*Original Article*

# Validation and determination of the sensing area of the KINOTEX sensor as part of development of a new mattress with an interface pressure-sensing system

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**Summary** **The purpose of the present study was to examine the validity of the KINOTEX sensor via comparison with an existing sensor and to determine the sensing areas for a new alternating-air mattress that incorporates an interface pressure-sensing system. The study design was an evaluation study to validate and determine the sensing area of the KINOTEX sensor in comparison with another sensor. Study participants were fifty-one healthy volunteers over eighteen years of age, and the two sensors were placed between participants and an alternating-air mattress. We measured the contact area, full weight load, and maximum pressure in the calcaneal region using two sensors and obtained a graphic pressure distribution of > 40 mmHg in the lateral and supine positions. Correlation coefficients between sensors were $r = 0.88$ ($p < 0.001$) for the contact area, $r = 0.89$ ($p < 0.001$) for full weight load, and $r = 0.72$ ($p < 0.001$) at maximum pressure in the calcaneal region. Ninety-one percent of the pressure distribution was recorded in the central 50 cm of the bed, and 94.6% was recorded within an area 160 cm in length need the foot of the bed. We investigated the correlation between the KINOTEX sensor and an existing sensor and determined the necessary sensing area. Results suggested the feasibility of developing a new alternating-air mattress incorporating an interface pressure-sensing system to help prevent pressure ulcers.**

***Keywords:*** Pressure ulcer, Prevention, Mattress

## Introduction

Pressure ulcers are a common complication among the elderly and patients with spinal cord injuries or other conditions and have a significant effect on the length of hospital stay and unplanned rehospitalization (*1,2*). An ulcer is both difficult and costly to manage once it occurs, and tends to recur easily. Prevention of pressure ulcers is therefore a critical component of care in encouraging patients' rehabilitation and independence (*3*). A large-scale survey of pressure ulcers in Japan revealed a prevalence of only 3.6% in all types of hospitals (*4*). In contrast, the prevalence of pressure ulcers in the United States is reported to be 14.3-15.6% in acute-care settings (*5*) and 27.7% in long-term care facilities (*6*). Although the prevalence of pressure ulcers in Japan is relatively low, the proportion of severe pressure ulcers (stage III or IV) is high: stage III ulcers represent 22.5% of all pressure ulcers and stage IV ulcers represent 12.1% (*7*); the equivalent figures in the United States are 10% and 7%, respectively (*6*). This

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ailment has a great impact on patients' quality of life and medical costs in Japan, and the need to prevent this ailment is clear (*8,9*).

Pressure ulcers occur as a result of irreversible ischemic tissue dysfunction caused by prolonged diminishment or cessation of soft tissue perfusion between bone and the skin surface due to external forces applied to the body (*10*). Thus, the intensity and duration of external force are the most important factors in their development (*11*), and these factors are commonly controlled by the use of an alternating-air mattress (*12*). This type of commercially available mattress reduces the intensity of the normal force of the patient's body by adjusting the pressure within internal air cells according to the patient's weight and increasing the contact area with the body. It also limits the duration of that pressure via the inflation or deflation of air cells (*13,14*). However, this type of adjustment system presents some difficulties in its use with Japanese patients. Many Japanese patients have extreme bony prominences, which constitute one of the most important risk factors for pressure ulcers (*15*). The extremely high interface pressure from these prominences occurs independent of body weight and can result in severe pressure ulcers. Therefore, a method of preventing pressure ulcers based on the actual interface pressure itself is required.

A Cello (CR-270, Cape Ltd., Kanagawa, Japan) (*16*) pressure-measuring device was used to evaluate the intensity of local interface pressure at a specific point in time; however, the interface pressure changes readily with the slightest motion by the patient, and detecting how pressure is usually applied has not been possible. Inconclusive identification of the regions to which interface pressure is applied leads to situations in which the pressure is not sufficiently reduced, leading to the development, deterioration, and recurrence of pressure ulcers (*17*).

To overcome this problem, the interface pressure must be constantly monitored and regions where the critical pressure is applied for certain duration must be identified. If these steps were part of the alternating-air mattress system, the interface pressure could be successfully reduced according to the patient's position and movement, resulting in optimal efficacy for the alternating-air mattress. Considering the problems noted above, a new alternating-air mattress containing a pressure-sensing system must be developed in order to adequately control the interface pressure for the whole body.

Some currently available mattresses measure air pressure with a sensor pad; the purpose of such a system, however, is the automatic adjustment of air pressure to suit the user's weight, size, and position, rather than measurement of interface pressure intensity (*18*).

Sensors that employ various sensing principles are available: pressure-sensitive and conductive-ink film sensors, Piezo-resistive sensors, and air-pressure appreciation sensors. In pressure-sensitive and conductive-ink film sensors, the applied principle is that the electrical resistance is inversely proportional to the load of ink between the electrodes (*19,20*). This sensor is the most sensitive of all sensors but is very expensive and less versatile because of the low durability of the ink. Piezo-resistive sensors that utilize elemental devices convert stress into voltage (*21*). This sensor cannot follow curved surfaces and this causes difficulties when applied to the human body and to air mattresses. Air-pressure appreciation sensors detect air leaks from small air-filled pockets when a load is applied to the top sheet (*22*). This system is difficult to use in clinical practice because the equipment used to detect the air pressure is unwieldy. These examples indicate that the available sensors are inadequate for use in air mattresses.

With these problems in mind, the present study focused on a fiber-optic tactile sensor (KINOTEX sensor, NITTA Corp., Osaka, Japan) incorporating new sensing technology and developed an instrument to measure interface pressure over the entire body. Because the problems inherent in available sensors have been resolved in this sensor, it should enjoy clinical use. Features of the new sensing technology include envelopment, noninvasiveness, and durability. The mechanical properties of the KINOTEX sensor have already been validated in comparison to the BIG-MAT sensor, which is a sensor commonly used for research purposes. When simultaneously applying a particular pressure to the KINOTEX and BIG-MAT sensors, Pearson's product-moment correlation coefficient between the output values of the two sensors was $r$ = 0.88 ($p < 0.001$). As correlations above 0.75 indicate a very good to excellent relationship (*23*), this indicates the high degree of sensing validity for the KINOTEX sensor, despite the differences in measurement principles.

The validity of using the KINOTEX sensor with the human body must be demonstrated prior to its clinical use, and placement of the sensing points must be considered when measuring interface pressures over the whole body and in various body positions. The purpose of the present study is to investigate the validity of the KINOTEX sensor when sensing a human body and to determine the sensing areas and placement of the sensing points based on the interface pressure distribution data for the whole body in supine and lateral positions.

## Materials and Methods

### *Participants*

Healthy volunteers over the age of eighteen were recruited and informed of the research methods. Only those volunteers who understood the design, objectives, and risks of the study and who gave informed and written consent participated in the study. They were informed that participation was entirely voluntary and that data obtained from the survey would be analyzed in a depersonalized format.

*Materials*

KINOTEX is a technology that employs a new sensing principle: a change in optical properties is proportional to the extent of deformation in common polymer foam materials caused by an external influence such as pressure (Figure 1). Optical fibers are implanted in pairs. The light from a light-emitting diode is carried to the integrating cavity of a sensing point by one fiber, the light in the cavity is passed to a photodiode through another fiber, and the external force is calculated by measuring the illumination energy intensity. In the KINOTEX sensor prototype used in this study, the pitch indicating the interval between sensing points was 3.2 × 2.2 cm and sensing area was 50 × 180 cm in the center of 88 × 180 cm polymer foam that included 1,080 sensing points. Saturation sensitivity, which meant the maximum value of normal force which could be read by the sensor, was 4 N; creep, which was gradual deformation of a material under pressure, was 0.9% (120-180 sec); hysteresis, which was a lag occurring between the application and removal of a force in elastic materials, was 30%; and the sampling rate, which indicated the number of samples per second, was 1.0 Hz. The KINOTEX sensor is fabricated from urethane foam as a polymer foam material. The sensor was enclosed within a shade cover because the sensing principle utilizes a change in optical properties.

The KINOTEX sensor was evaluated in comparison to the BIG-MAT sensor. The latter is a pressure-sensitive and conductive-ink film sensor that measures the reduction of resistance for each sensor element due to loading of the element in the normal direction. The sensing principle of this sensor has been described elsewhere (*18*). Briefly, the striped matrix of row and column electrodes consist of an electrically conductive silver ink and are printed directly onto two separate polymer films. The pitch was 1.016 × 1.016 cm, the sensing area was 89.4 × 195.1 cm and included 16,896 sensing points, saturation sensitivity was 171 mmHg, creep was 1.2% (120-180 sec), hysteresis was 6.1%, and the sampling rate was 4.0 Hz.

The placement of the two sensors was considered beforehand. Basically, the BIG-MAT sensor is not suitable for curved surfaces. Therefore, the BIG-MAT was placed on the KINOTEX sensor to prevent the body from sinking too far, and the two were placed on an alternating-air mattress (TriCell, CAPE CO LTD., Kanagawa, Japan); the centers of the sensors and the mattresses were aligned.

The BIG-MAT sensor does not always measure pressure accurately, as it tends to wrinkle easily. This problem was addressed for each position of the participant by measuring the pressure distributions after wrinkles were removed. The two sensors were then equilibrated and calibrated before they were set. For all participants, the mattress was set to static mode and based on initial tests the input value of the user's weight was standardized to 30 kg to meet certain conditions and to prevent bottoming-out or saturation of the sensor.

*Protocols*

The room temperature was adjusted to 28 degrees Celsius. After the sensors were set as described above, the KINOTEX and BIG-MAT sensors were turned on. Participants were informed of the objectives and procedure of the research and gave their written consent after they entered the room. The participants wore short-sleeved T-shirts and gym shorts to standardize the measuring conditions. After verifying that each sensor was in working order, the participants were asked to lie on the sensors in the lateral position. At this time, wrinkles in the BIG-MAT sensor were removed as much as possible. Since creep could reduce the accuracy of this study, the pressure distribution data from the KINOTEX and BIG-MAT sensors were recorded and saved 2 min after the positions were stabilized; simultaneous digital photographs were taken to capture the position. Participants were then asked to lie in a different lateral position, which was captured by digital

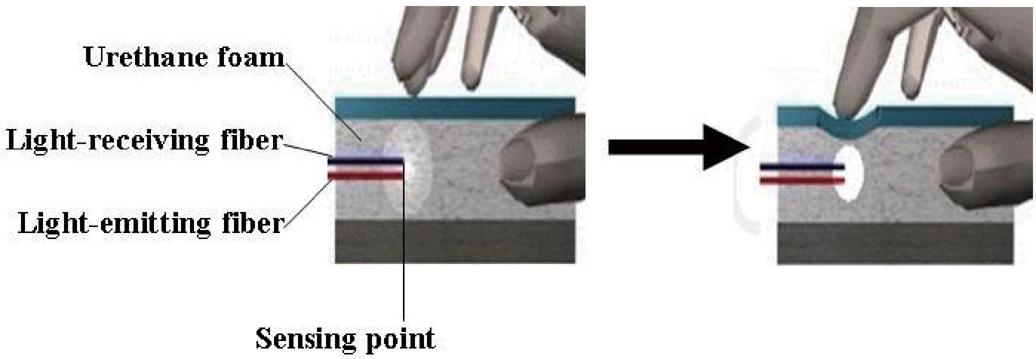


**Figure 1.** Optical properties of the KINOTEX sensor change in proportion to the extent of deformation in the common polymer foam material.

photography, and the pressure distribution data were similarly recorded. Finally, participants were asked to lie in the supine position with their hands folded on their stomach, this position was captured by digital photography, and the pressure distribution data were similarly recorded. This study was conducted between December 22, 2005 and January 17, 2006.

*Data analysis*

Pearson's product-moment correlation coefficients were calculated from the output of the sensors using the pressure distribution data from the supine position alone. A linear relationship between the output of the two sensors was sought because of the different measurement principles used by each. The items considered in the data analysis were the contact area for the sensor, full weight load, and maximum pressure at the calcaneal region. The contact area ($cm^2$) was defined as the superficial measurement of the sensing region of the sensor. Full weight load (kg) was defined as the total load in the sensing region of the sensor. Maximum pressure at the calcaneal region (mmHg) was defined as the highest individual sensor value in the region. Pressure at the calcaneal region was chosen to represent maximum pressure because (i) the calcaneal region is a common site of pressure-ulcer development; (ii) this region has the most pronounced bony prominence, even in healthy subjects; and (iii) measurement in this region is difficult because of its small contact area. As there was a relatively large difference in pitches between the two sensors, comparison of the maximum pressure at the calcaneal region involved the mean pressure for a square area; in relation to a sensing point area for the KINOTEX sensor (7.04 $cm^2$), this area consisted of nine sensing points with a center point yielded the highest pressure with the BIG-MAT sensor (9.29 $cm^2$). This method accounted for differences in area between the pitches of the two sensors.

The distribution of data measured by the BIG-MAT sensor in the lateral and supine positions was used to determine sensing areas. Pressure distribution information for the head was considered unnecessary and was excluded from analysis because pillows are placed under the head in clinical practice. The pressure distribution data for all participants and all positions were overlaid, the maximum values at each sensing point were identified, and a graphic representation of data equal to or greater than 40 mmHg (Figure 2) was created. Pressure of 40 mmHg and above is perceived to be the critical pressure for pressure ulcer development (*17*). A rectangular sensor with a longitudinal side of 192 cells, as illustrated in Figure 2, was then visualized within the 88 × 192 cells of the BIG-MAT sensing area d (BIG-MAT cell interval: 1.016 cm). This rectangle was moved by 1 cell, from a to b in Figure 2, and percentages for the number of pressure distribution points within the rectangle were plotted for all pressure distribution points (the percent coverage for the pressure distribution area) at each point. This analysis was repeated for 30, 40, 50, 60, and 70 cells from the transverse side, and the maximum percent coverage for the pressure distribution area in each rectangle was plotted; the best transverse length and sensor location were determined according to the result. To determine the longitudinal dimension, rectangular sensors with a transverse side of 88 cells and longitudinal side of 30-160 cells were visualized, and the percent coverage when moving the rectangles from a to c in Figure 2 and the maximum percent coverage for each rectangle were plotted.

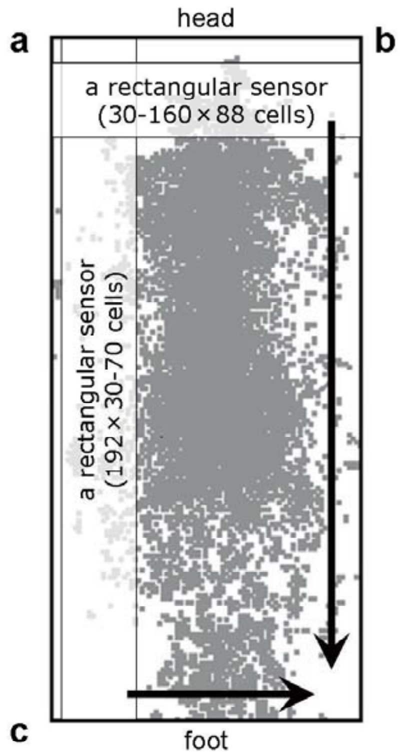


**Figure 2.** Rectangular sensors are visualized to calculate the percent coverage of the pressure distribution area.

All statistical analyses were performed using Statistical Analysis System ver. 9.1 (SAS Institute Inc, Cary, NC, USA). $P < 0.05$ was considered statistically significant.

## Results

*Participant characteristics*

Table 1 shows the demographic data for study participants. Twenty-seven (52.9%) of the 51 participants were female. The mean age ± SD of all participants was 34.4 ± 10.1 years. Body Mass Index (BMI), which indicates relative weight for height, was normal (BMI: 18.5-24.9) in forty-one (80.4%) participants according to the Classification of Overweight and Obesity by BMI (*24*). Three

**Table 1.** Participant characteristics ($n = 51$)

| | |
|---|---|
| Sex: *n* (%) | |
| Male: | 24 (47.1) |
| Female: | 27 (52.9) |
| Age: mean ± SD (y) | 34.4 ± 10.1 |
| Height: mean ± SD (cm) | 164.5 ± 8.7 |
| Weight: mean ± SD (kg) | 57.4 ± 10.4 |
| BMI: *n* (%) | |
| ≤ 18.4 | 7 (13.7) |
| 18.5 - 24.9 | 41 (80.4) |
| 25.0 ≤ | 3 (5.9) |

Abbreviations: SD, standard deviation; BMI, body mass index.

participants classified as overweight (BMI ≥ 25.0) were male and none of the participants were classified as obese (BMI ≥ 30.0).

*Validity of KINOTEX sensor*

Pearson's product-moment correlation coefficients between the KINOTEX and BIG-MAT sensors were $r = 0.88$ ($p < 0.001$) for the contact area, $r = 0.89$ ($p < 0.001$) for the full weight load, and $r = 0.72$ ($p < 0.001$) for maximum pressure at the calcaneal region (Figures 3, 4, and 5). Correlation coefficients of 0.50-0.75 indicate a good relationship, while those above 0.75 indicate a very good to excellent relationship (*23*); all three of the coefficients obtained in the present study met this criterion.

*Determination of the sensing area*

Figure 6 presents the pressure distribution for values equal to or greater than 40 mmHg, as obtained from the maximum pressure distribution data for all participants and all positions. Figure 7 shows the maximum percent coverage of the pressure distribution area with respect to changes in the transverse length of the rectangular sensor. These values occurred when the rectangle was positioned in the approximate center of the BIG-MAT sensor for all transverse lengths. The maximum percent coverage of the pressure distribution area with respect to changes in the longitudinal length of the rectangular sensor is shown in Figure 8. Wide variations in pressure distribution were recorded in the foot region in comparison to other areas.

## Discussion

The clinical validity of the KINOTEX sensor was assessed by comparing it to an existing sensor and by taking the sensing area into consideration. The results provide a solid foundation for the development of a new air mattress that contains a pressure-sensing system and that contributes to the prevention of pressure ulcers in clinical settings.

*Validity test for the KINOTEX sensor*

This study compared the output of the KINOTEX

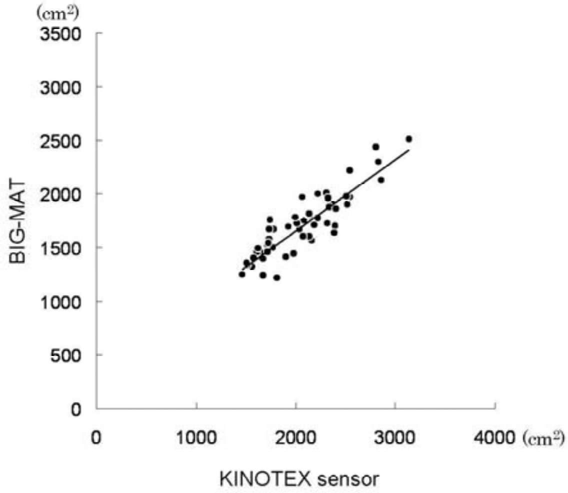


**Figure 3.** Correlation coefficients for contact areas.

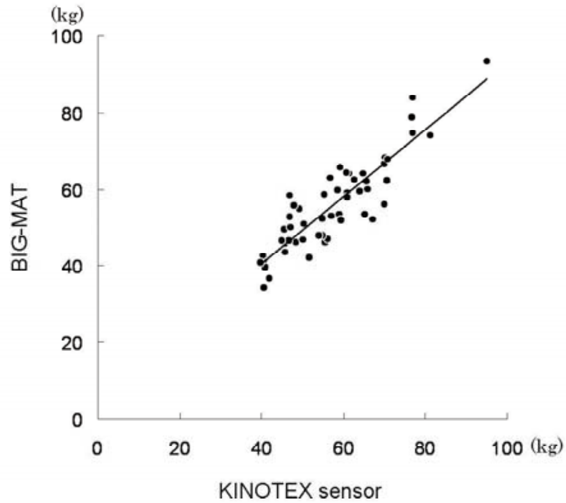


**Figure 4.** Correlation coefficients for a full weight load.

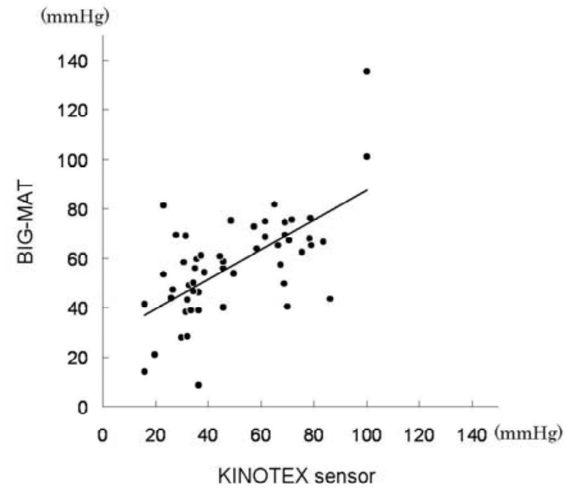


**Figure 5.** Correlation coefficients for maximum pressure at the calcaneal region.

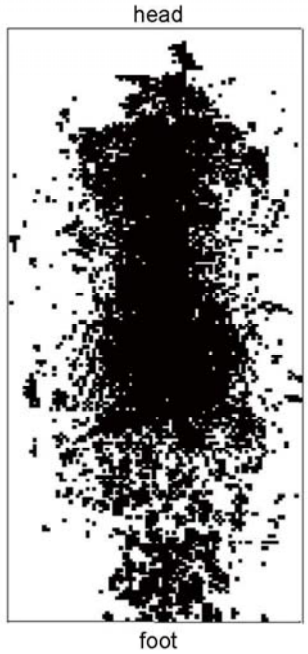


**Figure 6.** Pressure distribution of over 40 mmHg, obtained from the maximum values of pressure distribution data for all participants and all positions.

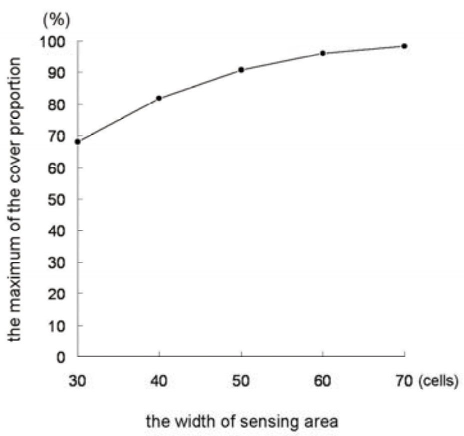


**Figure 7.** Maximum percent coverage of the pressure distribution area in each rectangle when the transverse side is changed.

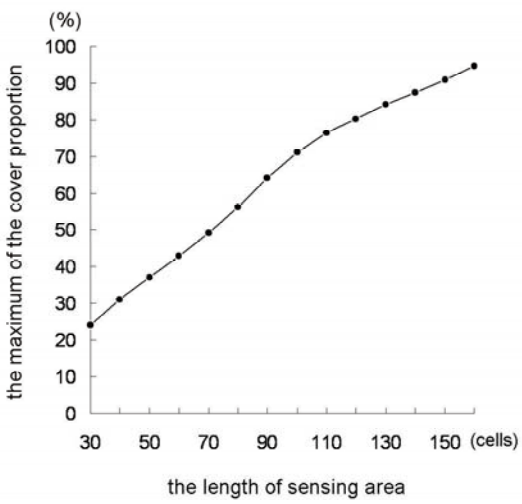


**Figure 8.** Maximum percent coverage of the pressure distribution area for each rectangle when the longitudinal side is changed.

and BIG-MAT sensors and used Pearson's product-moment correlation coefficients to test the validity of a new instrument that measures interface pressures for human patients. The BIG-MAT sensor is one of the most accurate and reliable devices for pressure-sensing (*25,26*). In preliminary analysis, Pearson's product-moment correlation coefficient between the full weight load measured by the BIG-MAT sensor and the participants' weight was $r = 0.88$ ($p < 0.001$, data not shown); the output of this sensor was therefore considered accurate.

The results of this study indicate a good to excellent correlation between the output values for the contact area, full weight load, and maximum pressure at the calcaneal region and similar values obtained with existing high-sensitivity pressure mapping sensors. This demonstrates the validity of the KINOTEX sensor as an instrument for interface-pressure measurement. Although the measurement of pressure at bony prominences is difficult due to the small contact area, which can easily fall between sensing points, good results were obtained for maximum pressure at the calcaneal region; this suggests the clinical usefulness of the KINOTEX sensor. However, other conditions such as a smaller contact area and a higher pressure than saturation sensitivity should be considered in order to accommodate various body sizes and positions.

The correlation coefficient was also used to compare the two sensors with differing measurement principles. While a strong correlation was shown, the slope of the line was relatively low for maximum pressure at the calcaneal region. A conversion factor is therefore needed to map one to the other.

*Determination of the sensing area*

Ideally, sensing points would be placed throughout an air mattress; however, it is uneconomical to place sensors in areas where interface pressure is applied less intensely. Thus, the sensing area must be limited to enable efficient use of the sensors. The measurement results for the BIG-MAT sensor in the lateral and supine position suggest that a width of 50 cm in the center of a bed is sufficient for the transverse side of the sensing area, taking the whole body and each position into consideration. In this study, 90% of the pressure distribution equal to or greater than 40 mmHg occurred in the 50 BIG-MAT cells (= 50.8 cm), and the percent coverage of the pressure distribution area increased insignificantly, even when the width exceeded 50 cells (Figure 7). The longitudinal side of the sensing area should cover the entire area except the 30-cm head region. Results demonstrated that the percent coverage increased significantly as the length increased (Figure 8) and that the pressure distribution results for the calcaneal region varied widely compared with those for other areas (Figure 6). This variation in the calcaneal region could reflect the fact that different participants' heels were placed at different locations for each body position. A larger sensing area at the foot of the bed is needed in order to monitor pressure at the calcaneal region, which is one of the most common and important sites of pressure ulcer development. A longitudinal sensing area 160 cm in length is recommended, and no sensors should be located in the head region.

This determination enabled the distribution of sensing points to be restricted to 47.3% of the BIG-MAT sensing area (88 × 192 cm).

*Clinical use of the KINOTEX sensor*

The current study found the KINOTEX sensor to be valid for monitoring interface pressure over the whole body. This is a new approach that has not previously been attempted in clinical settings. Reflecting the current sensing area results when using the KINOTEX sensor will facilitate more efficient monitoring.

The KINOTEX system enables the simplification of nursing care and improved education for patients and family members regarding pressure-ulcer prevention. This is because pressure values can be presented graphically and the pressure distribution can be displayed in color on-screen.

KINOTEX sensors may be incorporated into alternating-air mattresses in the future. However, reducing the thickness of the urethane foam, 10 mm in the current KINOTEX sensor, should help to increase its efficacy as a clinical tool. Its clinical durability and economic efficiency must also be examined in comparison to the standard protocols for the prevention and management of pressure ulcers.

The present results may be generally applicable for certain individuals like, for example, patients whose physical attributes are close to the standard Japanese attributes and for inpatients in acute care settings. This study did not include physical attributes that are unique to the elderly in Japan or those from other countries. The elderly in Japan are at very high risk of developing pressure-ulcer because of problems concerning weight loss, bony prominences, and joint contracture. An additional point to note is that there are fewer obese patients in Japan. Further research is needed regarding sensing areas and pitch before KINOTEX sensors can be used with every patient.

The present study was conducted to test the static criteria of the KINOTEX sensor; further studies are needed to evaluate dynamic criteria for its use in clinical settings.

## Conclusions

The current study investigated the correlation between the KINOTEX sensor and an existing sensor and evaluated the sensing area of the KINOTEX sensor. Results demonstrated that the KINOTEX sensor is a valid an instrument for measuring interface pressure in healthy volunteers. The sensing area of the KINOTEX sensor required a width of 50 cm in the central area and a length of 160 cm, excluding the head region, to measure interface pressures for the whole body. The results of this study suggest that new air mattresses incorporating this pressure-monitoring sensor are feasible. Such mattresses would help to prevent pressure-ulcers.

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