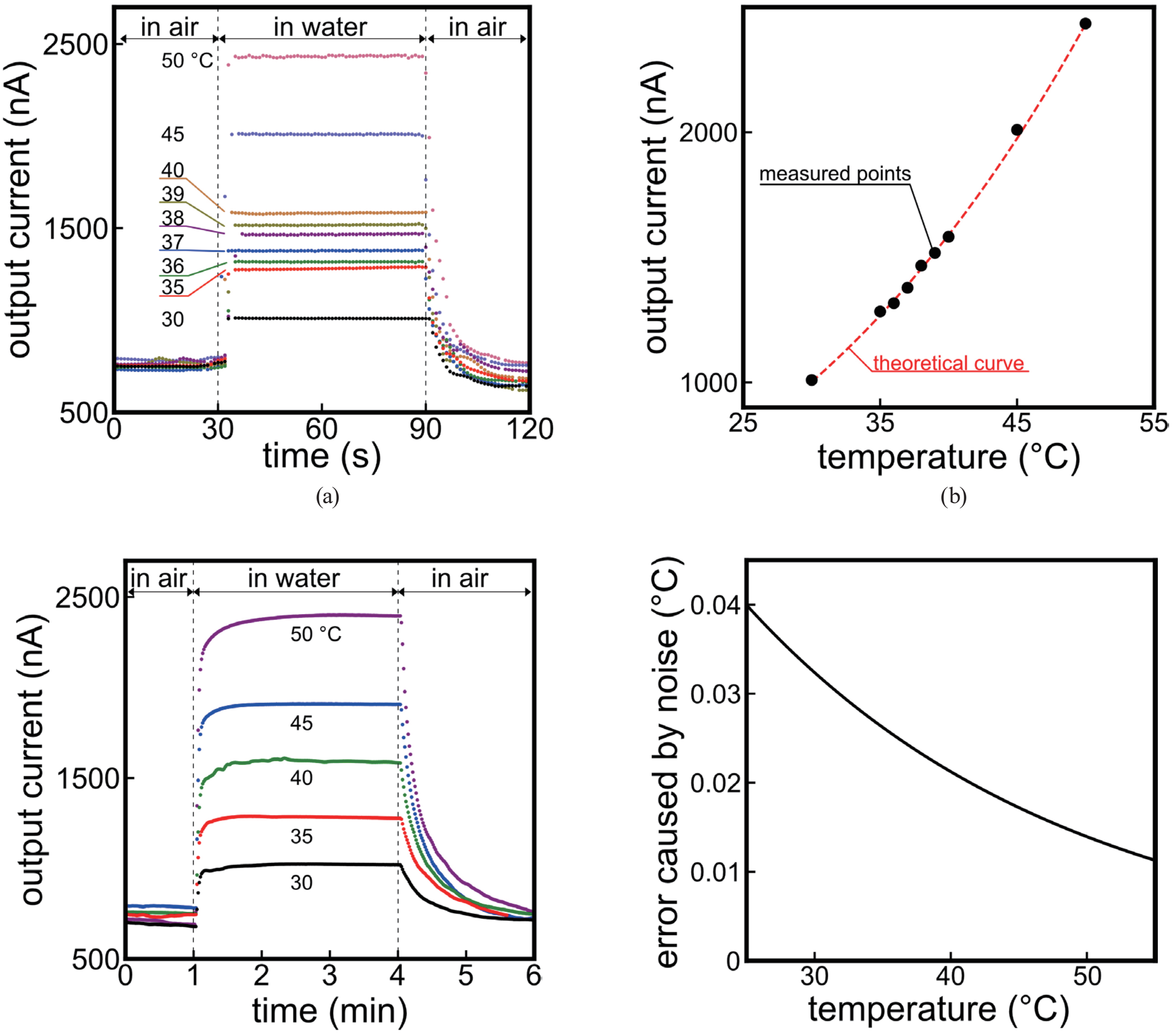


(a)



(b)

Fig. 2. (Color online) (a) Instruments for evaluation of effects of environmental disturbances on body, skin, and oral temperature. (b) Experimental protocol.



(a) (b)

(c) (d)

Fig. 3. (Color online) (a) Response curves of the wireless thermometer. (b) Comparison between measured temperatures and theoretical curve of the wireless thermometer. (c) Response curves of the MG thermometer. (d) Relationship between error caused by current reading noise and temperature.

$T90_{recovery}$ (60.0 s) after sealing the thermistor. The thermal conductivity of PETG is lower than that of water. Even with a PETG layer as thin as 0.5 mm, $T90_{rise}$ and $T90_{recovery}$ were about four times longer after sealing the thermistor. Moreover, the output current values for any given temperature before and after sealing the thermistor showed a proportional relationship with a slope of 1.01 and a correlation coefficient of $R = 0.999$. Thus, the sealing of the wireless thermometer did not affect the temperature quantification. On the other hand, Bueno *et al.* reported that the steady-state error for a thermometer embedded in an MG was 0.2 °C, as obtained in a water bath test.(22) In addition, it was reported that the steady-state error is not affected by the embedding materials.(17)

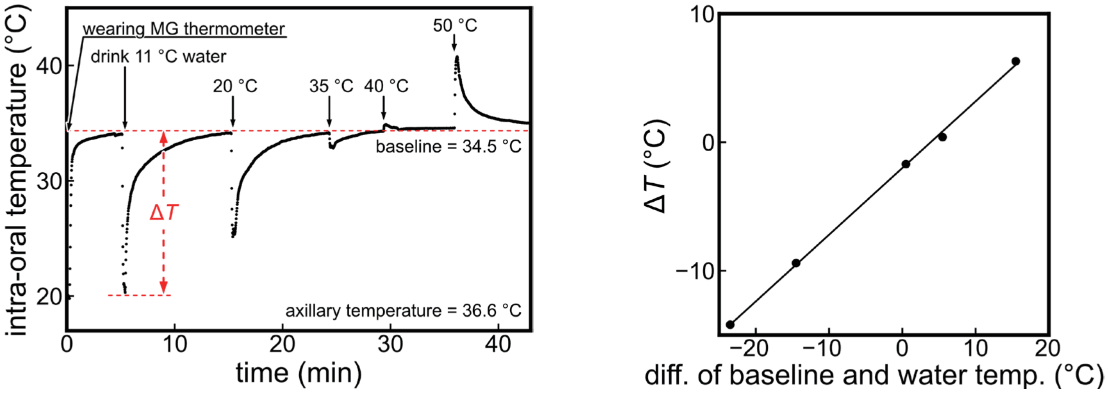
As a result of curve fitting of the steady-state values of the sensor response at each water temperature, as shown in Fig. 3(c), a calibration curve of the temperature for the MG thermometer was obtained [Eq. (1)]. The average standard deviation of the current reading by the MG thermometer was 1.4 nA in an environment with a stable temperature. As shown in Fig. 3(d), the variation of the temperature values calculated using Eq. (1) caused by a current change of 1.4 nA at 30 to 50 °C was in the temperature range of 0.01 to 0.03 °C. Therefore, the indicated temperature value included an error range of at least ±0.03 °C. This number did not include the effect of temperature drift from the circuit, humidity, external pressure, etc. MG thermistors were calibrated before every experiment; thus, we considered that biases because of heat from the measurement circuit or by self-heating of the thermistor were canceled. In addition, since the thermistor element was sealed in the MG layers by vacuum forming, humidity around the thermistor was considered stable. Also, because of the sensor position, the thermistor element was pressurized by only the oral soft tissue such as the buccal mucosa. That pressure was considered much smaller than the pressure given from vacuum forming. Therefore, the pressure effect could be negligible. Note that to eliminate the effects of individual differences, every fabricated sensor needs to be calibrated before use in this method.

$$Temperature\ (^\circ\mathrm{C}) = 290.73e^{0.0421\times output\ current\ (\mathrm{nA})} \tag{1}$$

3.2 Changes in intra-oral temperature upon drinking cold and hot water

Figure 4 shows the result of intra-oral temperature monitoring before and after ingesting water of different temperatures. The intra-oral temperature at rest (baseline) was 34.5 °C. A change in intra-oral temperature occurred upon drinking both cold and hot water. The results suggest that the MG thermometer can monitor rapid changes in intra-oral temperature caused by short events. We observed a longer response time for both $T90_{positive\ recovery}$ (changing from lower temperature to baseline) and $T90_{negative\ recovery}$ (changing from higher temperature to baseline) than the response time seen in Fig. 3(c). Newman *et al.* reported that drinking an ice-cold beverage had a greater effect than drinking a very hot beverage on intra-oral temperature and that the effect was sustained for 10 min.(23) Therefore, it was considered that the long recovery time obtained in this experiment did not originate from the device but rather represented the characteristics of the temperature dynamics of the oral cavity. As shown in Fig. 4(b), a proportional relationship was observed between the difference between the intra-oral and water temperatures and the change in intra-oral temperature caused by ingesting water (ΔT). We hypothesized that when the temperature difference between the oral temperature and water was zero, ΔT would also be zero. However, there was a y-intercept of –2.01 °C as can be seen from Eq. (2). A possible cause of this negative shift was mouth breathing during the ingestion of water, which decreased the intra-oral temperature.(24)

$$\Delta T\ (^\circ\mathrm{C}) = 0.519 \times diff.\ of\ baseline\ and\ water\ temp.\ (^\circ\mathrm{C}) - 2.01 \tag{2}$$



(a) (b)

Fig. 4. (Color online) (a) Time course of intra-oral temperature upon drinking water of various temperatures. Δ*T* represents the change in intra-oral temperature caused by ingesting water. (b) Relationship between difference of baseline and drinking water temperature and Δ*T*.

3.3 Monitoring intra-oral temperature during office work

Figure 5 shows the time series data obtained by a participant wearing the MG thermometer while performing standard work in an office. Since the MG thermometer was easily detachable, the participant took lunch with it detached, then attached it after lunch to begin measurements. Such ease of detachment and reattachment cannot be achieved with implantable devices. In addition, stable intra-oral temperature monitoring was possible without interruption over 3 h, despite the telemeter being placed in the water-rich oral cavity. This result indicates that there were no problems with wireless communication inside and outside the oral cavity and that the MG thermometer was securely sealed. In a post-experiment questionnaire, participants reported no difficulty in working while wearing the MG thermometer. Particularly, subjects did not experience any problems with speech, swallowing, or other oral movements, but some commented that they were aware that they were wearing a device. Such discomfort is expected to lessen with longer wearing time. According to the results, the developed MG thermometer can be used for the unconstrained measurement of intra-oral temperature.

3.4 Effect of environmental temperature on intra-oral temperature

Figures 6(a) and 6(b) show the intra-oral and axillary temperature, skin temperature, heart rate, room temperature, and humidity from top to bottom with air conditioning set at 20 and 30 °C, respectively. There were no differences in intra-oral temperature, axillary temperature, skin temperature, and heart rate with or without wearing a non-woven mask at both environmental temperatures. Although the results of this experiment were limited to 30 min, the risk of heat stroke was considered low for office work while wearing a non-woven mask in a hot and humid environment.

Table 1 summarizes the average values at each environmental temperature. A large effect of environmental temperature on heart rate and skin temperature was observed. Several studies

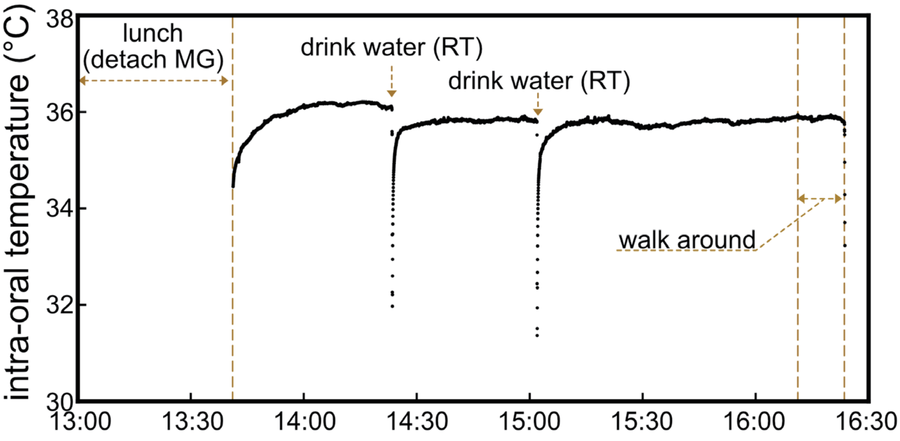
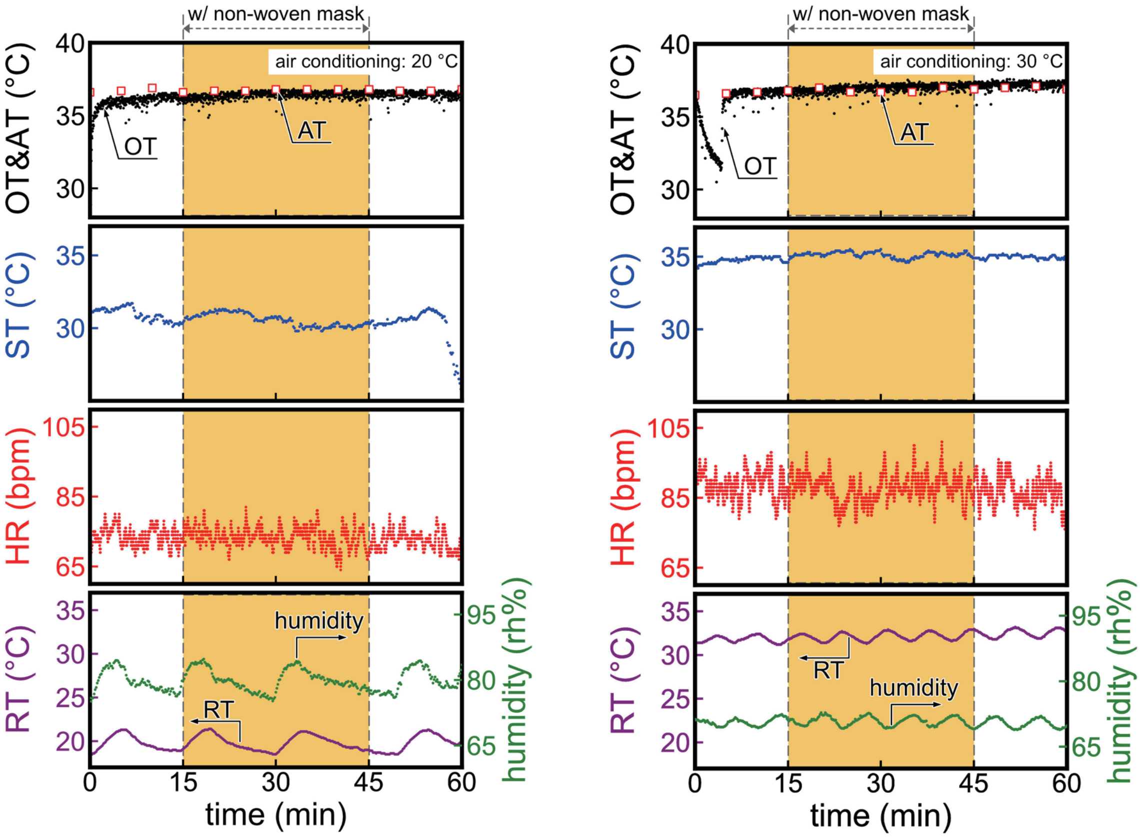


Fig. 5. (Color online) Result of intra-oral temperature monitoring in an office work situation. RT represents room temperature.



(a) (b)

Fig. 6. (Color online) Intra-oral temperature (OT) and axillary temperature (AT), skin temperature (ST), heart rate (HR), room temperature (RT), and humidity (from top to bottom) at (a) 20 °C and (b) 30 °C.

have reported that ambient temperatures lower or higher than 22 °C increase the heart rate even for a person at rest.(25,26) However, it would be difficult to conclude that the reasons for the large

Table 1
Summary of average values at different environmental temperatures.

	Intra-oral temperature (°C)	Axillary temperature (°C)	Skin temperature (°C)	Heart rate (bpm)
20 °C	36.4	36.7	30.6	72.8
30 °C	37.1	36.8	34.9	87.7

changes in heart rate observed in this experiment depend solely on environmental factors. The skin temperature is known to decrease due to perspiration and is also sensitive to environmental influences.(27) Hence, the accurate monitoring of body temperature based on skin temperature measurement will require additional sensors and algorithms that cancel fluctuating disturbances. In contrast, the intra-oral temperature was not affected by the ambient temperature. Therefore, the continuous monitoring of body temperature by the MG thermometer can be realized with a simpler configuration than that for skin temperature measurement.

4. Conclusions

We fabricated a wireless MG thermometer with continuous measurement capability. Although the wireless thermometer was encapsulated between two layers of MG material, no noticeable effects were observed that would be problematic for the response time and quantification to temperature changes. The MG thermometer successfully followed rapid changes in intra-oral temperature when a participant ingested water, provided stable wireless measurement in a real-world setting, and monitored the intra-oral temperature without being affected by environmental disturbances. An MG device has also been developed that takes advantage of the oral cavity as an entry point for food to estimate what is being eaten through the use of an inertial sensor and a thermometer.(28) The wireless monitoring of intra-oral temperature demonstrated in this study has potential applications in various research areas, such as evaluating the performance of athletes, assessing the quality of sleep, and detecting infectious diseases and heat stroke early as part of preventive medicine.

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