

ФИЗИЧЕСКИЕ ПРИБОРЫ ДЛЯ ЭКОЛОГИИ,
МЕДИЦИНЫ, БИОЛОГИИ

DEVELOPING A BIO-MECHANOTRONIC PROBING SYSTEM
FOR ESTIMATING SOFT TISSUE YOUNG'S MODULUS *IN VIVO*

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In many medical applications such as rehabilitation, clinical palpation, and manipulation of organs, it is important to characterize soft-tissue properties accurately. This paper presents a bio-mechatronic probing system that could be used for estimating soft tissue Young's modulus *in vivo*. The system employs an electromagnetic spatial displacement sensor. The accuracy and reliability of the system were investigated. In addition, the effect of indentation rate on the variation of the values of the measured effective Young's modulus was also studied. A series of elastomers with different Young's modulus (ranged from 13.08 to 36.19 kPa) were assessed with both the probing system and a Hounsfield material testing machine. Intra-individual and inter-individual variations of the system were tested by five independent operators. The probing system was applied to assess the effective Young's modulus of human body parts *in vivo*. Fifteen healthy female subjects with age of 22.5 ± 4.3 years old were included for the *in vivo* test. The system was shown to be highly accurate ($R^2 = 0.995$) in comparison with the results obtained by the mechanical testing machine and had good reliability (intra-individual variation = 5.43%, inter-individual variation = 5.99%). The average effective Young's modulus of the region of umbilicus were 13.33 kPa and 10.71 kPa for two different sites, respectively. Based on the results obtained, it is believed that this probing system was an accurate and reliable tool for rapidly assessing the mechanical properties of human body tissues *in vivo*.

1. INTRODUCTION AND RELATED WORK

The probing test is an effective method to assess the mechanical properties of soft tissues *in vivo* or *in vitro*. The assessment of the mechanical properties is important not only because of its ability to indicate the presence of a disease or tissue disorder for diagnosis, but also due to its indispensability in the construction of a bio-mechanical human model for the evaluation of pressure garment, with the development of the theoretical solutions, indentation has been widely used to assess the mechanical properties of skin and subcutaneous tissue on bony substratum [1–3]. The properties of various soft tissues *in vivo* has been widely reported in the literature, such as the very thin layer of soft tissue covering the anterior medial tibia [4], forearm and thighs [5], residual limbs [6], fibrosis neck tissues [7], and plantar foot tissues [8].

Most of the information was used for the tissue characterization and diagnosis in the previous studies. However, little amount of data for the *in vivo* mechanical properties of soft tissues covered by tight-fit wear, such as the breast region, umbilicus region, and buttocks, is available. This makes it difficult to model the interaction between these soft tissues and the tight-fit wear.

Many types of indentation instruments have been reported for the assessment of tissue mechanical properties in the literature. Such instruments usually employ a load cell to measure the loading force, and a dis-

placement sensor, such as a linearly variable differential transformer (LVDT) [9, 10], a potentiometer [11], or a laser distance monitor [12], to record the tissue deformation according to the displacement of the indenter. However, the structures of these mechanical indentation apparatuses were either complicated or large, which are not convenient for *in vivo* tests.

Some researchers developed small and portable probing systems for the assessment of plantar-foot tissues and breast tissue [13]. The ultrasound probing system can measure the tissue deformation by tracking the ultrasound echo reflected from the substrate bone. When the thickness of soft tissue increases, the attenuation of ultrasound will increase so that it will be difficult for ultrasound sensor to collect the echoes reflected from the substrate bone. Hence, the ultrasound probing system is not suitable for the assessment of thick tissues.

In this paper, a new small probing system consisting of a load cell and an electromagnetic sensor, is presented and employed. Its accuracy and reliability were investigated as well. The main use of this new system would be to measure the mechanical properties of "thick" tissues, such as the breast, buttock, and tissues in umbilicus region.

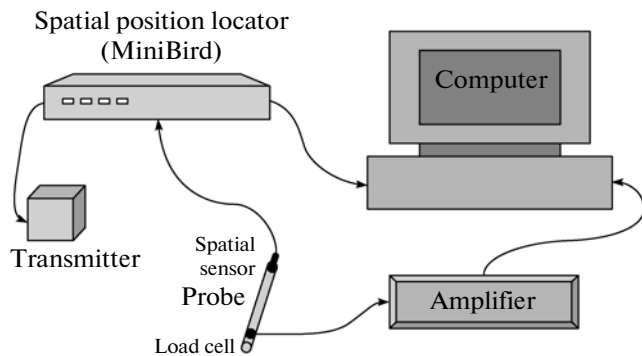


Fig. 1. The diagram of the probing system.

2. EXPERIMENTAL SETUP AND SOFT TISSUE YOUNG'S MODULUS ESTIMATION

The probing system consisted of a small, flat-ended probe and a PC with software for data acquisition (Fig. 1). As shown in Fig. 2, the probe is composed of a load cell (ELFS-T3M, Entran Devices, Inc., Fairfield, NJ, USA) and an electromagnetic spatial sensor (MiniBird, Ascension Technology Corporation, Burlington, VT, USA). The diameter of the rigid cylindrical indenter was 9 mm. The indentation force was measured by the load cell. The position and orientation of the indenter tip, which was used to derive the indentation depth, was measured by the electromagnetic sensor.

The spatial data including three translations and an orientation matrix were transferred from the control box of MiniBird to the computer through its RS232 serial port. The sampling rate of MiniBird could be as high as 100 Hz so that sufficient data could be collected to improve the accuracy of the spatial information by averaging.

During the indentation process, the probe was held perpendicular to the tissue surface and moved along its axial direction up and down. Thus, the indentation depth was calculated from the moving distance of the electromagnetic sensor. The indentation depth was controlled within 10% of the tissue thickness (i.e. $\Delta h/h \cong 10\%$). Each indentation was completed within 2 seconds to obtain an instantaneous response of the tissue.

The widely used Hayes model applied in ref. [8] was used to estimate the tissue Young's modulus, E , assuming that the Poisson's ratio, ν , is 0.49 (nearly incompressible tissue) and the aspect ratio constant, κ , is 1 since the ratio of the probe radius to tissue thickness is much lower than 1.

3. PROBING SYSTEM CALIBRATION

The load cell was calibrated using an electronic balance with a range of 5 N and a sensitivity of 1 mN. The calibration measurement indicated a highly linear response for the force sensors ($R^2 = 0.998$). The positional accuracy of MiniBird was tested using a 3D translating device (Parker Hannifin Corporation, Irvine, CA,

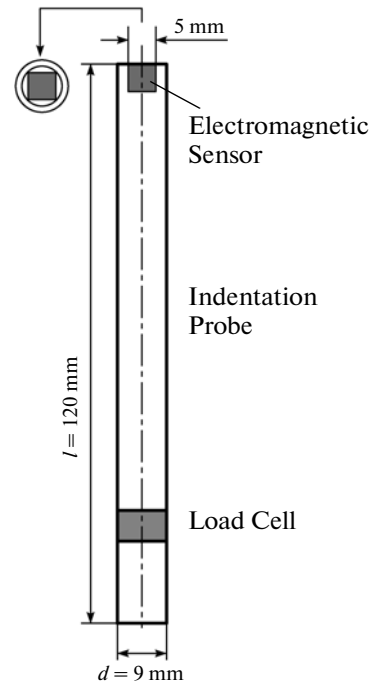


Fig. 2. The mechatronic probe.

USA) whose positional accuracy and resolution was $1 \mu\text{m}$. An average accuracy of $0.06 \pm 0.21 \text{ mm}$ when the distance between the sensor and the transmitter was within 30 cm was obtained. For the experiments reported in this paper, the distance between the spatial sensor and the transmitter was kept as short as possible to achieve accurate results (in a range of approximate 10–20 cm).

The accuracy of the new probing system was assessed by testing a number of elastomers ($n = 4$) with different Young's modulus using the probe, and a Hounsfield material testing machine (H10KM, Tinius Olsen, Ltd. UK). Serial tests were conducted on each elastomer with different indentation rates. The correlation between the effective Young's modulus of four elastomers as determined from the probe and the Hounsfield testing machine was investigated.

Both inter-individual and intra-individual repeatability were tested. The inter-individual repeatability test involved five operators, identified as A to E. All the operators were asked to use the probe to test the same phantom using a constant speed (approximately 5 mm/s) for ten sequential trials. All the operators were blinded to the results of the others' assessments. The standard deviation of the consecutive measurements of a single operator was defined as intra-individual variability of that operator's measurements. The variation of the mean of all operators was defined as inter-individual variability. Two-way ANOVA (Minitab 14.1, Minitab Inc., PA, USA) with the main factor – operator and the nuisance factor – trial, was used to analyze the intra- and inter-individual variations.

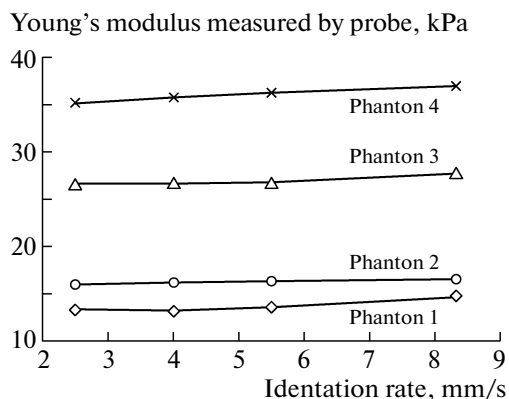


Fig. 3. The relation between the Young's modulus of the elastomers and indentation rate. The error bar indicated the standard deviation of ten repetitive measurements.

4. EFFECT OF INDENTATION RATE

As the indentation process with the probe was manually driven, the rate of indentation cannot be precisely controlled. The effect of variation in indentation rate on the values of effective Young's modulus was examined. Four elastomers were tested using four indentation rates: 2.5, 4, 5.5 and 8.3 mm/s. Each elastomer was indented for ten trials at each rate. One-way ANOVA 8 (Minitab 14.1, Minitab Inc., PA, USA) was carried out to examine the effect of indentation rate.

5. *IN VIVO* TEST ON HUMAN BODY

For the purpose of design of shaping underwear and simulation, the Young's modulus of human body, especially the parts of breast, waist, abdomen and hip, need to be examined. In this study, two test sites were selected in the region of umbilicus, above and under navel approximately 3 cm. Site *A* located at the waist line, and site *B* located at the level of the crest of ilia.

Fifteen female subjects with age of 22.5 ± 4.3 (mean \pm SD) years old, body weight of 61.3 ± 9.4 kg and height of 166.1 ± 18.5 cm were tested. The subject was asked to stand erectly and hold the breath for 3 seconds during the indentation process. Each site was probed with five loading-unloading cycles with an average indentation rate at 6.5 mm/s.

The soft tissues at these two sites include skin, fat, muscle and the inner organs like stomach and intestines. The measured Young's modulus was an average value of these tissues. Hence, it was an effective value. The thickness of the tissues was regarded as more than 100 mm for the calculation of effective Young's modulus using ultrasound imaging.

6. RESULTS ANALYSIS

In this section, the various results obtained from the tests are given. Figure 3 shows the relationship between the values of Young's modulus of four elas-

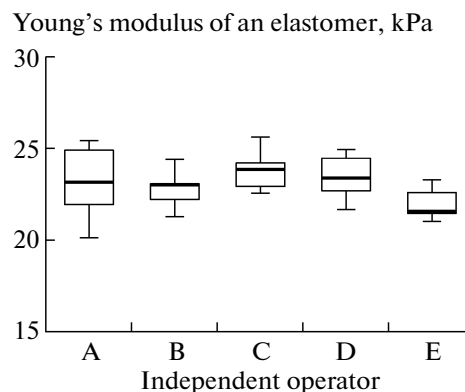


Fig. 4. The plot of ten repetitive measurements of an elastomer with the probe by five operators (A–E). The graph illustrates the relatively small intra-individual variation, as demonstrated by the maximum and minimum Young's modulus values. Moreover, the Young's modulus readings (median) did not show significant difference within individual operators.

tomers and the indentation rate. The mean percentage standard deviation of the Young's modulus, *E*, obtained from the tests of four elastomers using three indentation rates was 6.8 percent. It was found, that there was a slight trend of the Young's modulus, *E*, to increase with the indentation rate. This meant that the mechanical behavior of the elastomers might have time-dependent phenomena, especially for the elastomers labeled as *A*.

However, one-way ANOVA suggested that there was no significant effect of indentation rate on the values of Young's modulus at 5% level with p -value = 0.6. Hence it was concluded that the modulus of the elastomer was rate-insensitive within the range from 2.5 to 8.3 mm/s. Applying the indentation tests on elastomers, a coefficient of variations was found intra-individually (5.43%) as well as inter-individually (5.99%) for repeated measurements of a phantom by 5 independent operators. Figure 4 shows the box plot of the values of Young's modulus obtained from the repetitive measurements.

Two-way ANOVA also indicated that neither operator factor nor trial factor had significant effect on the values of the Young's modulus at 5% level, i.e. both the intra-individual repeatability and the inter-individual repeatability were quite good. There was a very good correlation ($R^2 = 0.995$) between the Young's modulus of the four elastomers as determined directly from the indentation probe and the Hounsfield material testing machine (Fig. 5). A Bland-Altman plot (Fig. 6) gave an indication of the size of errors between the values of Young's modulus measured by the two devices. The mean difference d was 0.48 kPa and the standard deviation s was 1.26 kPa. From the Bland-Altman plot, most of the differences lied between $d - 2s$ and $d + 2s$. It was acceptable for clinical purpose [14].

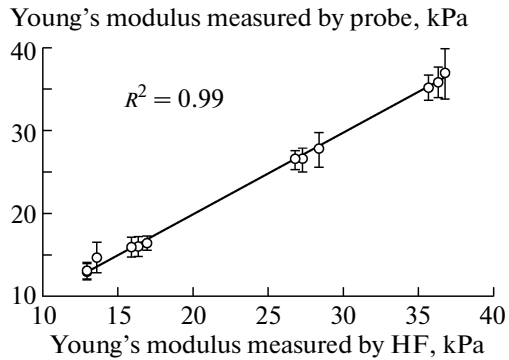


Fig. 5. The correlation between the Young's modulus of the four elastomers as determined directly from the probing system and the Hounsfield material testing machine.

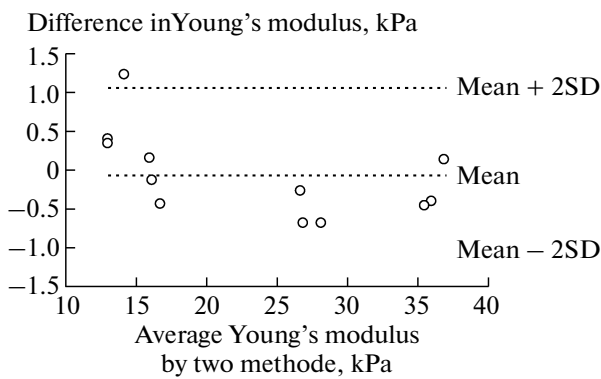


Fig. 6. The Bland-Altman plot to test the agreement between the Young's modulus measured by the probing system and the Hounsfield material testing machine.

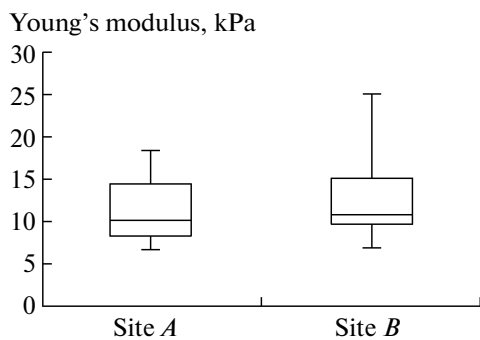


Fig. 7. The effective Young's modulus of the *in vivo* measurements on fifteen female subjects.

Figure 7 shows the results of *in vivo* measurements of soft tissues on female subjects. The average effective Young's modulus of site A was 13.33 kPa and 10.71 kPa for site B. It was found that there was large variation of the values of effective Young's modulus (32% for site A and 36% for site B) within different subjects probably

due to differences in age, body weight and size of the various subjects involved in the tests.

7. DISCUSSION AND CONCLUSIONS

This paper presents a small, portable probing system that could be used for estimating soft tissue Young's modulus *in vivo*. The results of this study showed that the probing system was an accurate and reliable tool for assessing the effective Young's modulus of human tissues *in vivo*. The general region of the manual indentation rate lied from 2 to 9 mm/s. The Young's modulus measured by the probe was found very well correlated to that measured by a standard material testing machine. The Bland-Altman plot indicated that the accuracy of the probing system was suitable for the clinical use. The inter-individual variations in the measurements were small. These variations were primarily due to the fluctuation in loading the probe tip during the data collection and the indentation rate control of each operator. Several groups have been developing dynamic probing systems, in which the indentation rate was precisely controlled. However, they are limited in the constant indentation depth, which makes them difficult to apply on soft tissues with various thicknesses. Moreover, their reliabilities need further investigations [15].

The soft tissues located in waist and abdomens of female subjects were assessed quantitatively *in vivo* using the probing system. The effective Young's modulus was comparable with those of breasts [16]. In conclusion, the results demonstrated that this indentation system is a potential tool for rapidly assessing the stiffness of soft tissues *in vivo*. The system is portable and easy-to-control. It can be used to measure the effective Young's modulus of various human body parts, especially those parts with thick soft tissues, such as breast, waist, abdomen, hip and thigh, for which it is difficult to assess using the ultrasound indentation technique.

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