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An in-shoe device to measure plantar pressure during daily human activity

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ABSTRACT

In this work, we report the development of a novel device, integrated into a shoe, to monitor plantar pressure under real-life conditions by reducing the spatial and temporal resolution. The device consists of a shoe insole with seven pressure-sensitive conductive rubber sensors and a wireless data transmission unit incorporated into a smaller measurement unit. One advantage of this approach is that the mass and volume of the measurement unit are less than 1/10th and 1/50th, respectively, of that reported for other devices. A comparison experiment was conducted for validation of the device using the F-scan system, and the initial test of the device was conducted by recording unobstructed gaits of one young adult subject and two elderly subjects. Each subject performed a straight, level walking trial at a comfortable speed for 7 m without any assistive device while wearing the in-shoe device. Changes in the plantar pressure during gait were recorded. Compared with the young subject, the pressure under the heel of the elderly subject was found to be smaller and less steep. This in-shoe device can be used to monitor plantar pressure during daily living and is expected to be useful in various clinical applications.

1. Introduction

To date, a number of devices have been developed to measure plantar pressure. However, there are significant variations in the data acquisition systems, such as the type of pressure sensors and the number and arrangement of the sensors used in these devices. A number of existing devices, such as the F-scan system and the Pedar Mobile system, measure plantar pressure via a thin sheet of matrix pressure sensors. These devices have been used in dynamic applications that require high-resolution pressure measurements in specific settings [1]. For example, using the F-scan system, Han et al. [2] quantified the path of the centre of pressure, and Brown et al. [3] evaluated the efficacy of pressure redistribution for various foot orthoses. Similarly, using the Pedar Mobile system, Hessert et al. [4] evaluated foot pressure distribution during walking in young and old adults, and Mizelle et al. [5] measured the centre of pressure of stroke patients. Although these devices have contributed to the basic analysis of human gait, some limitations have been noted from a therapeutic viewpoint. In particular, they are not designed for daily, real-time, and/or feedback use in therapy-directed research.

The design and usability of currently available systems can also be a limitation due to the placement of device components. The data-recording device is regularly positioned on the subject's hip using a belt with wires running the length of the leg, to connect the foot sensors to the data recording unit [1]. The systems also have a limited operating time (25 min to 6 h) depending on the device's and/or PC's data memory. Finally, they are relatively expensive [1]. Because of these limitations, current systems have not been widely used for daily monitoring of gait dysfunction. Simpler, low-cost devices to measure plantar pressure have been proposed with compromised specifications, including temporal and spatial resolutions.

To provide ease of use, Hermie et al. [6] developed an insole device equipped with eight pressure sensors that could be attached and removed from the subject's own shoes. Using this device, the gait patterns in three patients with different diagnostics were measured and the features of gait were analysed. The eight sensors were arranged to cover the entire shoe insole; two sensors were located on each the great toe and the heel, and the remaining four sensors were equally spaced on the insole. Pressure data was recorded at a sampling rate of 50 Hz and stored on a wired desktop personal computer. Thus, use of the device was limited to indoor environments.

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Focusing on cost-effectiveness, portability and long-term data recording potential, Wersch et al. [7] developed a device that was equipped with seven conductive polymer pressure sensors. This inexpensive sensor is thin and flexible and does not interfere with natural human gait. The device was portable and had a longer continuous operation time (8 h), and data were stored in a data recorder. However, this device was limited by the size (200 mm × 180 mm × 70 mm) and mass (800 g) of the data recorder, which needed to be placed in a backpack on the subject.

Meanwhile, to improve the size, comfort, usability and portability, Authier et al. [8] developed a shoe device equipped with four load sensors that used a wireless data acquisition system to collect force data. The wireless device was capable of continuous data acquisition and recording for 7.5 h. However, a belt around the ankle was still used to connect the foot sensors to the wireless transmitter, in order to record data.

Research in this field is still ongoing, because current plantar pressure measurement systems for daily use have limitations in terms of usability and features, such as the size and mass and the limited recording time. To achieve more widespread use, smaller/lighter weight recording devices with longer recording time are needed. Additionally, for greater convenience, the device should be wireless and the method of fixing the data recorder on the subject should be comfortable and have an unobtrusive appearance. Therefore, we have developed a novel device to overcome the previously discussed limitations of earlier devices, by incorporating the data transmission unit in a smaller plantar pressure measurement unit integrated into a shoe. This device was used to monitor plantar pressure under real-life situations, albeit by reducing the spatial and temporal resolution. The measurement unit is 15 mm × 25 mm × 8.5 mm in size, with a mass of 12 g, excluding the power source. Compared with previously discussed devices, this novel device is smaller and lighter. Also, because the pressure sensors are fixed on the shoe insole, the device can be inserted into the subject's own shoes. Thus, the user wears one's own shoe, which is comfortable and does not interfere with the natural gait. Furthermore, the device is energy efficient and can record for more than 20 h. A comparison study was conducted to validate the device using the F-scan system, and the initial tests of the device were conducted by recording the unobstructed gaits of one young subject and two elderly subjects. We believe that the device is suitable for daily monitoring of plantar pressures.

2. Device design

2.1. Pressure sensor and calibration

Fig. 1 shows the pressure-sensitive conductive rubber sensor (PSCR sensor, Yokohama Image System Co., Ltd., Japan) used to measure plantar pressure. Because the sensor is small, flexible and thin, the user's natural gait is not affected. The external size of the sensor is 15 mm × 10 mm × 0.8 mm, and the pressure-sensitive area of conductive rubber is a 7-mm-diameter circle. Pressure was measured based on the principle that the electrical resistance of the conductive rubber decreases when pressure is applied.

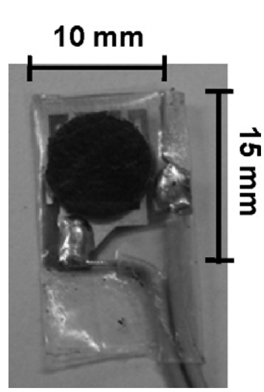

Fig. 1. A pressure-sensitive conductive rubber sensor (PSCR sensor) that was used to measure plantar pressure.

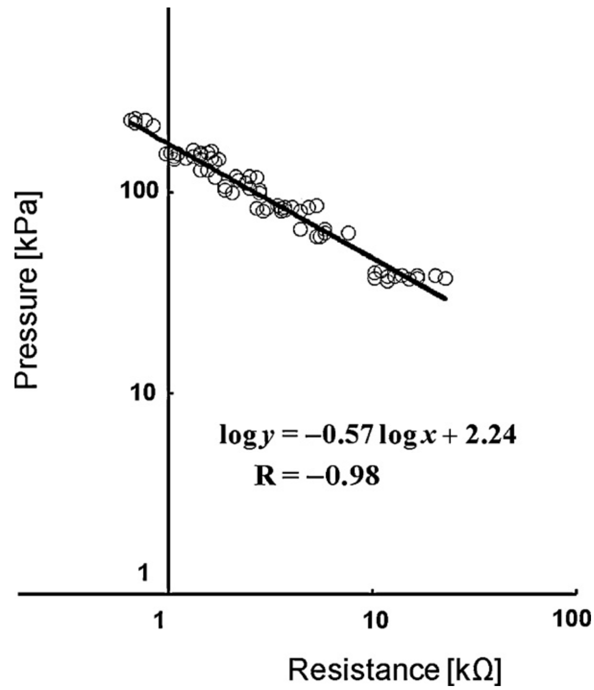

Fig. 2. The relationship between pressure and rubber resistance.

The PSCR sensor was calibrated as follows: the PSCR sensor was placed on a load cell (force sensor, LMA-A-20N-P, Kyowa Electronic Instruments Co., Ltd., Japan), so that the same load was applied to both sensors and the output values of the load cell (N) and the resistance (Ω) of the PSCR sensor were measured during static loading with several weights (metal blocks). Fig. 2 shows the typical relationship between pressure and resistance of a PSCR sensor on a logarithmic scale. The vertical (y) and horizontal (x) axes represent pressure and resistance, respectively. The sensor responds

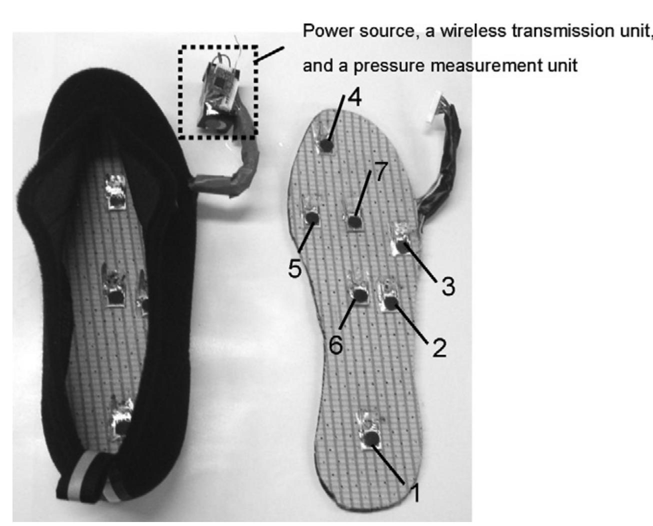

Fig. 3. All-in-one in-shoe device developed to measure plantar pressure. Sensors were placed at seven locations: heel (sensor #1, H), lateral midfoot (#2, LM), lateral forefoot (#3, LFF), great toe (#4, GT), head of first metatarsal (#5, 1st Met), centre midfoot (#6, CM), and centre forefoot (#7, CFF).

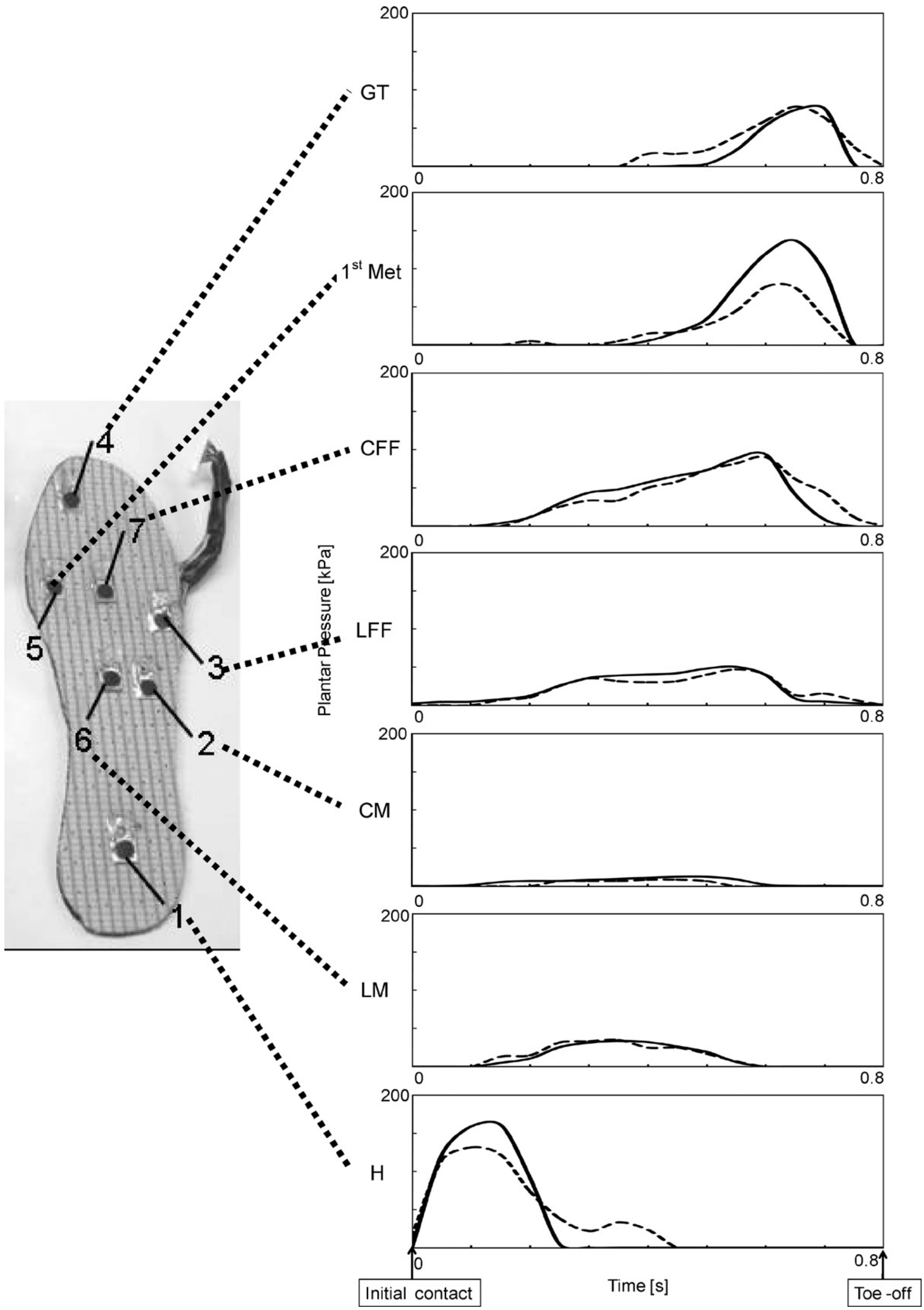

Fig. 4. Pressure patterns obtained from our device and a F-scan system placed on the right foot during a step in a healthy 25-year-old subject.

to stimuli in the range of 25–250 kPa. As shown in Fig. 2, pressure was converted to resistance based on the calibration data, resulting in the following equation and correlation coefficient: $\log(y) = -0.57\log(x) + 2.24$ and $r = -0.98$.

All PSCR sensors were calibrated in this manner before tests. Based on this equation and variations in the data plotted in Fig. 2, the maximum error was estimated to be approximately 15% across the measurement range.

2.2. The in-shoe device

Fig. 3 (left) shows the external view of the in-shoe device, which consisted of a shoe insole containing seven pressure sensors, a wireless transmission unit (2.4 GHz), a pressure measurement unit, and a power source. The measurement unit is 15 mm × 25 mm × 8.5 mm in size, with a mass of 12 g, excluding the power source. Each shoe, containing a measurement unit, weighs 160 g. The power source (lithium battery, 3 V, 850 mAh) had a life of approximately 20 h during continuous operation. Pressure values from each sensor were digitised by a 10-bit analogue-digital converter at a sampling frequency of 20 Hz and transmitted to a mobile personal computer (PC-MP40H, Sharp Co., Ltd., Japan). The maximum transmission distance was approximately 10 m. Fig. 3 (right) shows a shoe insole and the locations of the seven pressure sensors. The sensors were placed at seven locations chosen based on gait kinetics as well as normal and pathological foot anatomy: heel (sensor #1, H), lateral midfoot (#2, LM), lateral forefoot (#3, LFF), great toe (#4, GT), head of the first metatarsal (#5, 1st Met), centre midfoot (#6, CM), and centre forefoot (#7, CFF). The cost of the device was approximately $1000 (US), excluding the mobile personal computer. Several devices were fabricated to fit a variety of shoes sizes (18 cm, 22 cm, 23 cm, 24 cm, and 25 cm).

2.3. Device validation

We validated the device by measuring plantar pressure during gait, and compared values with those recorded using the F-scan system (Tekscan, Inc., Boston, USA). To measure plantar pressure in equivalent regions, the seven PSCR sensors were fixed (using adhesive tape) at the positions on the sensor sheet corresponding to the F-scan sensors. Each PSCR sensor covered the area of four sensing points on the F-scan sheet. The average of the pressure values for the four F-scan sensing points was calculated and compared to the corresponding PSCR sensor value. A female subject (25 years old) wore the shoes with the sheets inserted and was instructed to walk for a distance of 5 m at a comfortable speed. During the experiment, changes in the plantar pressure were measured simultaneously by our device and the F-scan system. We compared the data recorded by both devices, and the results are shown in Fig. 4. The vertical and horizontal axes represent plantar pressure and time, respectively. The plantar pressure curves obtained from both devices are shown on the same graph. As shown, the peak plantar pressure values recorded by the two devices were similar. For example, the peak plantar pressure value at sensor #4 (GT) was 75.4 kPa with our device versus 78.3 kPa with the F-scan. Differences in peak pressure ranged from −2.9 kPa to 29.3 kPa (−3.9 to 18.2%) at the H, LM, LFF, GT, and CFF. The greatest pressure difference (60.2 kPa, 44.0%) was found at sensor #5 (1st Met), which may be attributed to sensor characteristics. For example, local plantar pressure loading may cause the sensor sheet of the F-scan to deform (wrinkle) or separate from the insole, causing a distortion in the readings. Further experiments revealed that the time difference for the peak phase was <50 ms and that the pressure difference was within the error of the PSCR sensor. The magnitude of the plantar pressure values obtained in this experiment was consistent with those reported elsewhere [9,10]. Thus, the device was confirmed to provide a quantitative estimate of human plantar pressure.

3. Materials and methods

3.1. Subjects

One healthy young subject (female, 22 years old, body weight: 50 kg) and two elderly subjects (both female, 89 years old, body weight: 43 kg and 45 kg) participated in this experiment. The elderly subjects were becoming frail, and used a cane or a rollator for daily ambulation. Neither subject reported experiencing any falls in the month prior to the study. All subjects participated in gait measurement after providing informed consent for the experimental procedures. The study was conducted in accordance with the Helsinki Declaration of 1975 and approved was by the local Ethics Committee of Tokyo Healthcare University (Tokyo, Japan). The measurements were conducted in an elderly day-care centre in downtown Tokyo.

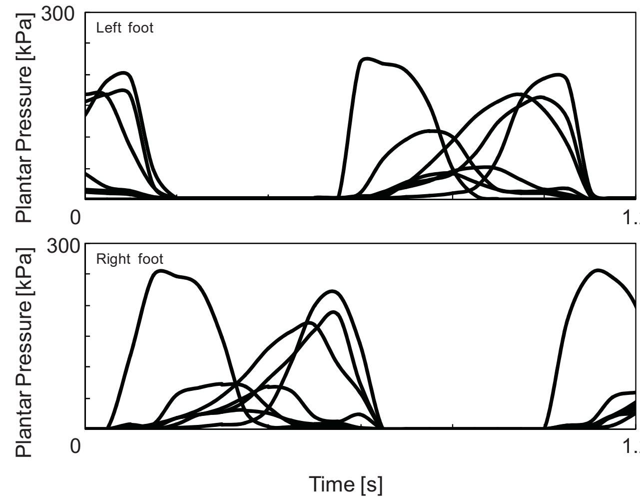

Fig. 5. Representative pressure patterns from sensors placed on both feet during a step in a healthy 22-year-old female.

3.2. Experimental protocol

Each subject wore the device and performed a level, straight walking trial at a comfortable speed for 7 m without using an assistive device. Changes in the plantar pressure during gait were measured continuously. The pressure data during transitional gait (i.e., the first 4 steps and the last 4 steps) were excluded from analysis, so only data obtained during steady gait were analysed. Bias output data applied to the sensors by wearing the shoes were measured and compensated for, as follows: prior to gait trials, the subject sat on a chair and raised the lower legs while wearing the shoe device, the pressure was recorded by each sensor during this unloading activity, and these preload values were subsequently subtracted from all data obtained during the gait trials.

4. Results

Fig. 5 shows the pressure data collected during steady gait from the healthy young subject (both feet). This figure clearly shows the swing and stance phases. The pressure curves during a step of the right foot are magnified and shown separately for each sensor in Fig. 6. The pressure value of sensor #1 (H) increased when the heel was thought to strike the ground. The increase in pressure recorded by sensor #4 (GT) marks the period when the entire plantar surface was thought to be in contact with the ground. As the subject moved forward, the remaining pressure sensors responded sequentially from the heel towards the toes. The pressure recorded by sensor #1 (H) returned to zero when the heel was thought to lift off the ground. At the peak pressure recorded by sensor #4 (GT), the toes were thought to push off the ground for forward propulsion. The pressure values from all sensors returned to zero when the entire foot was raised in the air.

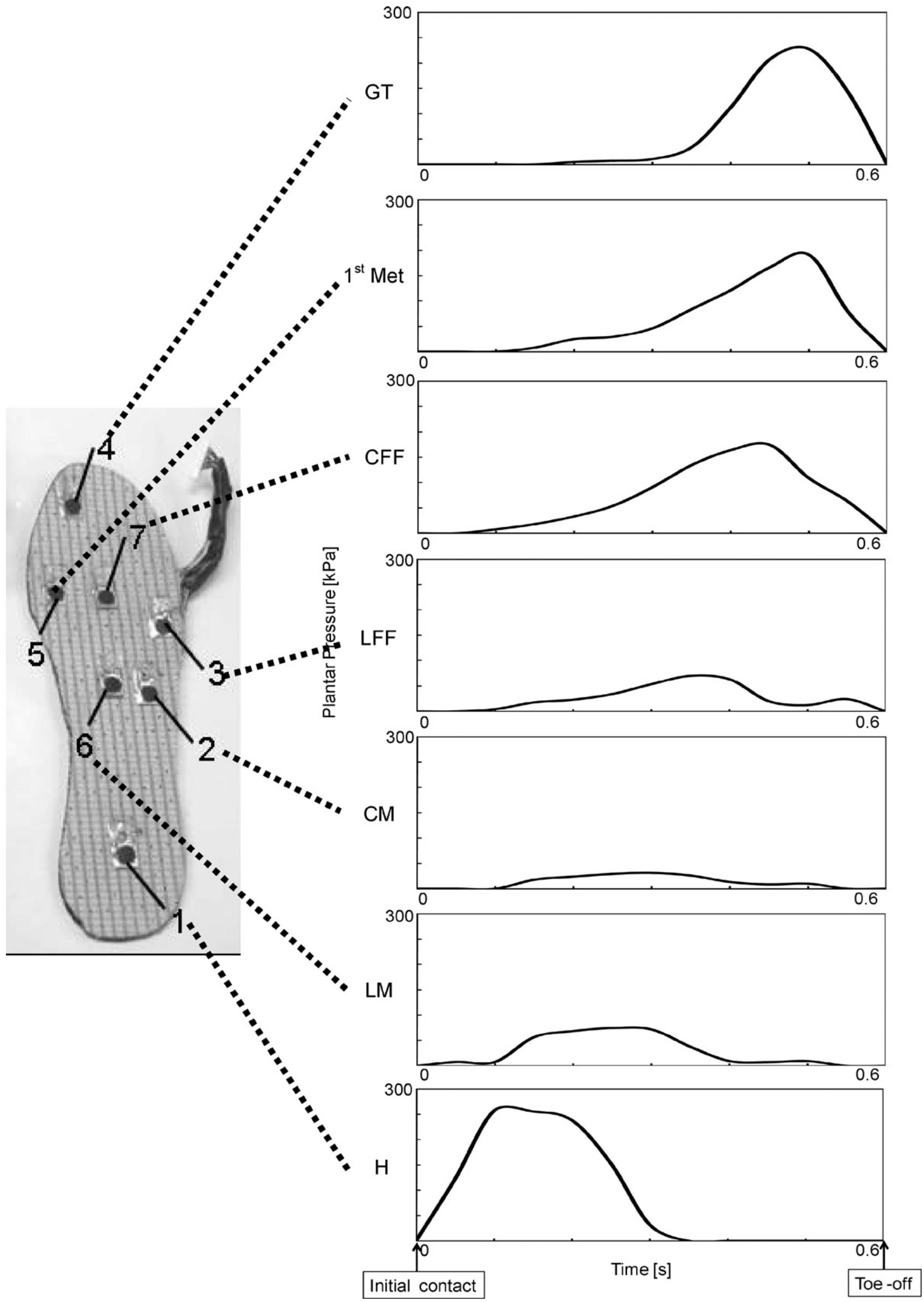

Fig. 6. Pressure patterns recorded by an individual's sensors during a step. The data are the same as those shown in Fig. 5. The pressure patterns for the right foot have been magnified and separated by sensor for clarification.

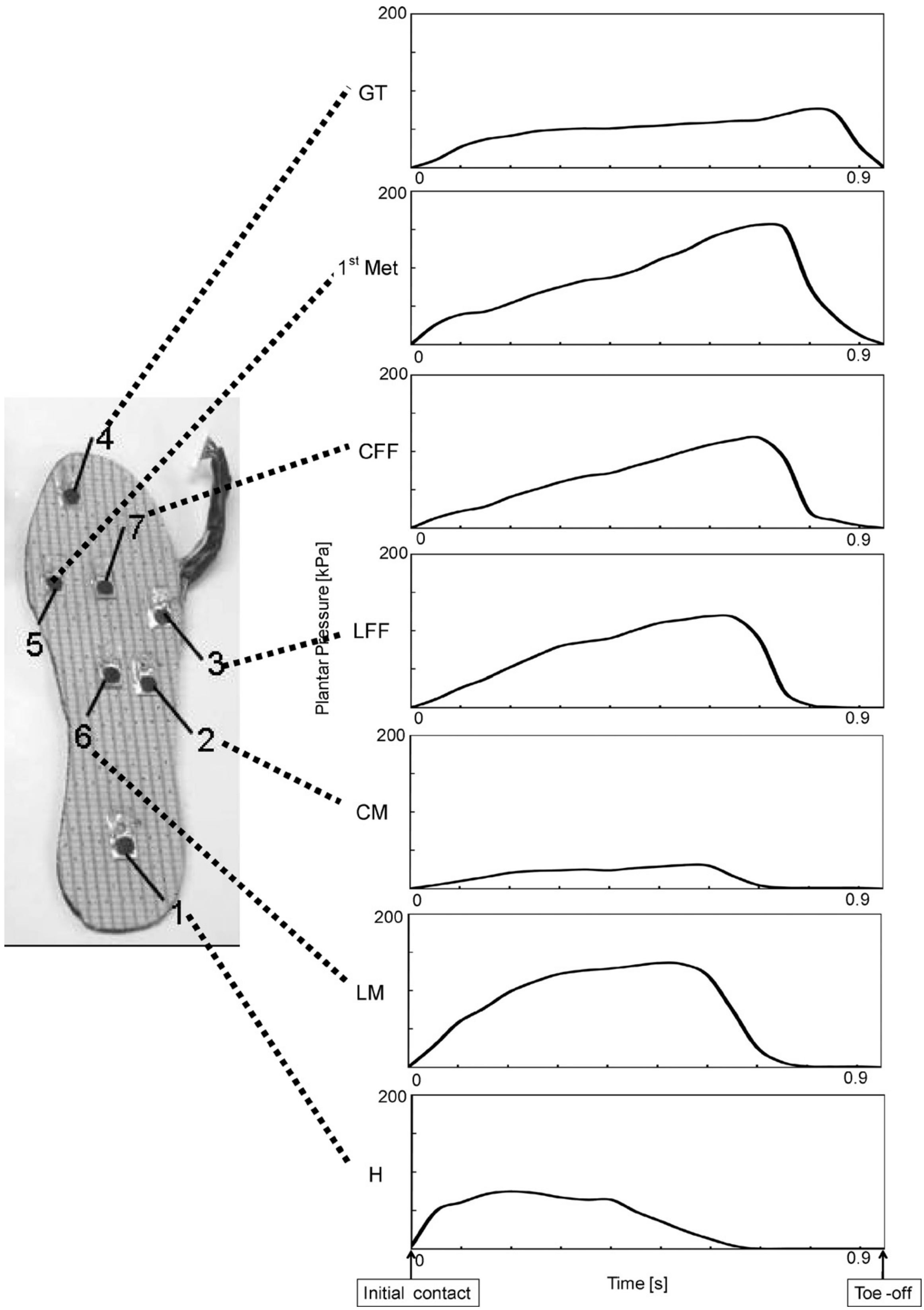

Fig. 7. Representative pressure patterns recorded by each sensor in the right foot during a step in an elderly 89-year-old subject.

Fig. 7 shows the results obtained from one elderly subject (89 years old, right foot). Compared with the data from the young subject (Fig. 6), the pressure for sensor #1 (H) was lower and the gradient was less steep. Because the pressure values around the toes (sensors #3 (LFF), #4 (GT), #5 (1st Met), and #7 (CFF)) increased simultaneously with sensor #1 (H), the entire plantar surface was thought to make contact with the ground at nearly the same time. In this subject, the foot contact seemed to be made by the entire

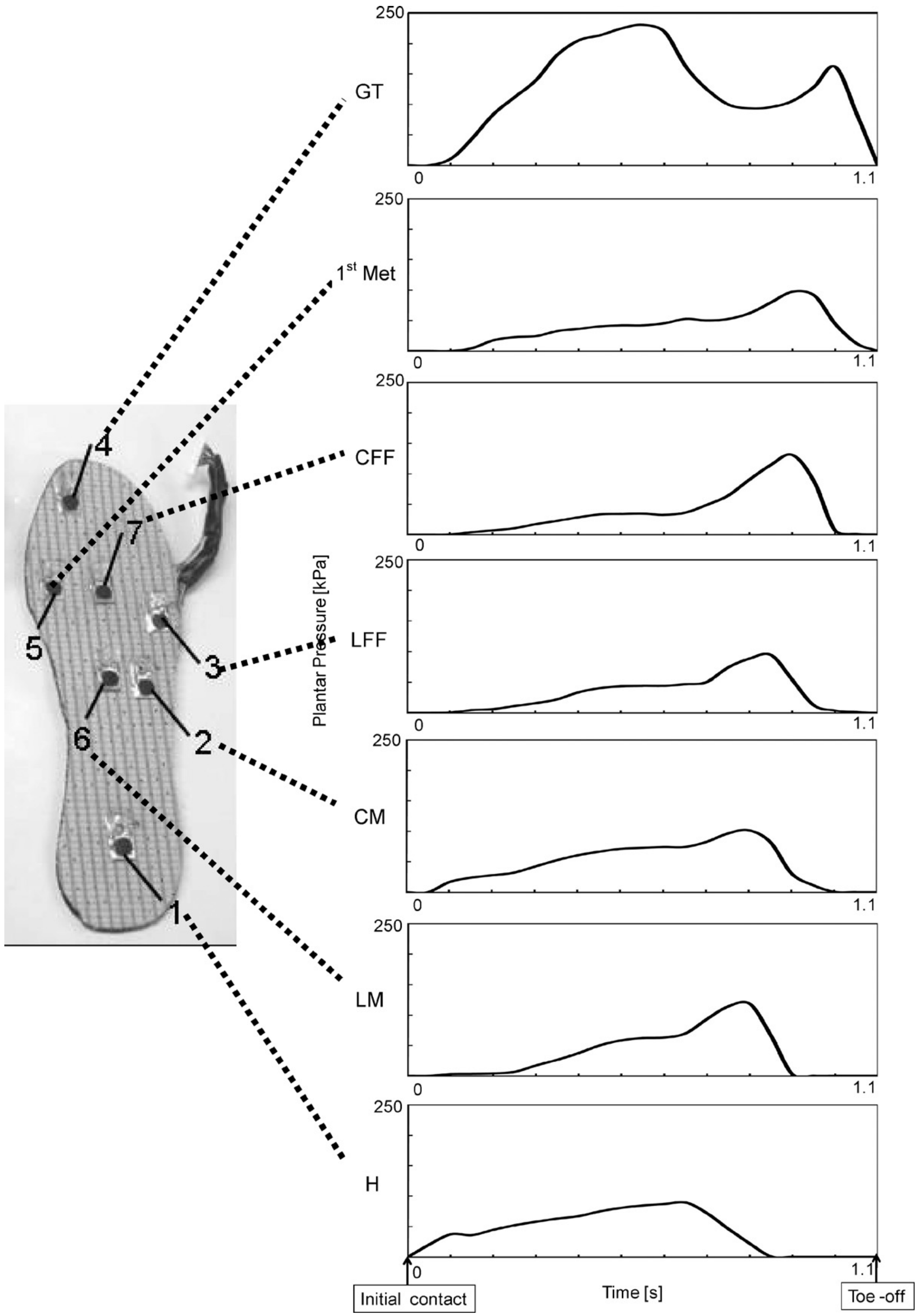

Fig. 8. Representative pressure patterns recorded by each sensor in the left foot during a step in the second elderly subject, also aged 89-years old.

plantar surface rather than the heel, which may be a key feature of gait in elderly individuals. Fig. 8 shows the gait data from the second elderly subject (89 years old, left foot). In this subject, the curve of sensor #4 (GT) showed two peaks during a step, which suggests instability during gait.

5. Discussion

In the present study, we developed a prototype in-shoe device to monitor plantar pressure during natural walking. The device was designed to be user-friendly and to record natural gait easily and safely. We found no technical failures of the device during the gait tests, and it functioned as intended in all subjects. The wireless transmission worked reliably when tested inside the elderly day-care centre as well as outdoors. Furthermore, the device could be inserted into the subject's own shoes to monitor gait. A disadvantage of the technique is that all sensors must be calibrated before gait measurements begin, because degradation of the PSCR occurs over time. To avoid this laborious procedure, the pressure sensor should be replaced by a less susceptible sensor to enable longer use. When evaluating the plantar pressure distribution recorded by in-shoe devices, it is necessary to consider the properties of the shoe. Kernozek et al. [11] compared plantar pressure data recorded by an in-shoe Pedar system with those recorded by a force plate to evaluate the reliability of the Pedar system. They found that the in-shoe pressure distribution differed from that of barefoot walking on a rigid platform. This is unsurprising because the mass and the mechanical properties of the shoes, including the sole, insole and outer materials, would affect in-shoe plantar pressure. Thus, the pressure data recorded by in-shoe devices should be carefully evaluated considering the material and/or physical properties of the shoe. Also, the measurement range was limited to the area near the mobile personal computer, because the maximum transmission distance was approximately 10 m. Future work will extend this distance using other data transmission methods, which will make the device more suitable for daily monitoring of plantar pressures.

An advantage of this approach is that the shoe insole can be prepared to fit various shoe sizes at a low cost. Furthermore, the mass and volume of the measurement unit are less than 1/10th and 1/50th, respectively, of that reported for other devices. From a user perspective, the all-in-one shoe design means the user will only need to wear the shoe, which is comfortable and does not affect gait. Finally, the device was energy efficient and able to record data for more than 20 h.

Biomechanical devices, including motion-capture video cameras [12–16] and force plates [12–14], are widely used to analyse human gait. These devices have made important contributions to the understanding of gait with regards to kinetics, kinematics, and muscle activity. However, the use of these devices is usually limited to a laboratory environment [17], and natural unobstructed human motion may be compromised by interaction with these laboratory-bound devices. Human motion analysed by these devices tends to differ from daily human activities [18,19]. For example, Schepers et al. [20] noted that in order to obtain clinically relevant data, research into system that operate outside of the gait laboratory are required. They also emphasised the need for measurements in the work place or at home. Similarly, Najafi et al. [21] stated that the quantitative assessment of daily human activities was a key determinant in evaluating the quality of life of subjects and an objective and reliable technique that could be used under daily living conditions was needed. We propose that our device could be used as a convenient device to measure plantar pressures during daily living. One application of this, and similar devices, is fall prevention in elderly individuals [22,23]. Numerous studies on fall prevention and/or the analysis of fall mechanisms have been conducted [4,24], but the methods used in these studies were inappropriate for falls that occurred in specific environments, such as the subject's home [25]. The device reported here has several advantages, such as its all-in-one shape, convenient form, portability, and ability to be used in almost all daily activities. Thus, it would be suitable to measuring plantar pressures in elderly individuals on a daily basis.

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