The Optimal Anatomical Position and Threshold Temperature of a Temperature Data Logger for Brace-Wearing Compliance in Patients with Scoliosis

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Abstract:

Introduction: Although strict compliance with brace wearing is important for patients with scoliosis, no study has analyzed the most ideal conditions for temperature logger accuracy. We evaluated the optimal brace position and threshold temperature for the logger and determined the reliability of its measurements in patients with scoliosis.

Methods: Five temperature loggers were embedded into holes generated at five different brace positions (right scapula, right chest, left chest, lumbar, and abdomen) within the brace. We compared measurement errors at each position using different threshold temperatures to determine the ideal anatomical position and threshold temperature. Under the ideal conditions determined, we calculated the reliability of the temperature logger readings in three healthy participants.

Results: Measurement errors (i.e., differences between the actual and logger-recorded brace wearing times) were the lowest at the 28°C and 30°C threshold temperatures when the logger was positioned at the left chest and at 30°C at the abdomen. Among these three temperature/position combinations, we considered the abdomen to be the least affected by the shape of the brace; thus, the placement of the temperature logger at the abdomen using a threshold temperature of 30°C was the most ideal condition.

Conclusions: The placement of the temperature logger at the abdomen using a threshold temperature of 30°C was the most ideal condition, with the reliability of the logger being 97.9%±0.9%. This information might be useful for scoliosis management teams, and this temperature logger provides a valuable clinical tool.

Keywords:
scoliosis, brace, compliance, temperature, logger

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Introduction

Brace treatment for adolescent idiopathic scoliosis (AIS) is reportedly effective for preventing spinal curvature progression. Patient compliance with brace wearing affects the treatment outcome[1,2)]. However, because wearing a brace is stressful and restricts daily movements, patients often stop wearing the brace and discontinue treatment[3-5)]. Moreover, patients may not report their accurate brace wearing time to medical staff, purposively overestimating the time to appease the staff. Therefore, the accurate measurement of brace wearing is crucial for patients with AIS.

Recently, several researchers reported the usefulness of electronic compliance monitors for brace treatment. Most electronic compliance monitors consist of a sensor, clock, and battery-powered temperature logger to record sensor

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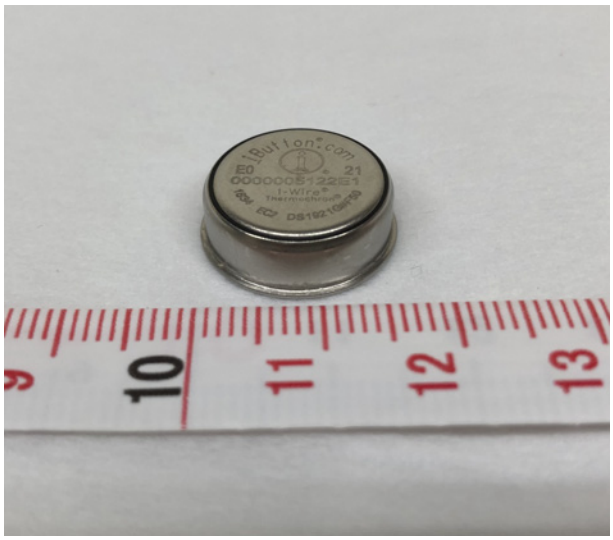

Figure 1. The temperature logger used in this study.

readings. These monitors are generally categorized as temperature sensing[1,6-8], force sensing[9-11], or both force and temperature sensing[12], of which temperature sensing is the most popular monitoring method. These compliance monitors are placed in the brace and are set at a threshold temperature to enable the differentiation of ambient temperature from the skin temperature of the patient[1,7,12,13]. Wearing time is determined by a temperature logger embedded in the brace programmed to log the time at a given temperature. A temperature higher than the threshold indicates that the brace is being worn.

However, no reports have assessed the optimal position within the brace or threshold temperature of the temperature logger for obtaining accurate data. Moreover, the reliability of the logger has not been accurately analyzed under different anatomical positions/temperature conditions. Thus, the most ideal setting and reliability of temperature loggers are unclear, although patient compliance with brace wearing is associated with treatment outcome in patients with scoliosis[1].

This study aims to investigate the optimal position within the brace and the threshold temperature of the temperature logger and evaluate the reliability of the logger under the determined ideal conditions for the brace of the patient with AIS.

Materials and Methods

Design of the compliance monitor

The compliance monitor consists of a battery-powered temperature logger with a temperature sensor (Thermochron, KN Laboratories, Inc., Osaka, Japan). The temperature logger weighs 3 g, measures 17×17×6 mm, and can store 2048 recordings (Fig. 1). The accuracy is ±1°C (–40°C to +80°C). The logger cannot be recharged, but the battery lasts for 5 years or until the cumulative number of measurements exceeds one million. The monitor can measure temperature at intervals of 1-255 minutes using a real time clock. The monitor was set to record the temperature every 30 minutes for a total of 42 consecutive days. Data can be downloaded from the logger using an adapter that connects to a computer.

First study: optimal logger position and threshold temperature for logging

To determine the optimal position for temperature logging, the five temperature loggers were embedded in holes cut in five different positions (right scapula, right chest, left chest, lumbar, and abdomen) within the brace (Fig. 2). The first study, conducted in April 2018, aimed to measure the reliability of the electronic compliance monitor placed at different positions within the brace. A nurse who works in the scoliosis clinic (coauthor HK) was voluntarily recruited for this trial; she had no history of spinal deformity. She was asked to wear a custom-fitted thoracolumbosacral brace (Fig. 2), similar to that for orthosis for scoliosis, for 20 hours per day over 5 consecutive days.

The nurse recorded in a notebook the exact duration she wore the brace, and this was defined as the "real time." Temperatures above the threshold indicate that the brace is being worn, whereas temperatures below the threshold indicate that the brace has been taken off. The duration at which the temperature exceeded the threshold was calculated as the "log time." To determine the most appropriate temperature threshold, thresholds of 28°C, 30°C, and 32°C were compared. We calculated the percentage difference as (log time–real time) / real time)×100. The reliability under each condition was calculated as 100–(absolute value of the percentage difference). We then compared the reliabilities at each anatomical position and at three different temperature thresholds to determine the ideal anatomical position and threshold.

Second study: reliability test using three volunteers

A second study was performed in three healthy subjects to assess the reliability of the logger at the optimal position and threshold temperature determined in the first study. Two nurses and one medical clerk who work at a scoliosis clinic (coauthors HK, MO, and YI) were voluntarily recruited for this trial; none had a history of spinal deformity. They were each asked to wear a custom-fitted thoracolumbosacral brace over 20 hours a day for 7 consecutive days in August 2018. The tests were performed during the hottest month (August) in this region where our facility was located to validate the accuracy of the temperature monitor. We calculated the reliability of the logger in each participant under the conditions established in the first study. The institutional review board of our hospital approved this study protocol.

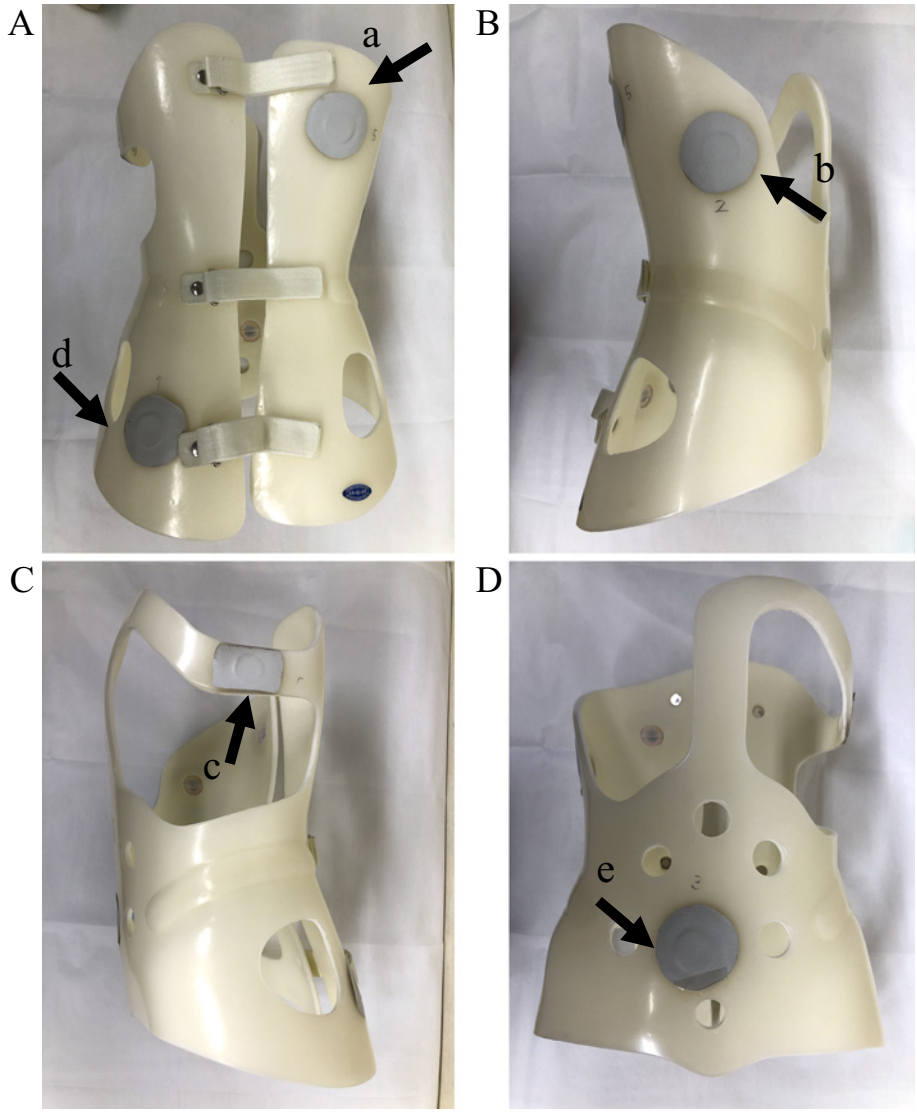

Figure 2. Custom-molded thoracolumbosacral orthosis instrument.
A, back; B, right; C, left; D, front.
Temperature loggers embedded into five holes cut at different positions within the brace. (a, right scapula; b, right chest; c, left chest; d, lumbar; e, abdomen)

Table 1. Average "Real Time" per Day of Wearing the Brace and the Compliance Rates over 5 Consecutive Days (First Study).

	Real time (recorded by notebook) (hour:minute/day)	Compliance rate (%)
Day 1	22:45	94.8
Day 2	21:55	91.3
Day 3	21:20	88.9
Day 4	22:50	95.1
Day 5	22:40	94.4
Mean±SD	22:18±0:35	92.9±2.4

SD, standard deviation

Results

First study

In the first study, the average "real time" that the brace was worn per day was 22:18±0:35. The overall compliance rate calculated by dividing the real time by 24 (total hours per day) was 92.9%±2.4% (Table 1). The "log time" was calculated at the different anatomical positions and temperature thresholds evaluated. As an example, Fig. 3 shows a plot of temperature versus time recorded by the logger when positioned at the lumbar position and using a threshold temperature of 30°C. Wearing time, indicated by the double-headed arrows, was defined as the duration at which the temperature exceeded 30°C. When the brace is not being worn, the temperature remains at a low level, similar to the ambient temperature. The dotted double-headed arrow indi-

cates the duration at which the brace was not being worn.

Fig. 4 shows the temperature recorded by the temperature logger over a typical day. It was judged that the brace was being worn whenever the temperature exceeded the designated threshold (28°C, 30°C, and 32°C). When this threshold was changed, the wearing time (log time) also changed. When the threshold was set to 28°C, the log time was calculated as 22.5 h (93.8% of the day). However, at the 32°C threshold, the log time decreased to 19.5 h (81.3%). Thus, increasing the threshold temperature resulted in a shorter log time. Calculating the log time from raw data obtained by the logger took only a few minutes using Microsoft Excel (Microsoft Corp., Redmond, WA).

Of all measurements recorded in the first study, the highest and lowest logger temperatures were 35.0°C and 23.5°C, respectively. In the first study, performed in April 2018, the average highest and lowest temperatures of the day were 21.6°C and 10.0°C, respectively. Thus, the logger temperature was higher than the ambient temperature at all times.

Table 2 shows the percentage differences in the log versus real times for different combinations between each of the five logger placement positions and each of the three different temperature thresholds. The lowest percentage differences were obtained when using the 28°C threshold at the left chest position, 30°C at the left chest, and 30°C at the abdomen. Among these three position/temperature combina-

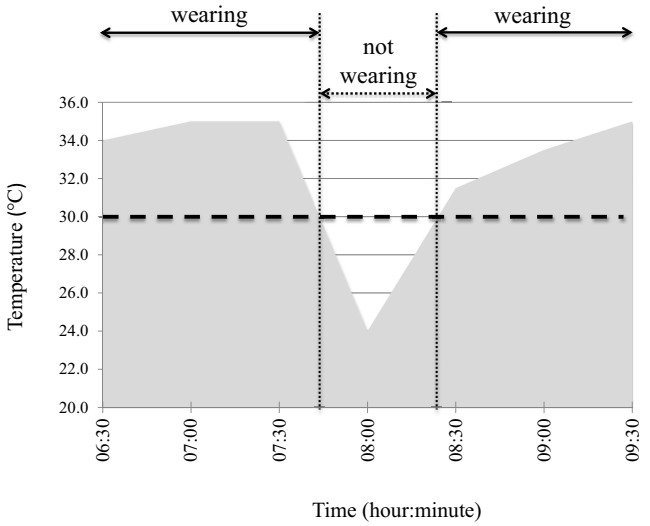

Figure 3. A typical temperature curve obtained by the temperature logger and our interpretation of the data.
Double-headed arrows and the dotted double-headed arrow indicate the durations of wearing and not wearing the brace, respectively. The dotted horizontal line represents the threshold temperature (30˚C).

Table 2. Percentage Differences between the "Real Times" and "Log Times" at Five Different Anatomical Positions Using Three Different Threshold Temperatures (First Study).

		Threshold		
		28˚C	30˚C	32˚C
Positions	Right scapula	−0.6	−8.4	−42.1
	Right chest	0.5	−0.6	−1.3
	Left chest	0.2	0.2	−2.1
	Lumbar	0.9	−2.5	−22.3
	Abdomen	0.5	−0.2	−2.8

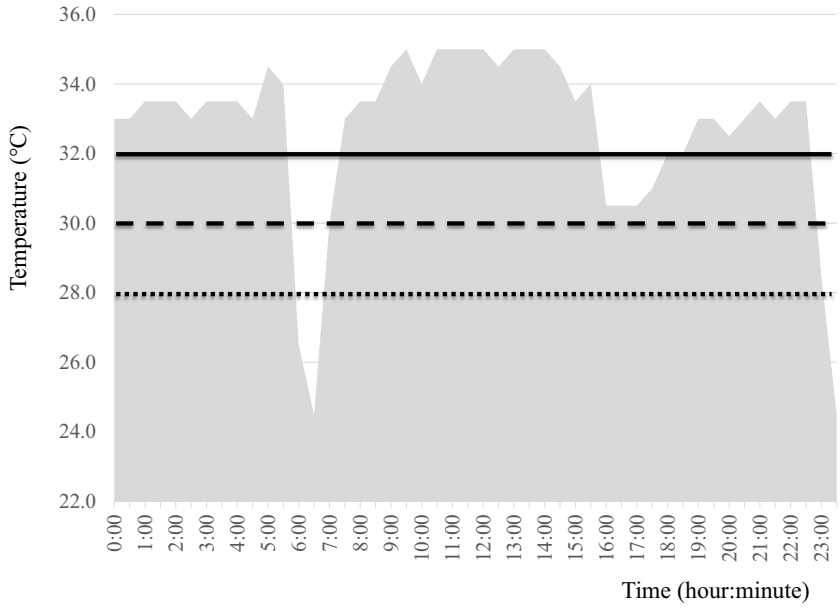

Figure 4. The temperatures recorded by the temperature logger over a 24-hour day. The three horizontal lines indicate the three threshold temperatures evaluated (solid line, 32˚C; dashed line, 30˚C; dotted line, 28˚C). Temperatures exceeding the threshold were defined as wearing time.

Table 3. Data from the Heathy Volunteers in the Second Study Showing the Average Time of Orthotic Brace Wear per Day, Recorded Either in Their Notebooks or by the Temperature Logger.

Subject	Real time (recorded by notebook) (hour:minute/day)	Log time (recorded by logger) (hour:minute/day)	% Difference (%)	Reliability (%)
HK	22:50	23:08	1.36	98.6
MO	19:40	19:00	−3.38	96.6
YI	22:14	21:56	−1.37	98.6
Mean±SD	21:34±1:22	21:21±1:44	2.04±0.95	97.9±0.9

The mean and standard deviation of the percentage difference were calculated using the absolute value of the percentage difference.
SD, standard deviation

tions, we considered the abdomen to be the least affected by the shape of the brace; thus, the placement of the logger on the abdomen at a threshold temperature of 30°C was the most ideal combination.

Second study

In the second study, three participants wore braces with a logger installed on their abdomen at a threshold temperature of 30°C (Table 3). These participants were asked to wear the brace for as long as possible; however, because MO took the brace off when playing volleyball, the wearing time was shorter for MO than for HK and YI. The average reliability among the three participants was 97.9%±0.9%. In August 2019, when the second study was performed, the average highest and lowest temperatures of the day were 32.4° C and 24.3°C, respectively. That average ambient temperature was sometimes higher than the threshold temperature.

Discussion

We found that placing the logger on the abdomen at a threshold temperature of 30°C was the most ideal condition. Under these parameters, we demonstrated that the reliability of the logger was 97.9%±0.9% according to the notes of the three participants receiving scoliosis care. This is the first study to evaluate the ideal anatomical placement and threshold temperature for temperature loggers used with scoliosis braces.

As determined in the first study, placing the logger on the abdomen at a threshold temperature of 30°C was the most ideal combination in terms of the difference between the "real times" and "log times." Although temperature loggers were sensitive in their place, no studies have compared the temperature logger readings among different positions within the brace. In previous studies, loggers were primarily placed at the lumbar mold[6,8,14-16] and sometimes at the abdomen[7]. However, our results indicate that the abdomen is one of the two most accurate positions for logger placement, perhaps because the logger rarely loses contact with the subject's body at this site. In addition, an abdominal logger has the advantage of not affecting the efficacy of the brace. Although the measurement error of the logger at the left chest position, as one study described[12], was as accurate as that at the abdomen, we consider placement at the left chest to be less ideal, because the adjustment of pads in areas such as the left chest is sometimes necessary during brace therapy.

Regarding the ideal threshold temperature, some clinical studies used sensor thresholds between 28°C and 32°C[1,7,14,17]. However, no previous studies have evaluated the optimal threshold temperature. When the ambient temperature is high and the threshold temperature is low, there is a risk of the logger mistakenly recognizing that the brace is being worn. In contrast, if the threshold temperature is set too high, the logger might not recognize the brace being worn. Among the 28°C, 30°C, and 32°C thresholds, we found 30°C to be optimal.

Under the conditions determined in the first study, our results from the second study demonstrated the reliability of the temperature logger to be 97.9%±0.9% by comparing notes among the three participants engaged in scoliosis care. Takemitsu et al. demonstrated a logger reliability of 97.6% by evaluating five volunteers for 1-3 days[6]. Our results were similar to those of Takemitsu et al. and Havey et al., who showed that the mean difference between the data recorded by a logger and those manually recorded in a diary was 0.9%±2.2%[9]. The error in their study was less than that in our study. However, the study by Havey et al. differed from our study in that the wearing time of the brace was only 1-8 hours per day, which is shorter than the actual clinical use; in addition, their investigation was conducted using four sensors at the same time[9]. In the current study, we were able to achieve the same reliability using a single temperature logger for approximately 20 hours/day.

To investigate the reliability of the temperature logger, the subjects must accurately record the total time of brace wearing in a notebook. In this study, nurses and clerical staff involved in the treatment of scoliosis voluntarily wore the brace. Compared with the volunteer participants in previous studies[6,9,12], our participants were more credible because they understood the significance of the research better. Moreover,

the experience of the three medical staff members of a scoliosis team wearing the brace for several days might be useful for the care of future brace patients.

If the ambient temperature is almost the same as the skin temperature, the accuracy of the temperature logger decreases. In fact, in the first study, conducted in April, the reliability of the logger in the most ideal setting was 99.8%. On the other hand, in the second study, conducted in August, the mean reliability of the three participants was 97.9%±0.9%. As expected, the reliability was slightly lower in August because of the higher ambient temperature; however, the error in August was only 2.1% or 30 minutes. This error is considered to be clinically acceptable. Thus, the ambient temperature did not greatly reduce the accuracy of the logger even in the hottest month. It may be because the participants spent a lot of times indoors with air conditioning in the hottest time of summer. Compared with force-sensing loggers[9-12], temperature sensing is simple to perform, and the data easy to analyze with sufficient accuracy, and our results, which showed a high reliability of 97.9%±0.9% even during the hottest season, support the clinical use of temperature sensing loggers.

Several limitations of this study should be acknowledged. First, the number of participants in this study was small. The participants had to wear the scoliosis brace most of the day and record the exact wearing time for several days. Because this preliminary trial could be a burden to healthy participants, we did not recruit additional participants. Katz et al. also conducted a similar study in which as few as three subjects were included[7]. Second, the present study used a thoracolumbosacral brace only because this type of brace is common. Different types of braces should be evaluated in future work. Third, the present study was performed in healthy subjects only. We need to evaluate logger function for a longer period in patients with AIS in a future study.

Conclusion

This study provides objective results confirming that the placement of the temperature logger of an electronic compliance monitor at the abdominal position of the brace using a threshold temperature of 30°C was the optimal condition for evaluating brace compliance in patients with scoliosis. Under this condition, our results also demonstrated that the reliability of the temperature logger was 97.9%±0.9%. This information can be useful for scoliosis management teams, and the temperature logger of electronic compliance monitors provides a valuable clinical tool.

Conflicts of Interest: The authors declare that there are no relevant conflicts of interest.

Author Contributions: Keita Nakayama and Toshiaki Kotani wrote and prepared the manuscript, and all of the authors participated in the study design. All authors have read, reviewed, and approved the article.

Ethical Approval: No. 29-015, Institutional review board of Seirei Sakura Citizen Hospital.

Informed Consent: Informed consent was obtained from all participants in this study.

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