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Properties of the flexible pressure sensor under laboratory conditions simulating the internal environment of the total surface bearing socket

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Abstract

The purpose of this study was to investigate the properties of the flexible pressure sensor under laboratory conditions simulating the internal environment of the total surface bearing (TSB) socket to determine optimal conditions for measuring normal stresses on the stump. The equipment used in the study was the Pressure Distribution Sensor System for Sockets. In a climatic chamber maintained at 37°C and 70% humidity the sensor sheet was mounted on a measuring apparatus loaded with three 10 kg weights, and output from the sensor was recorded. Because of sensor creep, a sample 60 seconds after loading was adopted as the measured output. Output was greater when weight was decreased than when weight was increased because of hysteresis (paired *t*-test, $p<0.05$). The sensor had temperature sensitivity but differences in output were not statistically significant (paired *t*-test, $0.10>p>0.05$). There were no significant differences in output among five sensor sheets or among five sections of four sensor sheets (two-way ANOVA, $p>0.05$), but repeated loading on the same section of the sensor sheet increased output (two-way ANOVA, $p<0.05$). Reproducibility and sensitivity distribution of the sensor are considered satisfactory under laboratory conditions, but measurements of rapid and repetitive movements may not be accurate and comparing subtle changes in output from a single sensor is not suitable. The reliability of the sensor in a clinical setting for measuring normal stresses on the stump with the TSB socket should be examined.

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Introduction

The patellar-tendon-bearing (PTB) prosthesis for trans-tibial amputees was developed at the University of California at Berkeley in 1957 (Radcliffe, 1961). Although the PTB socket provides a good fit for many trans-tibial amputees, some complain of excessive pressure on the patellar tendon area, limitation of knee flexion, and skin abrasions (Hachisuka *et al.,* 1995). Possible causes of these problems are that the PTB socket does not serve to suspend the prosthesis from the stump and that weight is borne mainly on an area previously considered insensitive to pressure. To resolve these problems, the total surface bearing (TSB) prosthetic socket (Staats and Hundt, 1987; Fillauer *et al.,* 1989), a type of suction socket in which weight is borne by the entire surface of the stump, has recently been used. Clinical studies have shown that the TSB socket is more comfortable and has less piston movement (Cluitmans *et al.,* 1994; Hachisuka *et al.,* 1998), most likely owing to its interface characteristics.

There are several studies on pressures at the stump-socket interface (Naeff and van Pijkeran, 1980[a,b] Quesada and Skinner 1991; Williams *et al.,* 1992; Sanders *et al.,* 1992; Sanders *et al.,* 1993), and the localized pressures can be divided into normal stresses perpendicular to the interface and shear stresses in the plane of the interface (Sanders *et al.,* 1992; Sanders *et al.,* 1993). Excessive normal stress can interrupt blood flow (Daly *et al.,* 1976), and shear stresses and normal stresses together can cause intradermal injury or skin abrasions (Sanders *et* *al.*, 1992). The authors previously found that the three factors that most affect the user's overall satisfaction with the TSB socket are comfort, ease of swinging prosthesis, and absence of piston movement during walking (Hachisuka *et al.*, 1998). Ease of swinging and piston movement may be related to suspension of the prosthesis, and comfort may be related to appropriate distribution of pressure, that is, low normal stresses on the stump. If this latter relationship could be proved, the comfort of the socket might be more objectively evaluated by measuring pressure distribution on the stump (Krouskop *et al.*, 1987).

Although transducers and strain gauges (Naeff and van Pijheren, 1980[a,b] Quesada and Skinner, 1991; Williams *et al.*, 1992; Sanders *et al.*, 1992; Sanders *et al.*, 1993) can accurately measure normal pressures and shear stresses, a specially modified socket with spaces or holes for sensors is needed. A thin, flexible pressure sensor sheet, although no more sensitive than force transducers and unable to detect shear stresses, can be placed between the stump and the amputee's own socket and used to measure normal pressures. Such a sensor has already been used to measure foot pressure in patients with diabetes mellitus or other disorders (Lord *et al.*, 1992; Saltzman *et al.*, 1992; Albert and Rinoie, 1994). In the authors' amputation clinic, the sensor has also been used to evaluate pressure distribution on the stump during fitting of the TSB socket in trans-tibial amputees with sensory disturbances on their stump due to diabetic neuropathy and thalamic hemorrhage. However, the reliability of the sensor for measuring pressure on the stump while the TSB socket is worn has not been established. Therefore, in this study the properties of the flexible pressure sensor were investigated under laboratory conditions simulating the internal environment of the TSB socket.

Materials and methods

The Pressure Distribution Sensor System for Sockets, [A] (the original model was F-Scan, and the sensor sheet was improved to increase accuracy and reliability), consists of a flexible pressure sensor sheet connected by a cable to a notebook-type personal computer, [B] with analysis software. The sensor sheets evaluated in this study were 32.5 cm x 17.9 cm in size and 0.15 mm thick. Each polyester sheet includes a matrix of 144 sensors printed with a silver-based conductive ink. When pressure is applied to the sheet, the resulting decrease in electrical resistance is recorded and analysed with the personal computer. According to the manufacturer's instructions, the sensor can detect pressure in the range of 0.21 to 4.9 N/cm^2 and is accurate within 5%.

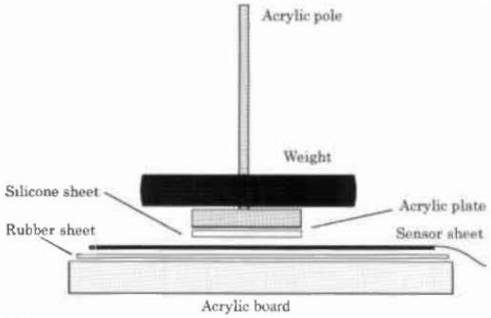

Fig. 1. Lateral view of the apparatus for testing the flexible pressure sensor. The stand for weights is placed on the sensor sheet spread on the rubber sheet covering the acrylic board.

The apparatus for testing the sensor simulated the stump-socket interface (Fig. 1). A 2 mm thick rubber sheet representing the skin was placed on a 10 mm thick acrylic board, and the sensor sheet was spread on the rubber sheet. The stand for the load consisted of a 3 mm thick silicone sheet, representing the silicone inner socket, a 5 mm thick acrylic plate, representing the rigid outer socket, and an acrylic pole attached to the plate with a 6 x 6 cm square base. The stand was placed on the sensor sheet covering a matrix of 36 sensors, and one, two, or three 10 kg weights were mounted on the stand. According to the results of the preliminary study, three 10 kg weights corresponded to the highest pressure on the stump when the TSB socket is worn. Total mass, including the stand, with zero, one, two, and three 10 kg weights was 0.254 kg, 10.760 kg, 21.587 kg, and 32.372 kg, respectively, as measured with a balance [C].

[A] Nitta, 8-2-1 Ginza, Chuo-ku, Tokyo, Japan; Pressure Distribution Sensor System for Sockets (the original model was F-Scan, Tekscan Inc., Boston, USA).

[B] IBM Japan, 3-2-12 Roppongi, Minato-ku, Tokyo, Japan; Thinkpad 370C.

[C] A and D Co., 2-10-7 Dozenzaka, Shibuya-ku, Tokyo, Japan, EP-12KA (0.1 g minimal measurable load).

All experiments were performed in a climatic chamber in which temperature (37°C) and humidity (70%) simulated conditions in the socket when worn (Takami *et al.*, 1985). Before each measurement, the sensor was calibrated with three 10 kg weights.

1. Creep characteristics of the sensor

Creep was defined as the increase in output with time under a given load. After calibration, one weight was mounted on the stand in the centre of the sensor sheet and output from a sensor in the third column from the medial border and the third row from the proximal border of a matrix of 36 sensors was obtained at each sampling (two samplings per second) for 180 seconds. After a 5 minute interval, two weights were placed on the stand and were measured, and then three weights were measured after a 5 minute interval.

2. Hysteresis characteristics of the sensor

Hysteresis was defined as the difference in output under a single load between increase and decrease in weight. Five minutes after calibration, no weight was mounted on the stand in the centre of the sensor sheet, and the output 60 seconds after loading was obtained from the sensor in the third column from the medial border and the third row from the proximal border of a matrix of 36 sensors. After 2 minutes, one weight was put on the stand and was measured. At 2 minute intervals, two additional single weights were placed on the stand and output was measured. Then, at 2 minute intervals, single weights were removed and output was again measured. This procedure was performed with five different sensor sheets. The hysteresis index was calculated with the following equation: [output with decrease in weight (g) - output with increase in weight (g)]/output with increase in weight (g) x 100.

3. Error of total output

The error of total output was defined as the difference in output between the actual loaded total weight and the measured total output. Five minutes after calibration, one weight was mounted on the stand in the centre of the sensor sheet, and the total output 60 seconds after loading were recorded from a matrix of 36 sensors. After 2 minutes, output was measured with two weights on the stand, then with three weights. This procedure was performed with five different sensor sheets. The error index was calculated with the following equation: [output (kg) – loaded weight (kg)]/loaded weight (kg) x 100.

4. Reproducibility of a single sensor

Reproducibility was defined as the difference in output when the same weight was loaded repeatedly on the same section of the sensor sheet. After calibration, three weights were mounted on the stand in the centre of the sensor sheet, and the output 60 seconds after loading was obtained from the sensor in the third column from the medial border and the third row from the proximal border of a matrix of 36 sensors. The weights were removed, then replaced 2 minutes later, after which output was again measured. This procedure was repeated five times with five different sensor sheets. The reproducibility index was calculated with the following equation: [maximal output (g/cm^2) – minimal output (g/cm^2)/mean output (g/cm^2) x 100.

5. Sensitivity distribution of a single sensor

The sensitivity distribution was defined as the difference in output when the same weight was loaded on five different sections of the sensor sheet. After calibration, three weights were mounted on the stand and the output 60 seconds after loading were obtained from the sensor in the third column from the medial border and the third row from the proximal border of a matrix of 36 sensors. The stand with the weights was placed in turn at the five sections (proximal medial, proximal lateral, central, distal medial, and distal lateral) of four sensor sheets. The sensitivity distribution index was calculated with the following equation: [maximal output (g/cm^2) – minimal output (g/cm^2)]/mean output (g/cm^2) x 100.

6. Temperature characteristics of a single sensor

The temperature characteristics were evaluated, comparing output at 37°C after calibration at 20°C and after calibration at 37°C. According to the manufacturer's instructions, output increases by about 1% with a 1°C increase in temperature. Because the sensor would be placed inside the TSB socket in a clinical setting, it is necessary to examine

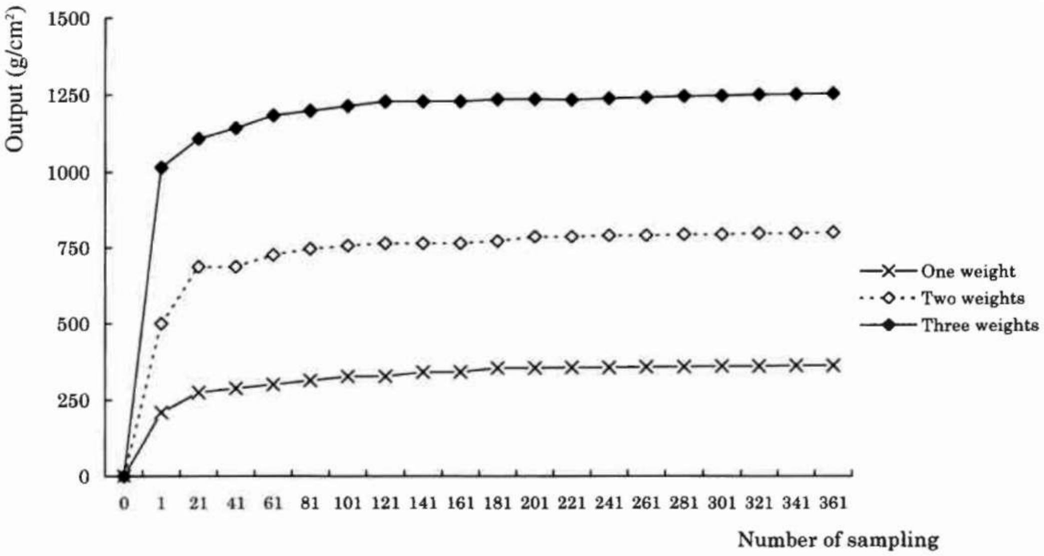

Fig. 2. Creep characteristics of the sensor. Output increased with time but increased only slightly after the 121st sampling One weight: 10.760 kg, two weights: 21.587 kg, and three weights: 32.372 kg.

whether the sensor reaches body temperature and is calibrated. After the sensor was calibrated with three weights at 20°C, the temperature in the climatic chamber was increased to 37°C and the output with the weights was obtained from the sensor in the third column from the medial border and the third row from the proximal border of a matrix of 36 sensors. After the sensor was calibrated again at 37°C, the output was recorded with the same weights at 37°C. This procedure was repeated with five different sensor sheets.

The above data are presented as mean ± standard deviation, and were analysed with a commercial packaged software[D]. The paired *t*-test, *t*-test, and two way analysis of variance (ANOVA) were used to compare hysteresis and temperature characteristics, distribution, and reproducibility and sensitivity. Differences with a p value of less than 0.05 were considered significant.

Results

1. Creep characteristics of the sensor

Output increased rapidly until the 61st sampling and then increased gradually. The pattern of output was similar with different weights (Fig. 2). Output was increasing before the 361st sampling, but the increase in output was slight after the 101st or 121st sampling. Therefore, the output at the 121st sampling (60 seconds after loading) was adopted as the measured output for the following measurements.

2. Hysteresis characteristics of the sensor

Output increased linearly in proportion to the loaded weight; however, output was significantly greater when weights were being

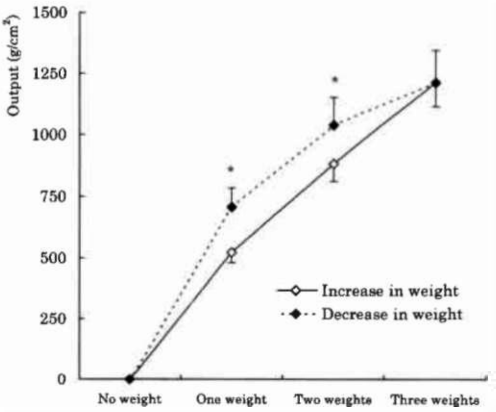

Fig. 3. Hysteresis characteristics of the sensor. Output increased linearly with the loaded weight; however, output was greater when weight was being removed. *:paired *t*-test, $p<0.05$. No weight: 0.254 kg, one weight: 10.760 kg, two weights: 21.587 kg, and three weights: 32.372 kg.

[D] SPSS Japan Inc. 2-2-22 Jingumae, Shibuya, Tokyo, Japan; SPSS 6.1J for Windows.

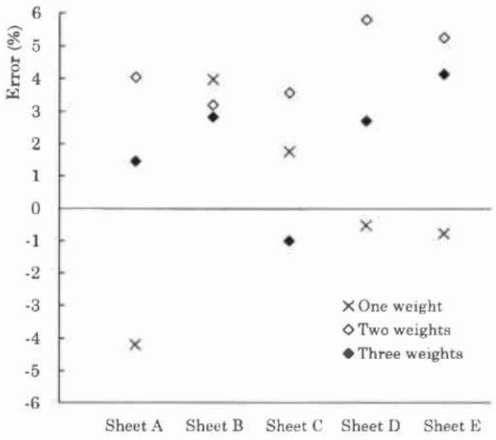

Fig. 4. Error of total output. Error indexes were calculated with the equation [output (kg) – loaded weight (kg)]/loaded weight (kg) x 100, and, except two trials, were within 5%. One weight: 10.760 kg, two weights: 21.587 kg, and three weights: 32.372 kg.

removed (Fig. 3; paired *t*-test, $p<0.05$). The hysteresis index for one weight (36.0±16.8%) was significantly greater than that for 2 weights (6.9±6.6%; paired *t*-test, $p<0.05$).

3. Error of total output

The error of total output except two trials was within 5% (Fig. 4), and the average absolute error was 3.0±1.6%.

4. Reproducibility of a single sensor

The average output was 1,141.0±44.2g/cm^2. No significant difference in output was found among the five sensor sheets, but output increased significantly with consecutive trials

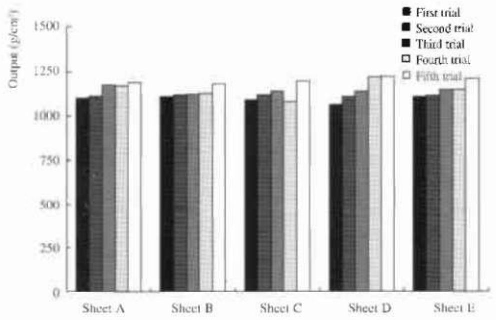

Fig. 5. Reproducibility of a single sensor. Three 10 kg weights were loaded five times in the centre of five sensor sheets. No significant differences in output were found among sensor sheets, but significant differences among trials were found (two-way ANOVA; sheet, $p>0.05$; trial, $p<0.05$).

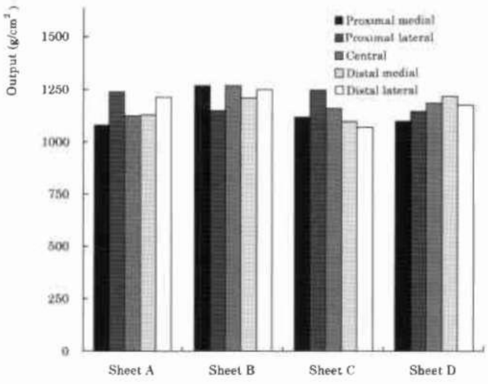

Fig. 6. Sensitivity distribution of a single sensor. Three 10 kg weights were loaded at the five sections of four sensor sheets; no significant differences in output were found (two-way ANOVA; sheet, $p>0.05$; portion, $p>0.05$).

(Fig. 5; two-way ANOVA; sheet, $p>0.05$; trial, $p<0.05$). The reproducibility index was 9.4±2.9%, indicating that the range of variation fell within 9.4% of the average output.

5. Sensitivity distribution of a single sensor

The average output was 1,174.6±64.0 g/cm^2, and there was no significant difference in output among the four sensor sheets and five sections of the sensor sheet (Fig. 6; two-way ANOVA; sheet, $p>0.05$; portion, $p>0.05$). The sensitivity distribution index was 12.3±2.9%, indicating that the range of variation fell within 12.3% of the average output. The variation in output of different sections of the same sensor sheet tended to be greater than that of repeated measurements in the same section of the sensor sheet, but the difference was not significant (*t*-test, $p<0.05$).

6. Temperature characteristics of a single sensor

Output after calibration at 20°C was greater than that after calibration at 37°C, but the difference was not significant (Fig. 7; paired *t*-test, $0.10>p>0.05$).

Discussion

A flexible pressure sensor would be helpful for measuring normal stresses on the stump because it can be inserted between the stump and socket, and it does not require any modification or remake of the socket. However, before the reliability of the sensor for measuring normal stresses on the stump in a clinical setting is

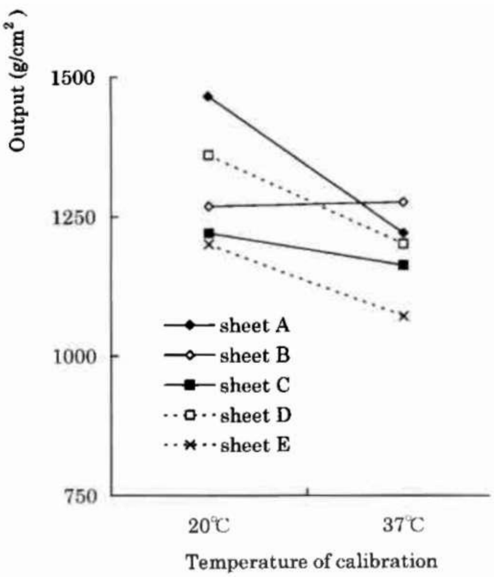

Fig. 7. Temperature characteristics of a single sensor. Calibration at 20°C tended to increase output, but the difference was not significant (paired *t*-test, $0.10>p>0.05$).

examined, properties of the sensor should be examined in a laboratory setting. Therefore, a measuring apparatus was devised made of the same materials as the TSB socket, and the properties of the sensor were examined in a climatic chamber simulating the environment inside the socket.

The sensor shows creep characteristics such that output from the sensor increases with time and does not reach a constant value. To improve the accuracy of measurement a sample at a constant time should be adopted as the measured output. Although samples at 30 to 60 seconds after loading may be used, a sample 60 seconds after loading was adopted on the basis of a graph of creep characteristics. The sensor shows hysteresis characteristics, for example, the output of a 21.587 kg load during a decrease in weight is 16.9% greater than that during an increase in weight. In a clinical setting, measurements should be performed from light to heavy loads.

The sensor is sensitive to temperature. When the sensor is used to measure pressure distribution of a socket, calibration at 37°C may be considered appropriate than calibration at a room temperature, considering the internal environment of the socket. However, the differences in output between after calibration at 20°C and at 37°C were not significant because the variation in output possibly reduces the variation due to temperature. Therefore, calibration at room temperature may be acceptable in a clinical setting.

The sensitivity distribution and the reproducibility of the sensor were satisfactory: the output of the sensor varied little among sections of the sensor sheet and among sheets. Although the error of the total output was less than 5% the error of single sensor output was considered more than 5% (≒sensitivity of the distribution index / 2). When the sensor is used to measure pressure distribution of the socket, the following points must be considered. Repeated loading on the sensor sheet increased output, and the range of variation of output from a single sensor in this laboratory setting was somewhat greater than that described by the manufacturer. This variation may be explained by the sensor's own properties, that is, considerable creep and hysteresis, and the characteristics of the measuring apparatus which was made of viscoelastic materials. In a clinical setting, it is thought that measurements of rapid and repetitive movements, for example, walking and running, is not accurate and that comparing subtle changes in output from a single sensor is not suitable because of the properties of the sensor revealed in a laboratory setting.

For actual measurement of pressures on the stump in a clinical setting, the sensor should be calibrated with three 10 kg weights, although at room temperature. The sensor sheet should be trimmed to fit the contour of the stump and to allow the socket to be put on easily. So that measurements can be made with increasing weight, pressures should be measured first with the amputee standing on the intact foot (unweighted), next on the intact foot and the prosthesis, and finally only on the prosthesis. The output of the sensor should be recorded 60 seconds after loading. However, the variation in output in a clinical setting may be greater than that in a laboratory setting because some errors may arise when a stump with a trimmed sensor sheet is placed in the socket and the sensitivity and reliability of the sensor has not been established under the convex or concave surfaces.

In conclusion, it was found that the Flexible Pressure Sensor System for Sockets measures pressures reliably in a laboratory setting but has some limitations. In the future, the authors plan to examine whether the sensor can reliably measure normal pressures of the socket in a clinical setting and the related comfort and pressure distribution.

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