Measurement of Core Body Temperature by an Ingestible Capsule Sensor and Evaluation of its Wireless Communication Performance

Kotaro Yamasue,* ** Hiroaki Hagiwara,* Osamu Tochikubo,* Chika Sugimoto,** Ryuji Kohno**

Abstract Measuring core body temperature is important in the study of human body temperature regulation in daily life. We measured core body temperature continuously using an ingestible capsule sensor that has excellent ambulatory utility in daily life. Daily temperature changes, including temperature increase during and just after bathing and temperature decrease during sleep, were observed in all subjects. Temperature readings and communication quality were found to be negligibly affected by the intracorporeal position of the capsule as determined by radiography, with no significant temperature difference among positions in the stomach, the small intestine and the large intestine. However, intake of hot or cold beverages during measurement should be avoided for accurate assessment. Loss of data from inside to outside the body was 3.7 ± 2.5% (1.4 ± 3.8% excluding sleeping hours). The increase in data loss during sleep was due to the change in position of the receiver. A loss of 0.66 ± 0.1% was obtained by placing the receiver less than 50 cm from the navel including during sleep, except during the first ten minutes after swallow. The path loss from inside to outside the body was estimated to be less than that of the capsule endoscope.

Keywords: core body temperature, capsule sensor, wireless communication, body area networks.


1. Introduction

Human body temperature comprises temperatures of the core and the shell. The core temperature refers to the temperatures of the abdominal, thoracic and cranial cavities, and the shell temperature refers to the temperatures of the skin, subcutaneous tissue and muscles. The core temperature is regulated by the brain, whereas the shell temperature is affected more by the skin, subcutaneous tissue and muscles. Measuring core body temperature is important in the study of human temperature regulation in daily life. Temperature measurements from an esophageal site at the level of the heart have been shown to correlate with pulmonary artery temperature readings, which are considered to be the best representation of the average internal temperature of the body. Rectal temperature has been found to follow the esophageal and pulmonary artery temperatures quite closely [1]. However, these methods are not suitable for ambulatory field-based users. As early as 1968, a temperature sensitive “radio pill” was proposed as a suitable device for monitoring core temperature [2]. It was developed by a research group from Johns Hopkins University and commercialized as the Cor Temp pill (HQ Inc., Palmetto, Florida, USA). Kolka et al. [3] compared the core temperature of four women measured by esophageal temperature at a pre-determined location in the esophagus using a calibrated thermistor and Cor Temp pill under chemical protective clothing. They reported that resting esophageal temperature (Tes) averaged 37.11 ± 0.27°C and resting pill temperature (Tpill) averaged 37.17 ± 0.27°C. A combination of exercise, clothing and ambient temperature (30°C) caused Tes to increase to an average of 38.67 ± 0.28°C and Tpill to increase to an average of 38.71 ± 0.33°C during an hour of treadmill walking. They concluded that Tpill is an accurate index of core temperature. Core Temp pill requires the user to enter calibration values into the receiver for each pill prior to use. The VitalSense sensor with the data recording system (Philips Respironics, Bend, Oregon, USA) were developed to provide more reliable means of measuring core temperature in ambulatory subjects [4]. McKenzie and Osgood [4] reported that the mean temperature of ten subjects was 36.93 ± 0.15°C and 36.96 ± 0.16°C for the capsule and rectal probe, respectively, with no significant difference between the means. There was a significant correlation between the capsule and rectal probe temperatures (R² = 0.80 for all data points, and R² = 0.90 for quiescent period). The percentage of missing data points was 3.1 ± 2.5% for the capsule and 11.4 ± 15.9% for the rectal probe (primarily due to probe slippage, but also due to removal for personal hygiene). Many studies have reported results under hot environments and during sports [5, 6], and core temperature change by calorie restriction [7]. However, there are
no reports on the temperature change related to the intracorporeal position of the capsule, and performance of the wireless communication. Capsule endoscopy, in which patients swallow a wireless capsule that transmits images from inside the digestive tract, has gained popularity[8]. Capsule endoscopy uses frequencies near the 400 MHz MICS (Medical Implantable Communication Systems) band. On the other hand, the VitalSense core temperature sensor uses a frequency near the 40.68 MHz band. We were interested in the difference of the communication system between the capsule temperature sensor and the capsule endoscope. The purposes of this study were to examine the daily core temperature change under ordinary conditions in relation to the position of the capsule monitored radiographically, as well as to evaluate the performance of the communication system and compare with that of the capsule endoscope.

2. Methods

2.1 Measurement of core temperature

We used the VitalSense sensor with the data recording system (Philips Respironics) as shown in Fig. 1. The reference numbers of the capsule and VitalSense RE monitor used in this study were 500-6100-02 and 500-0004-01, respectively.

The capsule contains two batteries (silver oxide cell, 1.5 V × 2), thermistor, modulator and antenna (Fig. 1). The surface of the capsule is covered by polycarbonate resin for medical use. This system is guaranteed by the manufacturer to be accurate within ± 0.10°C for the temperature range of 32 to 42°C. The capsule purportedly contains a helical antenna and the modulation mode is presumably delta modulation or frequency shift keying (FSK), according to the manufacturer’s patent [9]. The receiving unit contains three functional subsystems: a data demodulator and interpreter, microcontroller with sensor-tracking and data conversion algorithm, and an activation mechanism. An on-board microcontroller removes the interleaved bits and checks the error detection cord to determine if the incoming data is uncorrupted by the RF channel.

Six male participants (mean age, 65.7 ± 9.6 years) participated in seven experiments. They were asked to go about their normal daily activities but without intensive training, and to record their daily activities. The capsule sensor was activated by placing the capsule in front of the infrared communication window of the monitor. At least 2 h after eating, the participants swallowed the capsule with a cup of water. The monitor was attached to a hip belt during the day time. During bathing and sleeping, the monitor was placed near the subject. The temperature data was displayed on the monitor every 15 s. The intracorporeal position of the capsule was confirmed by X-ray photographs taken at 1- or 2-h intervals after ingestion for 8 h. The experiment was terminated when the capsule was passed or when the data reader stopped displaying temperature data. Participants recorded their daily activities on a recording sheet. Data for every 1 min and the packet loss were displayed on a personal computer when the monitor was connected.

The study protocol was approved by the ethics committee of Yokohama City University Graduate School of Medicine on the condition that a medical specialist removes any capsule that remains in the digestive system longer than ten days.

2.2 Wireless communication experiment

After the capsule sensor was activated by placing it in front of the infrared communication window of the monitor, we put an antenna capable of measuring the transmission spectrum near 40.68 MHz close to the capsule and measured the transmission spectrum using a spectrum analyzer (Agilent E4448A) to confirm the frequency, the interval of transmission and transmission power.

We then examined the communication data loss from changing the distance between the capsule and monitor (receiver) and changing the angle of the capsule in the horizontal and vertical directions, both inside and outside the body in the experimental room. Data loss was also examined when the capsule was placed in water in a metal box or a plastic case at a distance of 30 cm from the monitor, instead of a liquid phantom that imitates electrical constants of the human tissue [10]. Communication from the capsule inside the body was also confirmed by changing the distance of the monitor (receiver) from the navel level when the capsule was located in the intestine, as confirmed by radiography.

3. Results

3.1 Measurement of core temperature

3.1.1 Temperature change depending on sensor position after insertion or ingestion

The temperature increase was faster when the capsule was inserted in the anus, like a suppository, or in the auditory meatus than when ingested, but the attained temperature was lower than that measured after ingestion (Fig. 2).

3.1.2 Estimation of intracorporeal position of the capsule and core body temperature change

Radiographs were taken 0.7 h, 3.7 h, 6.7 h and 7.7 h after ingestion of the capsule. The capsule of subject A was estimated to be located in the stomach at 0.7 h after ingestion, in the upper small intestine after 3.7 h, at the entrance of the large intestine after 6.7 h, and at a slightly
different position in the large intestine after 7.7 h. Figure 3 shows the radiographs depicting the positions of the capsule in the stomach and in the large intestine at 0.7 h and 6.7 h, respectively, after ingestion.

The temperature change after ingestion for subject A is shown in Fig. 4. The subject swallowed a capsule 2.5 h after breakfast. He ate lunch 4 h after ingestion of the capsule and ate dinner 10.5 h after ingestion. He took a bath 1.5 h after dinner and went to bed 1 h after bath. The next morning after breakfast he went to the bathroom and the temperature was lowered to 25°C after a bowel movement. Between ingestion and lunch, he drank a cup of hot tea. Subject A repeated the experiment without any drink during meals. The results are shown in Table 1 as subject A-2.

Assuming that the capsule was situated in the stomach from 0.5 to 3 h after ingestion of the capsule, in the small intestine from 3.5 to 6.5 h after ingestion and in the large intestine from 7 to 10 h after ingestion, the mean temperature and standard deviation (SD) of six subjects who did mainly desk work during the measurement period are shown in Table 1. ANOVA detected no significant differences in temperature (p = 0.196) and coefficient of variance (CV) (p = 0.397) among the three capsule positions, although the variance of the temperature in the stomach was slightly higher than that in the small and large intestines. These results show that the temperature readings change little depending on the position of these nor in the digestive tract, but large changes result from activities such as bathing and sleeping.

Nobody ate a meal when the capsule was located in the stomach. Subject A drank a cup of hot tea during this period and a temperature higher than 39°C was recorded for 3 min; it took a total of 5 min for the temperature to return to the temperature before drinking the tea, as shown in Fig. 4. The CV of the temperature in the stomach was lower in A-2 than in A.

Table 1 Capsule temperatures in digestive tract.

<table>
<thead>
<tr>
<th>Subjects</th>
<th>Stomach</th>
<th>Small intestine</th>
<th>Large intestine</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>37.2 ± 0.56 (1.5)</td>
<td>36.9 ± 0.11 (0.3)</td>
<td>37.1 ± 0.14 (0.4)</td>
</tr>
<tr>
<td>B</td>
<td>37.17 ± 0.22 (0.6)</td>
<td>37.2 ± 0.18 (0.5)</td>
<td>37.1 ± 0.17 (0.5)</td>
</tr>
<tr>
<td>C</td>
<td>37.31 ± 0.38 (1.0)</td>
<td>37.34 ± 0.16 (0.4)</td>
<td>37.4 ± 0.14 (0.4)</td>
</tr>
<tr>
<td>D</td>
<td>37.33 ± 0.32 (0.9)</td>
<td>37.46 ± 0.21 (0.6)</td>
<td>37.73 ± 0.32 (0.9)</td>
</tr>
<tr>
<td>E</td>
<td>36.96 ± 0.11 (0.3)</td>
<td>36.89 ± 0.44 (1.2)</td>
<td>37.17 ± 0.2 (0.5)</td>
</tr>
<tr>
<td>F</td>
<td>37.33 ± 0.14 (0.4)</td>
<td>37.36 ± 0.09 (0.4)</td>
<td>37.33 ± 0.06 (0.2)</td>
</tr>
<tr>
<td>A-2</td>
<td>37.29 ± 0.1 (0.3)</td>
<td>37.17 ± 0.12 (0.3)</td>
<td>37.31 ± 0.15 (0.4)</td>
</tr>
<tr>
<td>Mean</td>
<td>37.23 ± 0.26 (0.7)</td>
<td>37.18 ± 0.19 (0.5)</td>
<td>37.31 ± 0.17 (0.5)</td>
</tr>
</tbody>
</table>

Values are mean ± SD (°C). Values in parentheses are coefficients of variation (%)
3.1.4 Data loss after ingestion
Data loss mainly occurred in the initial stage of ingestion and during sleep, especially during sleep, as shown in Fig. 5. The percentage of missing data points of four subjects (B, C, D and E) was $3.7 \pm 2.5\%$ overall and $1.4 \pm 3.8\%$ when sleep hours were excluded. Data was lost probably because of the distance of the capsule from the monitor during sleep. Two subjects (F and A-2) attempted to wear the monitor on their hip during sleep. The mean data loss of these two subjects was $0.69 \pm 0.1\%$ during the day excluding the first 10 min after swallowing the capsule, and there was no data loss during sleep. The capsule transit time of the seven experiments varied from 16 to 71 h, with a mean of $32.5 \pm 17.7$ h.

3.2 Wireless communication from inside to outside the body and outside the body
3.2.1 Examination of transmission spectrum
Experiment confirmed that the VitalSense capsule temperature sensor transmitted signals every 15 s at a frequency of 40.68 MHz and that the transmission power was $-85$ dBm. (Fig. 6)

3.2.2 Data loss from inside to outside the body and data loss outside the body
Outside the body, data loss changed according to the distance and orientation of the capsule. The transmittable distance was 70 cm when both the capsule and monitor were set vertically and 50 cm when the capsule was set horizontally outside the body. The transmittable distance was approximately 50 cm when the capsule was located in the intestine (Fig. 7). These data suggest that the difference in data loss from inside to outside the body and data loss outside the body is small, considering the angle change of the capsule in the body as shown in Fig. 3.

3.2.3 Data loss under various circumstances
No data loss occurred when the capsule was immersed in water within a well-sealed plastic case (polyester). Data loss occurred when the capsule was immersed in water within a well-sealed metal can, but did not occur when the lid of the metal can was removed.

4. Discussion
4.1 Core body temperature measurement
We evaluated the VitalSense telemetric monitoring system that consists of a monitor (receiver) and a thermistor-based ingestible capsule for measuring core body temperature. The disposable capsule was easy to swallow and provided an easy, unobtrusive way to measure core temperature. We first questioned whether the capsule temperature is affected by the intracorporeal position inside the digestive tract, but found that the difference was not significant. Our second question was whether the capsule detects temperature change, and observed temperature changes of about 0.6°C during ordinary desk work, as shown in Fig. 4. A possible factor is that the size of the capsule is small and that there is a temperature change between the wall of the organ and inside the organ, especially in the stomach, the volume of which is bigger than that of other digestive organs. McKenzie and Osgood [4] reported that the mean difference between capsule sensor reading and rectal probe reading in normal ambulatory adults was only 0.04°C except when subjects were engaged in exercise, and they observed a temperature change of about 0.6°C under normal conditions. Easton et al. [6] reported that there were no differences between Tpill and rectal thermister during both rest and exercise-induced hyperthermia. One concern is that subject A drank a cup of hot tea during rest and a temperature elevation of approximately 2°C
capsule endoscopy was observed. That may be one of the reasons why subject A showed higher CV when the capsule was in his stomach than in other sites. Engels et al. [5] pointed out that intake of 500 ml of cold water after an experimental body warming session (about 9 h after initial ingestion) lowered the capsule temperature by approximately 6°C, which then recovered gradually. They recommended avoiding or carefully controlling the intake of cold water when employing ingestible capsule technology. These results show that it is important to avoid drinking hot or cold beverages during measurements for accurate assessment. Another problem was that data loss was higher than expected. We expected a data loss of less than 1%. The frequency for monitoring body temperature is less than that for ECG, EMG and SpO2, and recording temperature data once every minute is sufficient in hospitals[11]. Occasionally, continuous data loss occurred when using the system. The possibility of continuous data loss decreases when the data loss is less than 1%. We examined the missing data rate and found that the main loss occurred during sleep. The manufacturer’s brochure recommended that the distance between the body and the monitor should be less than 1 m, but our experience suggests that less than 50 cm is more appropriate. We confirmed data loss of less than 1% by maintaining a distance less than 50 cm.

4.2 Implanted wireless communication system
This core temperature monitoring system uses implantable wireless communication similar to that used in capsule endoscopy. Generally, wireless communication in a free space cannot be applied to implanted communication systems. When signals travel from the transmitter to the receiver, there are losses due to absorption of electromagnetic wave power by the tissue and multiple reflective paths. Takizawa et al. [12] reported that frequencies of 611 MHz or less would be useful for capsule endoscopy applications in terms of error rate performance in experiments using a liquid phantom. Currently, frequencies of approximately 435 MHz (Given Imaging) and 315 MHz (Olympus) are used in capsule endoscopy. The VitalSense core temperature sensor uses 40.68 MHz. According to Friis’s transmission equation, path loss in free space can be calculated using equation (1):

\[ PL = \left( \frac{4\pi f d}{c} \right)^2 \]

where \( f \) and \( c \) stand for the frequency and speed of light, respectively, \( d \) is the distance between TX and RX antennas, and \( n \) is the pass loss exponent (normally 2 for propagation in free space). The path loss at a distance of 1 m is calculated to be 24.5 dB at a frequency of 400 MHz and 14.2 dB at 40.68 MHz. These figures refer to data in free space. There is great attenuation of radio signals in human tissue because of higher permittivity. However, the data loss of the VitalSense system between the inner and outer body was not very large (Fig. 7). Thus, we evaluated the path loss level of the VitalSense sensor compared to capsule endoscope that uses communication from inner body to outer body.

Regarding capsule endoscopy using a central frequency of 315 MHz, Homan et al. [8] estimated the receiving power \( (Pr) \) using equation (2) to be approximately \( -86 \) dBm, assuming \( BW = 10 \) MHz, \( NF = 5 \) dB, \( SNR = 13 \) dB and a bit error rate of \( 10^{-3} \), when applying FSK modulation.

\[ Pr = \frac{-174}{\log_{10}BW + NF + SNR(dbm)} \]

where \( BW \) is the bandwidth and \( NF \) is the noise figure. The input noise from electrical powers is \( -174 \) dBm and is calculated by \( P = K T \) (where \( K \) is Boltzmann constant and \( T \) is absolute temperature).

Transmission power \( (Pt) \) is estimated to be \( -43.4 \) dBm using equation (3), assuming \( E = 500 \mu V/m \) at \( d = 3 \) m.

\[ Pt = 10\log_{10}((E-d)^2/49) + 30(dBm), \]

where \( E \) is the electric field strength and \( d \) is the distance (m). Assuming the antenna to be a half wavelength dipole antenna, \( (E-d)^2 \) is divided by 49. To convert dBW to dBm, 30 dBm is added.

Assuming \( Pt = -45 \) dBm, considering the standard low power of the wireless station and the loss by antenna to be \( 10 \) dB, which is assumed considering the gain of receiving antenna and matching loss by the resistance of inductance, the allowable transmission loss through the inner body tissue is estimated to be \( 31 \) dB. The path loss estimated by a phantom experiment[12] is approximately \( 2.5 \) dB/cm at \( 400 \) MHz. The transmittable distance to observe the interior of the small intestine is approximately 12.5 cm.

In the case of the VitalSense system, we estimated \( Pr = -110 \) dBm using equation (2), by assuming \( BW = 0.04 \) MHz and adopting the same FSK modulation, NF, SNR and bit error rate as in the above example. The estimated \( Pt \) is \( -85 \) dBm by our measurements as shown in Fig. 6. The permissible transmission loss is estimated to be \( 25 \) dB. When the transmittable distance is 50 cm from inside the body to outside the body, the path loss is estimated to be \( 0.5 \) dB/cm. The low frequency of the VitalSense system might contribute to the low path loss.

4.3 Comparison of capsule temperature system and capsule endoscopy
We compared the capsule temperature sensor system and capsule endoscopy as two implantable wireless communication systems (Table 2). The main data of the capsule endoscopy are quoted from a previous study[8]. The sampling rate, frequency and transmission power of the capsule temperature system were confirmed by a spectrum analyzer. The percent data loss and mean capsule transit time are from our experiments.

A big difference between the capsule temperature sensor and capsule endoscopy is that the former transmits a small amount of data every 15 s and the data rate is approximately 80 bps, while the latter transmits two images every 1 s and that data rate amounts to several Mbps. The temperature sensor can be used during daily activities and the digestive system does not have to be empty, whereas capsule endoscopy is strictly used when the digestive system is empty. These differences explain
the variations in battery life and transit time. Capsule endoscopy is estimated to compensate for the degradation of received power using eight diversity antennas attached to the abdomen.

The incidence of heat stroke has increased not only during sports and work under hot conditions but also in ordinary life. Continuous measurement of core temperature is important for preventing heat stroke. If the cost of this capsule temperature sensor decreases, the use of this system will expand exponentially.

5. Conclusion

The ingestible capsule temperature system provides continuous, unobtrusive measurement of core body temperature in daily life. Temperature readings and communication quality were found to negligible affected by the intracorporeal position of the capsule as determined by radiography. However, intake of hot or cold beverages during measurement should be avoided for accurate assessment. The path loss from inside to outside the body for the ingestible capsule temperature system was estimated to be less than that for capsule endoscopy. However, the receiver (monitor) should be placed less than 50 cm away from the navel to avoid data loss by transmission.

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References


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