

Development of Smart Insoles for Gait Monitoring of Patients after Low Extremity Orthopedic Treatment

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Keywords: Gait Monitoring, Foot loading, Measuring insole, Measuring system

Abstract. The aim of our study was to develop a new measuring system that enables to measure foot loading and temporal variables during stance phase while walking. This device is not supposed to compete with expensive professional measuring systems, but it should be a system that will be available to patients in rehabilitation after articular lower limb operations.

Introduction

Walking is the most common human locomotion and it is essential for self-service. Walking stereotype is changing during life and in the elderly, walking can be affected by a long-term overload of the musculoskeletal system. Very often, knee and hip joints are overloaded and joint replacement is indicated. According to the Institute of Health Information and Statistics of the Czech Republic (ÚZIS), about 11 145 (43.78%) knee replacements and 14 312 (56.22%) hip replacements per year are performed. The results of treatment are assessed in several ways; clinical examination results may not always be consistent with X-ray images and computed tomography results [1]. Nevertheless, it is quite common that despite the satisfactory results of clinical examination, abnormalities in the gait pattern after surgery remain noticeable. Therefore, some authors attempt to use other instrumentation methods as for example pedobarography to evaluate treatment outcomes [2]. This method enables to measure foot loading at various time interval after the joint replacement. Research institutes and university researchers very often have the opportunity to use extremely expensive commercially available measuring systems with high resolutions but these systems are not accessible to be used by common patients after the joint replacement. This is the reason why one of this study objectives is to develop a pressure-sensing insole with high resolution while maintaining a low cost. This could be achieved through the research and understanding of flexible pressure sensors regarding their electro-mechanical response.

The measuring insole principle

The insole will be intended for patients after surgery of the lower limb joints. Being part of the shoe, it is clear that it will not be reusable for multiple patients. This is the biggest difference compared to, for example, cardiac monitoring systems, which are only lent to patients during the monitoring period and can be reused for other patients after simple disinfection. Therefore, the most important requirement for the design of the insole measurement system was the low cost of the resulting solution to make the insoles available for single use. It follows from this

requirement that the number of measuring points in the insole must be optimized so that the number of sensors is minimized while maintaining the possibility to measure the pressure distribution over the entire foot area with sufficient accuracy.

The design of sensors distribution in the insole is based on the pressure distribution measured by Emed forceplate (Novel, Munich, De) during one step (see Fig. 1).

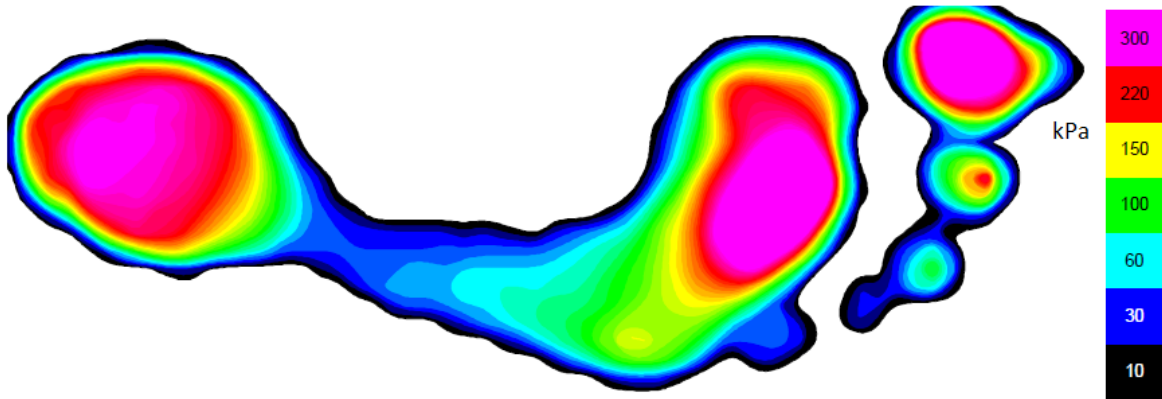


Fig. 1: Foot pressure distribution example

The foot pressure distribution shows three significant load areas [3]. If sensors are placed in these areas the entire measurement area will be covered. As a good compromise between the number of sensors and the resulting price, it was proposed to place eight pressure sensors in the insole area. The design of their location is shown in Fig. 2.

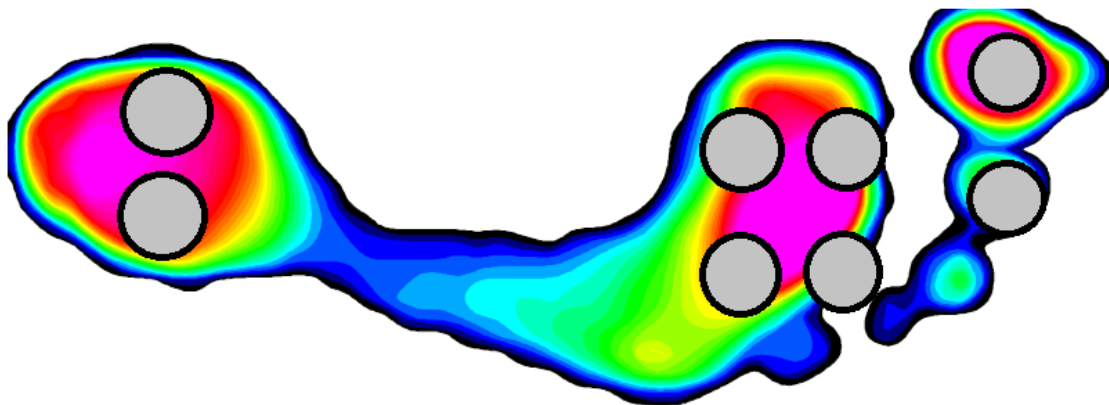


Fig. 2: The design of sensors location

Signals from the sensors will be led outside the insole into a microcomputer, which can be placed on top of the shoe including the power supply. The final solution assumes a separate microcomputer on each shoe, which is wirelessly connected, for example, to a mobile phone. The user application will evaluate data from both insoles and compare the load of lower limbs.

The pressure sensor and measuring insole design

The sensor is based on an elastic layer with electrodes on both sides. Electrodes and the elastic layer form a capacitor with the capacity according to Equation 1.

$$C = \epsilon_0 * \epsilon_r * \frac{S}{d} \quad (1)$$

where S is the area and d the electrodes distance, ϵ_0 and ϵ_r the vacuum and layer permittivity.

The capacitor is connected to an oscillator whose frequency depends on its capacitance. The electrodes distance and thus the capacitance and oscillator frequency are changed when the elastic layer is compressed by force. The sensor principle is shown in Fig.3.

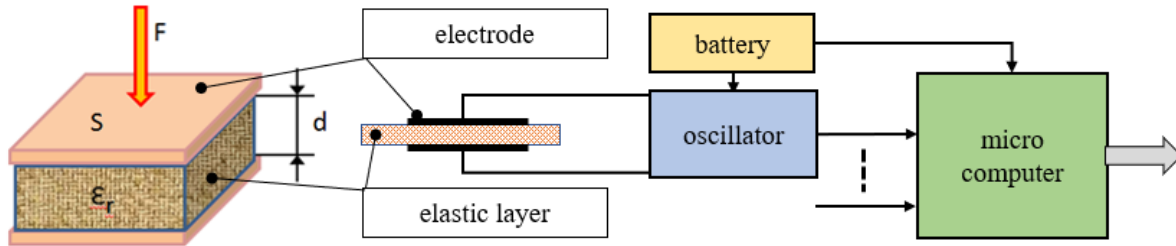


Fig. 3: The design of sensors location

Obviously, the capacitor's capacity with respect to the sensor dimensions considered is very small, in the order of picofarads. The theoretical capacitance and its corresponding oscillator frequency for electrode area 150 mm^2 and varying electrodes distance are shown in Table 1.

Table 1: Capacity and frequency dependence on electrodes distance

$d[\text{mm}]$	1.8	1.6	1.4	1.2	1	0.8	0.6	0.4	0.2
$C [\text{pF}]$	0.74	0.83	0.95	1.11	1.33	1.66	2.21	3.32	6.64
$f [\text{kHz}]$	174	172	168	164	158	150	139	120	86

It is evident from Equation 1 that the dependence of capacitance on electrode spacing is non-linear. The area where the sensitivity of the frequency to the distance change is good is indicated in red in the table. For the insole construction, it follows that the optimum initial thickness of the elastic layer is approximately 1.2 mm and must be compressed to 0.4 mm or less at maximum pressure. Then the frequency change will be sufficient to evaluate the pressure with the required accuracy. The nonlinearity of the dependence does not matter, because the computing power of the microcomputer enables realization of linearization in real time.

Due to the small capacitance of the active capacitor, it is necessary to minimize additional parasitic capacitances at the oscillator input. These parasitic capacitances (connected in parallel to the active capacitor) affect the frequency of the oscillator and reduce the sensitivity of the frequency to the capacitance change. Therefore, the length of the connecting wires between the capacitor and the oscillator must be minimized, the oscillator must be located as close as possible to the active capacitor. The oscillator integrated circuit will therefore be located directly in the insole. The insole must, of course, be flexible so that it can be used in the shoe during walking. The capacitor electrodes will therefore be formed on a flexible printed circuit board, on which the integrated circuits of the oscillators will also be placed. They will be in SMD design to keep their size as small as possible. The possible arrangement of the insole is shown in Fig 4.

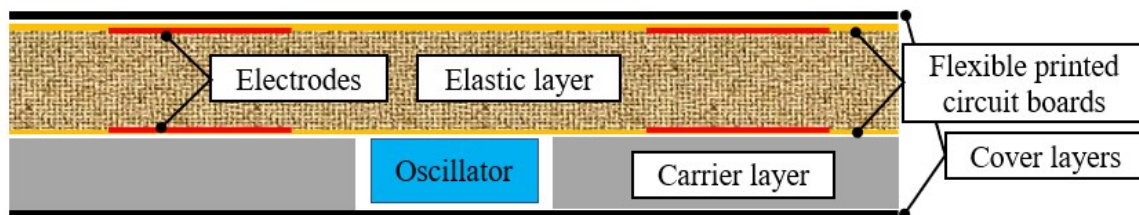


Fig. 4: The possible design of the measuring insole

The carrier layer forms the basis of the measuring insole. In the carrier layer there are openings for integrated circuits which are on the underside of the flexible printed circuit, on

which there are also the lower electrodes. The printed circuit is laid on the carrier layer. This is followed by an elastic layer and a second flexible printed joint with the upper electrodes. The cover layers are then on both sides of the insole. If the elastic layer has a thickness of 1.2 mm, the overall thickness of the insole is less than 4 mm, which is an acceptable result for using the insole in footwear.

The pressure sensor prototype

The properties of the elastic layer will have a major influence on the functionality of the entire measuring insole. The sensor prototype was therefore designed to measure the properties of various materials of the elastic layer. For this prototype a classic hard printed circuit instead of flexible was used, because basic verification of material properties will not be done directly in the shoe and therefore flexibility is not necessary. Electrode dimensions, oscillator circuit type, and its location on the underside of the printed circuit board have been retained. The plastic rigid pad also replaced the insole support layer so that the sensor with the elastic layer tested can be inserted to the testing device. The rigid pad ensures that only the elastic layer is compressed during loading. The sensor prototype on the plastic pad and the sensor with elastic layer are shown in Fig. 5.

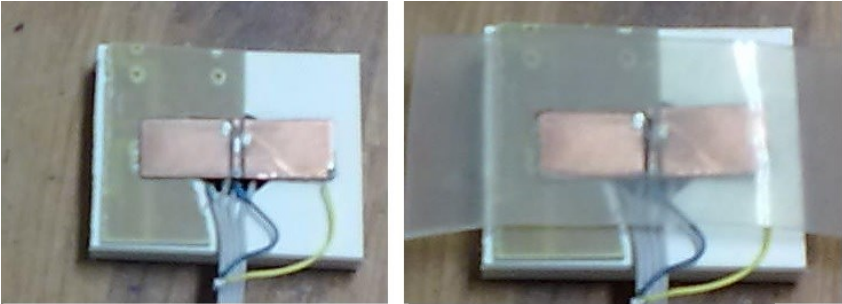


Fig. 5: The sensor prototype

Measurement of elastic layers properties

A simple device for measuring the properties of the elastic layer has been built (see Fig. 6). The elastic layer is compressed by the tightening nut. The sensor oscillator frequency, the achieved force and the elastic layer compression value are measured.

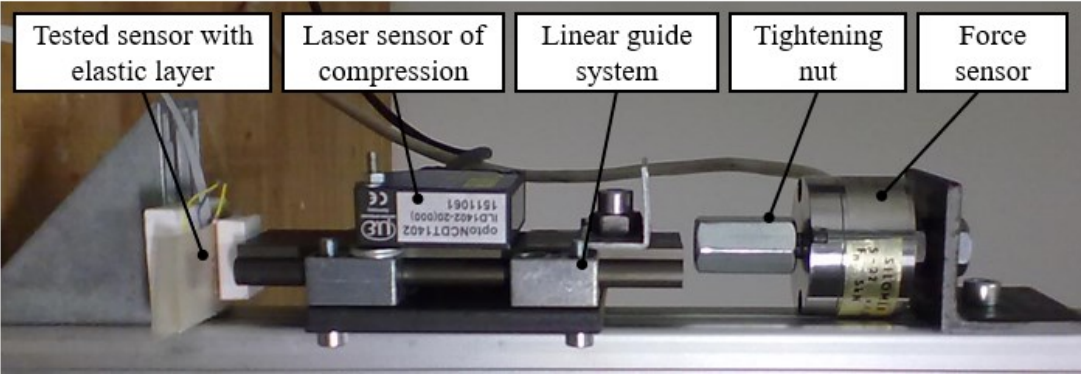


Fig. 6: The elastic layer testing device

The elastic layer is placed on the sensor and the top electrode is placed on the elastic layer. The whole is then inserted in the testing device. The oscillator is connected to the power supply and

all signals are connected to the Dewe 5000 measurement unit. The elastic layer is compressed manually by a tightening nut. The progress of all signals is recorded in the measuring unit. An example of a load cycle for one type of elastic layer is shown graphically in Fig. 7.

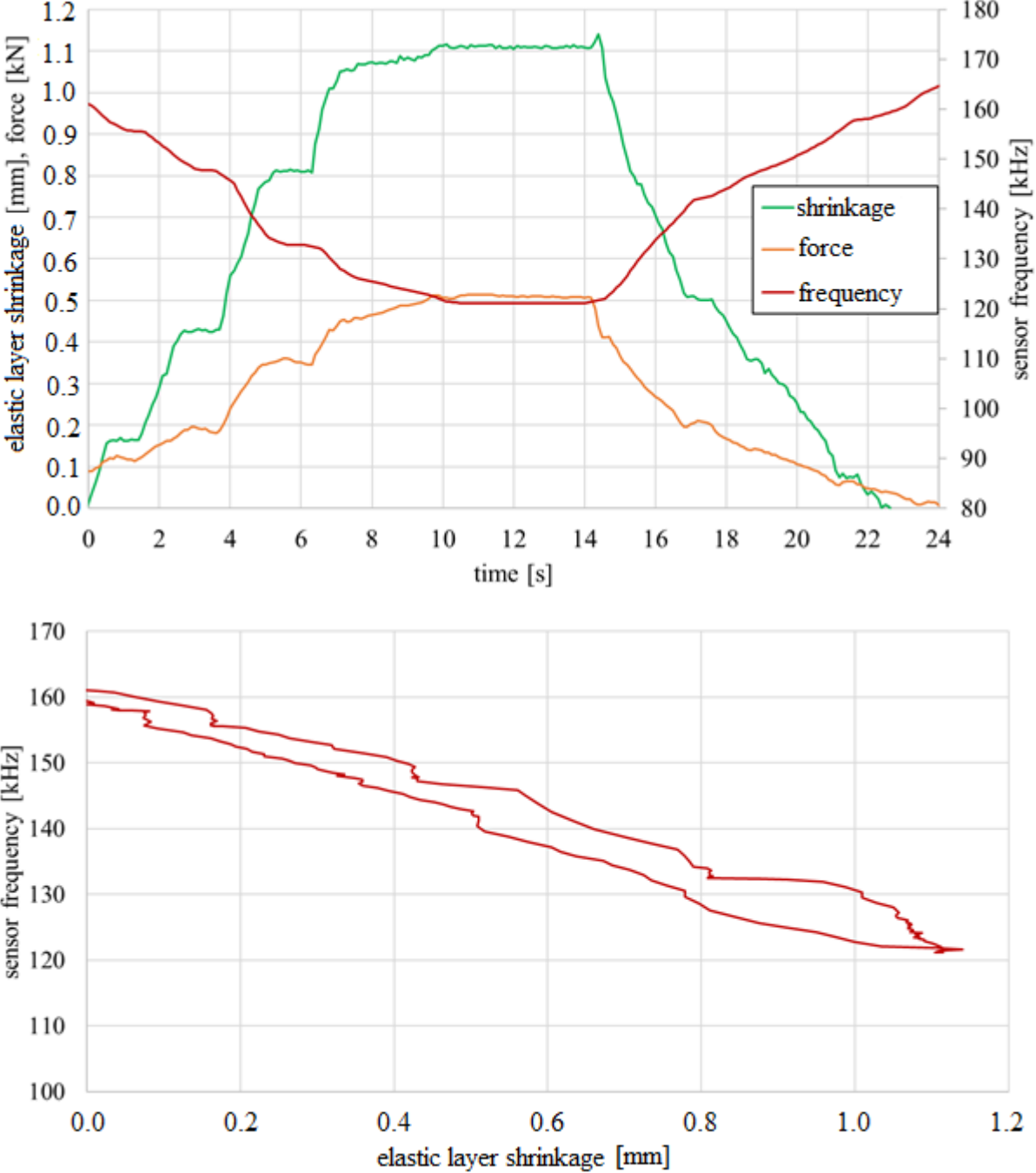


Fig. 7: Example of elastic layer load cycle (time record at the top, frequency dependence on compression at the bottom)

The cycle shown shows that the load with the hand-tightened nut is not smooth and even. However, this system is sufficient to verify the properties of the various materials of the elastic layer. The lower graph shows the hysteresis of the elastic layer measured.

The measurements made so far show that the properties of the elastic layer are absolutely crucial for the reliable operation of the entire measuring insole. The material of the elastic layer

must have minimal hysteresis and its stiffness must be such that the compression under walking load is within the required range.

Conclusions

The goal of device development is not to compete with expensive professional measuring systems, but to develop a system that will be affordable to patients in rehabilitation after lower limb joint operations. Due to the intended use, the initial measurement results with the prototype insole indicate satisfactory accuracy and repeatability of the measurement. Of course, the device does not reach the parameters (especially in the number of measured points) of expensive professional systems, but for a fraction of the price of these systems, it provides results corresponding to the intended use. This will allow its single-use by the patient during rehabilitation.

Acknowledgment

This publication was written at the Technical University of Liberec as part of the project "Research, development and application of advanced methods and technologies in technical mechanics, biomechanics and strength and elasticity" with the support of the Specific University Research Grant, as provided by the Ministry of Education, Youth and Sports of the Czech Republic in the year 2020. The role of students was to put together overview about previous studies of the topic.

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