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Measurement System for the Clothing Pressure of a Spinal Orthosis using Multiple Pressure Sensors

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Abstract. A spinal orthosis is used for rehabilitation after vertebral fractures. However, a spinal orthosis can cause discomfort to a patient because of clothing pressure during activities of daily living (ADLs). It is therefore necessary to quantitatively evaluate the clothing pressure and to develop a new design of spinal orthosis that decreases discomfort. We developed a system to measure clothing pressure using multiple pressure sensors. Furthermore, we studied the clothing pressure from the spinal orthosis using the proposed measurement system during a picking-up motion, which is one of the ADLs, under two different wearing conditions. The results showed that the measurement system can quantify the changes in pressure over time in different areas and under different wearing conditions during a picking-up motion. The results suggest that this system could be used to evaluate the differences in clothing pressure exerted by the spinal orthosis during ADLs under different wearing conditions.

1. Introduction

The prevalence of osteoporosis and related vertebral fractures has increased rapidly as a result of the aging population [1,2]. The loss of height resulting from vertebral compression fractures may lead to spinal deformities such as kyphotic alignment [3]. Hyperkyphotic alignment can cause new fractures as a result of stress on the anterior spinal column, and patients with hyperkyphotic alignment tend to lose body balance and thus have an increased risk of fractures related to falling [3]. Therefore, it is necessary to reduce spinal deformity and flexion for patients with osteoporotic vertebral fractures.

A spinal orthosis is commonly used for rehabilitation and symptomatic management after vertebral fractures [3]. A spinal orthosis maintains spinal alignment and limits flexion, thus reducing the load on the fractured vertebra [3]. Furthermore, a spinal orthosis also reduces fatigue and spasms of the paraspinal muscles [3,4]. Previous studies found that a spinal orthosis strengthened trunk muscles and improved posture for the treatment duration, and its use may result in an improved quality of life for the patient and enhanced ability to carry out the activities of daily living (ADLs) [3,5,6]. However, the clothing pressure from a spinal orthosis can be uncomfortable for a patient, which can lead to decreased compliance [3]. In addition, elderly patients are at risk for skin breakdown if the edges of the orthosis are not carefully padded, and their respiratory volume can be limited by excessive clothing pressure

[3]. It has been found that discomfort can be decreased by reducing the clothing pressure [7–9]. Therefore, we believe it is necessary to propose a new design and wearing method for spinal orthoses to decrease discomfort.

Previous studies have considered a lighter and softer orthosis [3,10]. Kato et al. found that there are no significant differences in the therapeutic effect for vertebral fractures between a rigid orthosis and a soft orthosis, but this study did not evaluate clothing pressure [10]. Katae et al. proposed using a new material and shape for the flank parts of the spinal orthosis based on quantitative evaluation of clothing pressure [11]. They investigated the relationship between bending load and the deformation of the flank parts and found that polycarbonate flank parts, which are easy to deform, can reduce clothing pressure in the experiment without examining the actual wearing condition [11]. Katae et al. also found that a spinal orthosis using polycarbonate flank parts rather than metal bar parts improved comfort while retaining therapeutic ability [12]. Although the reduction of clothing pressure has been attempted in these previous studies, they did not quantitatively and dynamically evaluate the clothing pressure on the human body in actual wearing conditions. It is considered that dynamic and quantitative evaluation of clothing pressure during actual ADLs is necessary for the development of a novel spinal orthosis that can further reduce clothing pressure.

In previous studies, clothing pressure was evaluated by indirect measurements such as simulation and theoretical calculation or by direct measurement [7]. In the research of Wu and Li [7], finite element analysis (FEA) and computer-aided engineering were used to simulate the stress and strain related to clothing pressure [7,13]. However, optical and CT scans are required for building the FEA model with high accuracy. Moreover, it is difficult to dynamically evaluate the clothing pressure of the participant in this way due to the physical restrictions during measurement and the potentially negative effect of the X-rays from a CT scanner on humans [7]. Therefore, it is considered that indirect methods are not suitable for dynamic measurement of clothing pressure during the actual ADLs. Direct measurements of clothing pressure have been performed using a fluid measurement system or piezoresistive-type pressure sensors [7]. However, a fluid measurement system is not suited to dynamic measurement, because it is based on Pascal's principle for considering the pressure of a stationary fluid, but the fluid is subject to temperature drift from body heat. Piezoresistive-type pressure sensors such as the FlexiForce sensor are very thin and have high sensitivity. They are therefore more suitable for evaluating the pressure of almost all curvature points on the human body than a fluid measurement system [7,14]. From these factors, it is considered that a measurement system using piezoresistive-type pressure sensors is most suitable for evaluation of the clothing pressure from a spinal orthosis during ADLs.

In this study, we developed a clothing pressure measurement system that quantitatively evaluates the clothing pressure from a spinal orthosis using multiple pressure sensors. In addition, in order to evaluate the developed measurement system, we compared the clothing pressure during a picking-up motion, which is one of the ADLs [15,16], with the results of simulations of clothing pressure in previous studies. We also investigated the clothing pressure from the spinal orthosis under different wearing conditions to see if this may help in the development of new designs and wearing methods in the future.

The rest of this paper is organized as follows. Section 2 introduces the developed clothing pressure measurement system for a spinal orthosis. Section 3 describes the experimental procedures that were conducted to evaluate the clothing pressure from the spinal orthosis during a picking-up motion with different chest belt conditions. Section 4 presents the experimental results and discussions. Finally, Section 5 presents the conclusions of this study and suggestions for future research.

2. Proposed System

Figure 1 shows an overview of our measurement system. This system consists of (A) a data logger (LP-WS1311, Logical Product, Japan), (B) an amplifier circuit for the pressure sensors (FlexiForce adapter 1120, Phidgets Inc., Canada), and (C) pressure sensors (FlexiForce, Tekscan, USA), which are mounted on the spinal orthosis. The data logger was used to store the voltage obtained from the pressure sensors via the amplifier circuit. Since the data logger was controlled wirelessly from a computer, clothing pressure was measured without restraining the user. Because it has a thin construction and flexibility, the FlexiForce sensor can be used to measure the force from various different orthosis surfaces [14]. However, such pressure sensors tend to sink into the skin where the subcutaneous fat is thick. There is thus a possibility that clothing pressures may not be measured accurately. Furthermore, when the contact area increases, the pressure is dispersed and is difficult to measure accurately [17,18]. For these reasons, the FlexiForce sensors in our proposed system are attached using a circular plastic film with a diameter of 30 mm to eliminate sensor sinking and spreading of the contact area. This film diameter was decided on by a previous study related to clothing pressure measurement [19].

Before the experiment, a dynamically changing pressure was manually applied simultaneously to the FlexiForce and an industrial load cell (Toyo Sokki, Japan) for calibration. In this calibration, the relational equations between the voltage data from the pressure sensor via the amplifier circuit and the force data obtained from the industrial load cell were calculated by linear regression. Figure 2 shows the pressure sensor placement in the measurement system. In this system, 16 pressure sensors were attached to the chest pad, back pad, axillary bar, abdominal girdle, and axillary girdle of a spinal orthosis (Figure 2). Positions A, C, and E were chosen because it was considered that the clothing pressure at these parts will be significant as a result of the three-point fixation principle [6,20] employed by common spinal orthoses. In addition, pressure sensors were also placed at position D because previous studies have shown that reducing clothing pressure at the axillary girdle improves comfort [11]. Furthermore, because clothing pressure from the edges of the device is related to skin destruction [3], the pressure at position B was also measured. The number of pressure sensors and the initial pressures differ depending on the sensor position on the orthosis, and the clothing pressures were normalized by the number of sensors and the initial pressure at each sensor position.

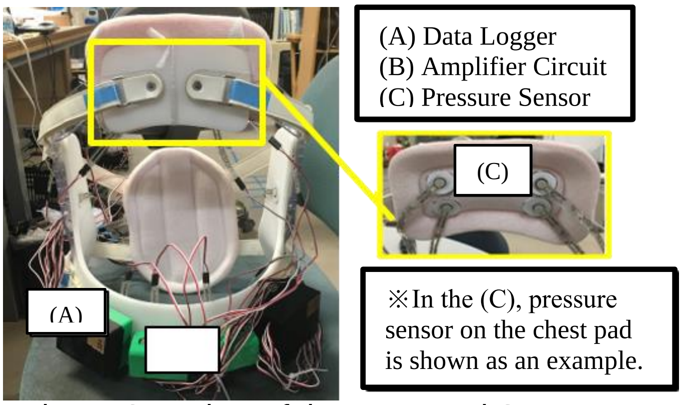

Fig. 1. Overview of the Proposed System

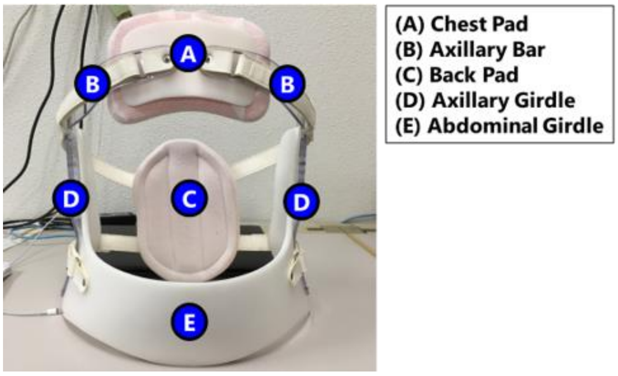

Fig. 2. Pressure Sensor Placement in the Proposed System

3. Experiment

The participant was a young healthy male (age, 24 years; body height, 169 cm; and body weight, 67 kg). The spinal orthosis for the participant was adjusted for size and fitting by one of the authors of this paper, who is an experienced orthotist. The participant received a description of this study and signed a written, informed consent form before participating. All experimental procedures were approved by the Ethics Committee for Human Research of the Graduate School of Life Science and Systems Engineering, Kyushu Institute of Technology (approval number: 19-11).

In this experiment, the participant was asked to pick something up from the floor. The reason a picking-up motion was selected was that this is one of the ADLs that is particularly restricted for an osteoporotic vertebral fracture patient who uses a spinal orthosis [16]. Figure 3 shows the picking-up motion for this experiment. In this motion, the initial posture was static standing, and a sponge ball of 70 mm diameter (26 g) was placed 300 mm forward from the center point between the toes, which was then picked up before resuming a standing posture; this was defined as the picking-up motion. The participant performed the picking-up motion 10 times using the left hand, which was the dominant hand. The participant performed this picking-up motion in two chest belt conditions (“Standard” and “Loose”). Figure 4 shows the two chest belt conditions for this experiment. In the “Standard” condition, the belt length was adjusted by the orthotist to the normal tension used to treat fractures. In the “Loose” condition, the length of both the left and right chest belts was 10 mm longer than that in the “Standard” condition. The participant performed the picking-up motion 10 times for each chest belt condition.

The data sampling rate was set to 100 Hz, and the data logger was controlled to start and stop recording wirelessly using LabVIEW-based (National Instruments, USA) software (LP-WSD009-0A, Logical Product, Japan). After collection, the voltage data from the data logger were saved to the computer via a USB connection and were converted to pressure data by the equations obtained from calibration. An average pressure was calculated using data from all sequences as representative values of the clothing pressure in each trial. In addition, the average values for each sensor position of the spinal orthosis and each chest belt condition were calculated by clothing pressure data obtained from 10 trials. This signal processing was performed using Matlab R2018 (Mathworks Inc., USA). The differences in clothing pressures between sensor positions of the spinal orthosis were analyzed statistically using the Kruskal–Wallis test and the Bonferroni method (significance level $p < 0.05$). In addition, differences in clothing pressures between chest belt conditions were analyzed by the Wilcoxon signed-rank test (significance level $p < 0.05$). These statistical analyses were performed using EZR [21].

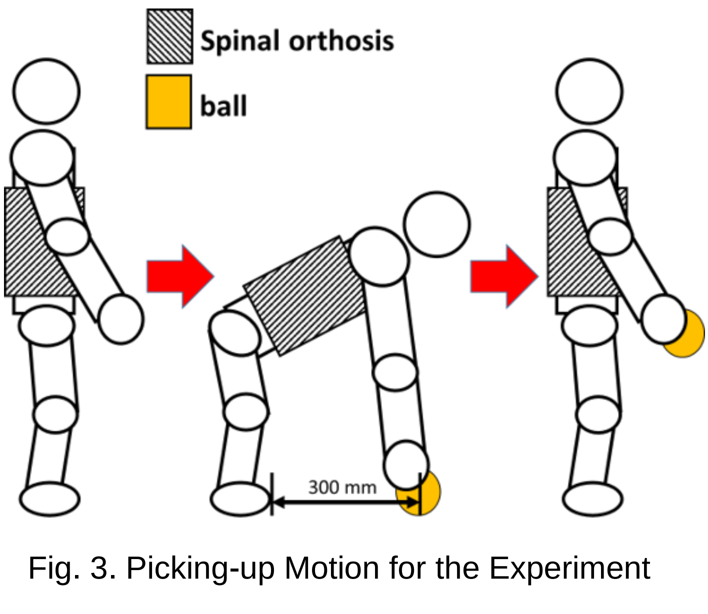

Fig. 3. Picking-up Motion for the Experiment

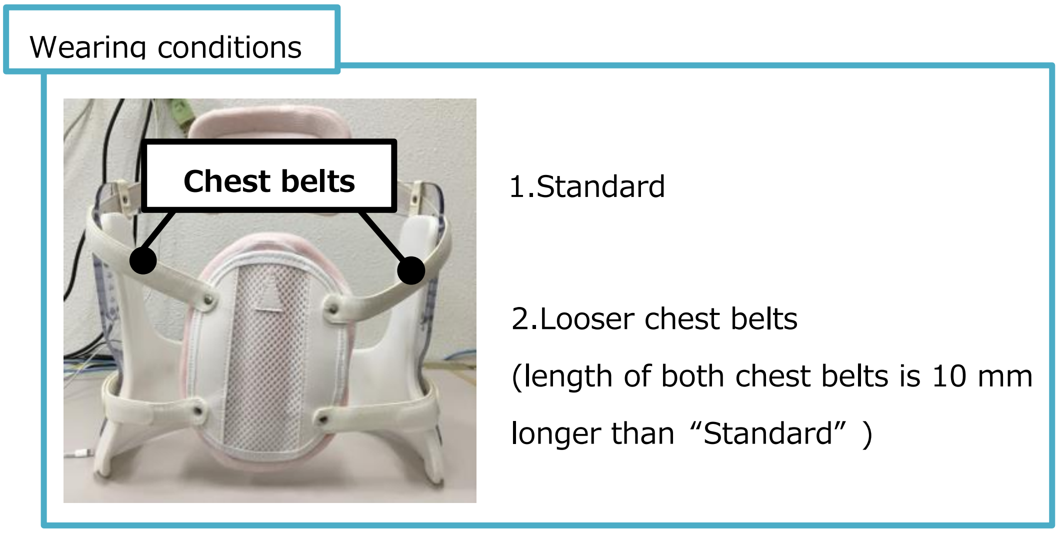

Fig. 4. Wearing Conditions

4. Results and Discussions

Figure 5 shows an example of temporal waveforms of clothing pressure that were obtained during a picking-up motion. It can be seen that the clothing pressure on the axillary girdles in particular increases from the trunk flexion/extension during the start and return of the picking-up motion. In addition, these results suggest that the clothing pressure on the back pad increases with the picking-up motion. These trends are similar to the computational simulation results from a previous study [22]. Thus, it is considered that the proposed system could be used to measure the time trends in clothing pressure.

From this result, it is considered that in new spinal orthoses it may be possible to fix the trunk when in the standing position and to have a mechanism that deforms the abdomen part when a large bending motion is required.

Figure 6 shows a statistical comparison of the average clothing pressures calculated from the waveforms recorded at different parts of the spinal orthosis. It can be seen that the clothing pressures at the back pad, left axillary girdle, and right axillary girdle were significantly higher than those at the rest of the parts. This orthosis limits the flexion movement of the trunk based on the principle of a three-point pressure loading system [6,20]. When the trunk is bent, force is applied to the chest pad, abdominal girdle, and back pad, and this force is applied in the direction the trunk extends. Therefore, it is considered that the reason the clothing pressure on the back pad was large was that the force was applied to only one point on the back pad, as compared with two points on the chest pad and abdominal girdle. This trend was the same for both the standard and looser chest belt configurations. In addition, the differences and trends in clothing pressures between each part measured by the proposed system are similar to the results of previous studies using computer simulations [22]. The congruent relationship with previous computer simulations indicates the possibility that the proposed method could accurately measure the clothing pressure at each point.

This result indicates it is necessary to reduce the clothing pressure on the back pad regardless of the wearing condition. One way to achieve this would be to widen the size of the back pad to distribute the pressure and therefore reduce the clothing pressure. In addition, it is considered that putting a pad on the abdomen could reduce the clothing pressure at the axillary girdle. These results suggest that the proposed system could be used to compare clothing pressures between parts of the orthosis for statistical analysis.

Figure 7 shows a statistical comparison of average clothing pressures calculated from the time waveforms between two wearing conditions of the spinal orthosis. This shows that the clothing pressures of the “Loose” condition were significantly lower than that of the “Standard” condition at all parts. This is likely to be a result of the “Loose” condition leading to clearances between the body and the spinal orthosis. This relationship is similar to the results of a previous study that evaluated static clothing pressures related to clearances between the body and a belt [20]. Thus, it is considered a possibility that the proposed system could evaluate the differences in clothing pressure during a picking-up motion under different wearing conditions. In addition, this indicates that the wearing comfort of the spinal orthosis could be improved by implementing a function to loosen the chest belt only during a picking-up motion. Differences in clothing pressure at the abdominal girdle between the two wearing conditions were smaller than those at other parts. The reason for this is considered to be that the “Loose” condition only affected the chest belt, which is far from the abdominal girdle.

These experimental results show the possibility that the proposed system could evaluate time-varying differences in pressure at different points of the spinal orthosis and under different wearing conditions. However, this study has potential limitations. It focuses on only one ADL with a single healthy male participant. Future work should evaluate the performance and ability of the proposed system in actual patients and with several other ADLs over a more extended period in real-life scenarios. We hope to be able to propose new wearing methods and designs for spinal orthoses by examining the relationship between clothing pressure and several ADLs using data obtained from the proposed measurement system. In addition, the proposed system could also be applied to a monitoring system to obtain a variety of information related to the compliance and comfort of patients using a spinal orthosis.

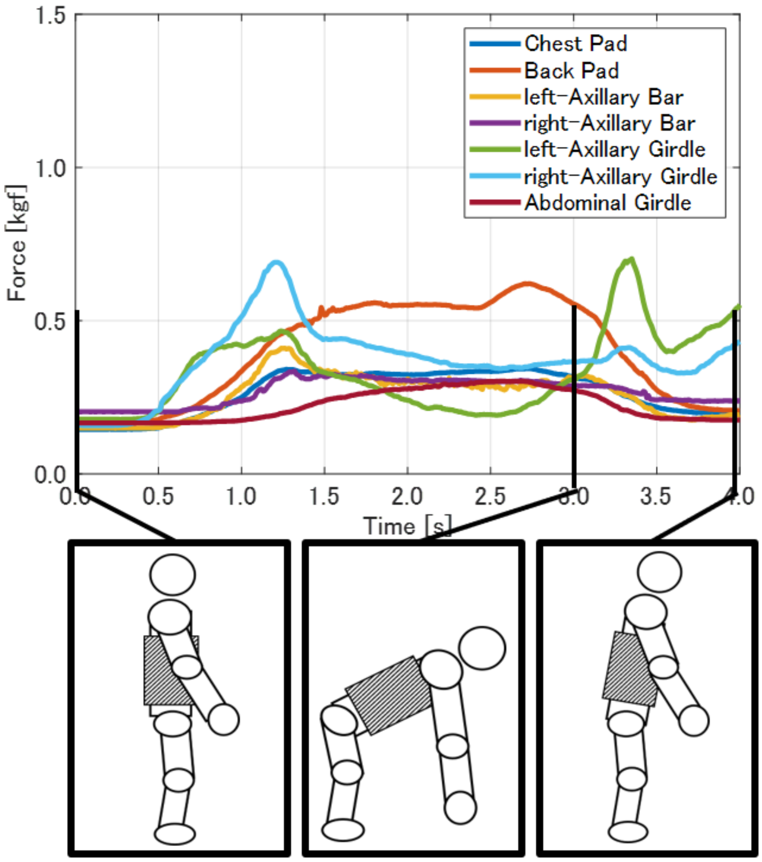

Fig. 5. Examples of Time Waveforms of Clothing Pressure

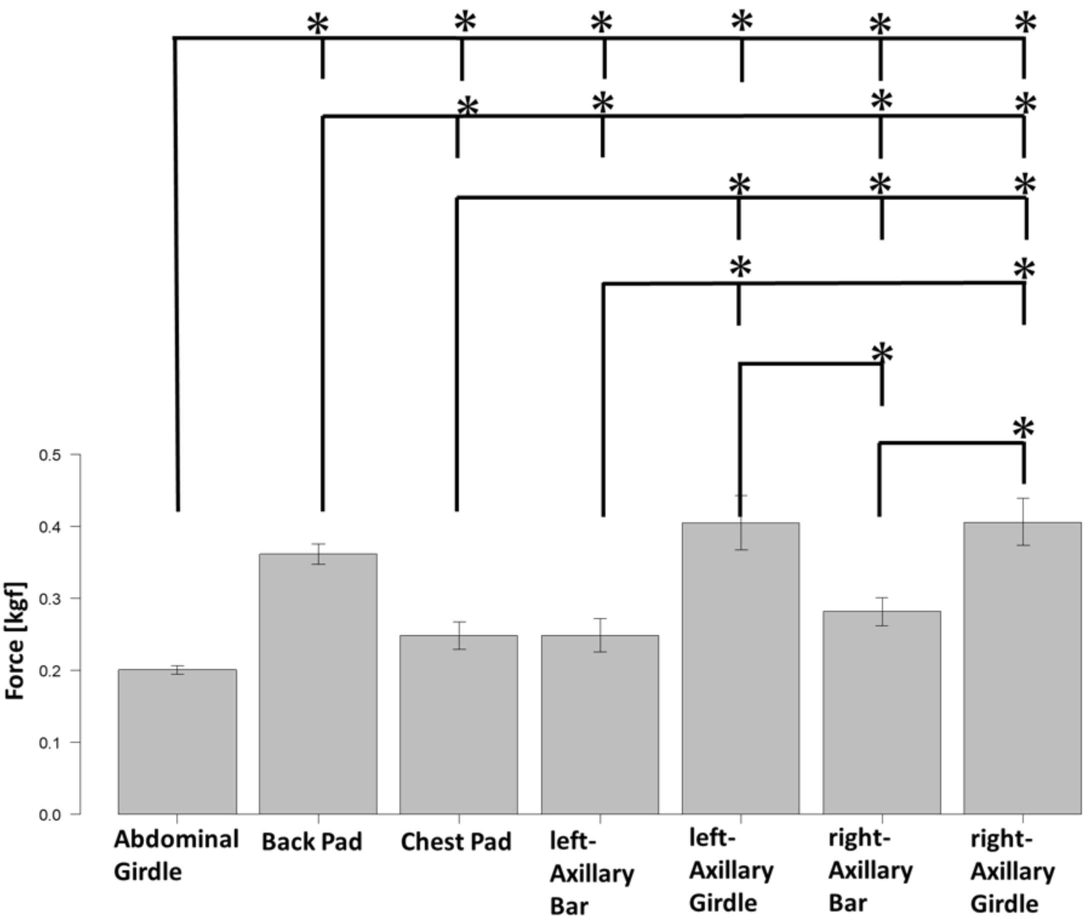

Fig. 6. Comparison of Clothing Pressures between Parts of the Spinal Orthosis (*significant difference: $p < 0.05$)

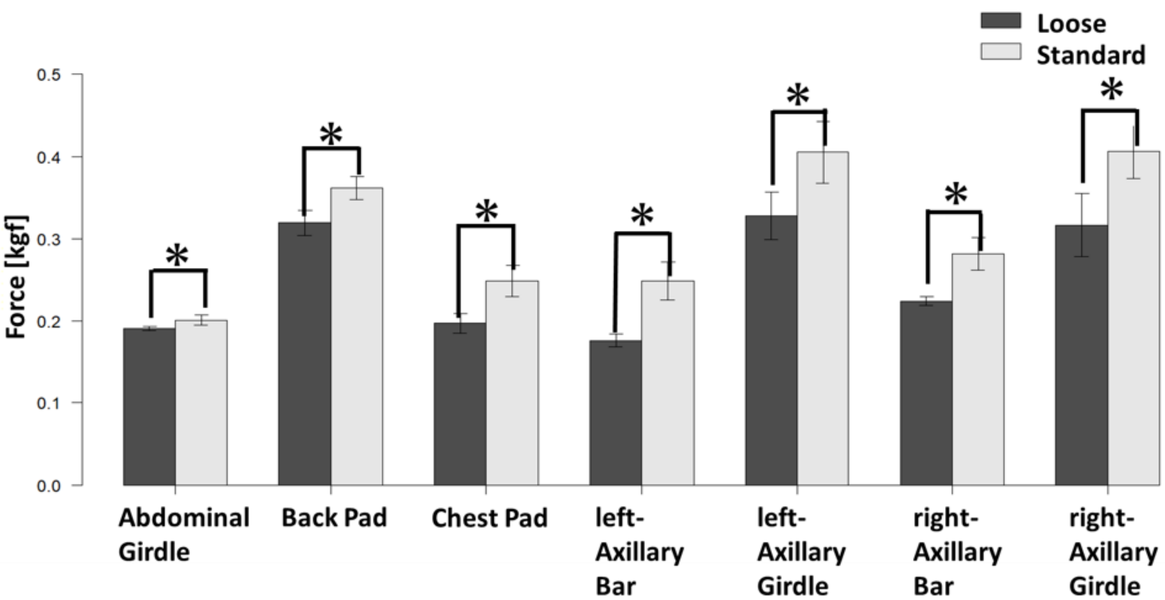

Fig. 7. Comparison of Clothing Pressures between Chest Belt Conditions (*significant difference: $p < 0.05$)

5. Conclusions

In this study, we proposed a clothing pressure measurement system using multiple pressure sensors with the aim of proposing new designs and wearing methods for spinal orthoses to increase comfort. In the experiments, we measured the clothing pressure of the spinal orthosis during a picking-up motion, which is an ADL. The results showed that the proposed system can measure time-varying pressure differences at different points and under different wearing conditions during a picking-up motion. These results suggest that the proposed system is useful for investigating new designs and wearing methods for spinal orthoses to improve comfort. In future research, several ADLs should be evaluated by the proposed system, and its feasibility for use in actual patients over an extended period during real-life activities should be examined. Finally, we intend to propose new wearing methods and designs for spinal orthoses by examining the relationship between clothing pressure and several ADLs using data obtained from the proposed measurement system.

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