

A New Tissue Hardness Meter and Algometer; a New Meter Incorporating the Functions of a Tissue Hardness Meter and an Algometer

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Abstract. [Purpose] The purpose of our study was to examine the reliability of a dual algometer and tissue hardness meter. [Subjects] Fourteen female American college students were used as test subjects for the tissue hardness meter, and 15 healthy Japanese adult males were used to test the algometer. All provided their informed consent. [Methods] Hardness of the rectus femoris muscle tissue was measured. Each subject sat in a resting position, with the knee bent at 60 degrees. The chair was fitted with a torque machine. Measurements were taken 3 times under each of the following conditions: No load (no muscle contraction) 10, 20, 30, 40 and 60 lbs and maximum load. Electromyograms of the rectus femoris were recorded simultaneously. The new algometer and a commercially available algometer (J-TECH) were tested for reliability. Pain threshold and pain tolerance were measured with both meters in the test subject's elbow joints and under the lateral epicondyle of the humerus. [Results] The correlation coefficient between tissue hardness and muscle contraction was high for each level of contraction, from no load to the maximum load of voluntary contraction; the reliability of the results was therefore high. The validity of the hardness measurement of the soft tissue for each load was also high. The reliability of both algometers was high. However, comparison of pain threshold and mean degree of tolerance revealed that the value was significantly lower with the new algometer. The new algometer was fitted with a switch for use by the test subject to end the test. The use of this switch resulted in highly accurate measurements. [Conclusion] This evaluation system will be useful in the future for providing objective evidence and making advances in rehabilitation medicine and other fields in the natural sciences.

Key words: Tissue Hardness meter, Algometer, Reliability

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INTRODUCTION

It is very important for the medical profession to employ evidence-based medicine (EBM). To achieve EBM in clinical practice, highly reliable, accurate, reproducible and valid assessments are essential. In a joint Japan-USA project we are

developing tools for a comprehensive anthropometric and evaluation system.

The aim of the project is to realize highly reliable, accurate, reproducible, inexpensive and easy-to-use tools for performing clinical measurements. These tools include an EMG, an accelerometer¹⁻⁶⁾, a joint goniometer, a dynamometer^{7,8)}, a thermometer, a

soft tissue hardness meter⁹⁻¹²⁾ and an algometer^{13,14)}. These tools will be applied widely to anthropometry. Their use will help to gather scientific evidence in rehabilitation medicine and many other fields.

Here, we report our analysis of a functional tool that can be used as a hand-held tissue hardness meter and an algometer simply by operating a switch. This function is revolutionary, because it means that one device can be used to measure both soft tissue hardness and pain, which are often closely related.

In the daily clinical evaluation of treatments and their effects we think that there is a close relationship between pain and tissue hardness. However, in the clinical setting we always find that the evaluation of tissue hardness tends to be subjective, in that evaluation depends only on the examiner's palpation and pain is expressed only as the patient's complaint, thereby making quantification difficult. Furthermore, measuring tissue hardness and pain with different instruments imposes additional costs and extra time for measurement.

Many studies have reported on the development of hand-held tissue hardness meters^{9-12,15-18)}, and algometers^{13,14,19,20)}. There have been discussions on the objectivity of the assessment methods, and many problems remain. With the instruments presented in these discussions, except for the one reported by Fischer^{9,10)}, measurement endpoints are often identified subjectively by the examiner. As a result, the accuracy and reliability of the test can vary with the examiner's skill.

In this report, we examined the improvements and the reliability of the measurements provided by a new, dual purpose, muscle hardness and algometer. We obtained electromyographic readings and tissue hardness readings using the tissue hardness meter at the time of changes in rectus femoris muscle strength. We then examined the relationship between the hardness and electromyographic results to determine the reliability of the meter. We found a correlation between muscle strength and muscle hardness, as well as between muscle strength and the integrated electromyogram at the time of the change in muscle strength. We discuss the possibility of quantification and qualification of muscle strength changes from the viewpoint of muscle hardness. Also, using the new algometer and a commercially

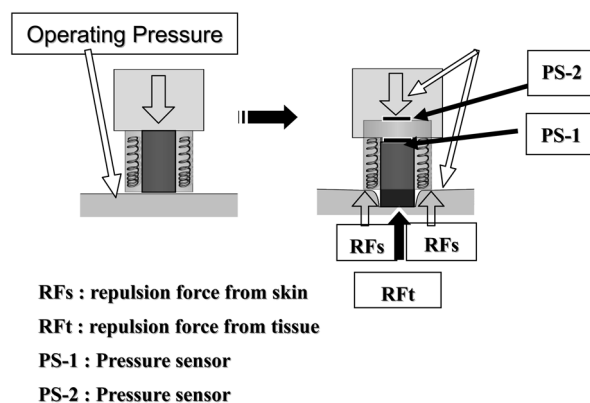


Fig. 1. Measurement mechanism.

Measurement mechanisms used by previous devices and the new tissue hardness meter. Previous device is shown on the left. It measures the depth and pressure of the tissue when pressure is applied by the examiner. The measurement is decided subjectively by the examiner. The new tissue hardness meter, shown right, has two built-in pressure sensors, PS-1 and PS-2. The measurement (PS-2) is determined objectively when the PS-2 value reaches a constant pressure (30 N) represents the hardness of the tissue.

available device, J-TECH, we measured pain threshold and pain tolerance and at the same time obtained visual analog scale (VAS) scores. On the basis of a comparison between the two meters, we investigated the reliability of each device and its relationship with subjective pain.

We introduce our tissue hardness meter and algometer through the results of these experiments.

SUBJECTS AND METHODS

The subjects of the tissue hardness meter test were 14 American female college students from whom we obtained informed consent. They suffered from no previous injuries causing gait disorder of the lower limbs or impaired brain function. Their mean age was 20.3 years (19–21 years), mean body weight was 63.4 ± 9.9 kg, and mean height was 164.4 ± 6.9 cm.

The measurement head of the new hand-held tissue hardness meter has external and internal diameters of 7.5 and 1 cm, respectively. Figure 1 shows the measurement mechanism used in previous devices and the new tissue hardness meter. The conventional meter (Fig. 1; left) measures tissue hardness, using one sensor, when pressure is applied by the examiner; this measurement is

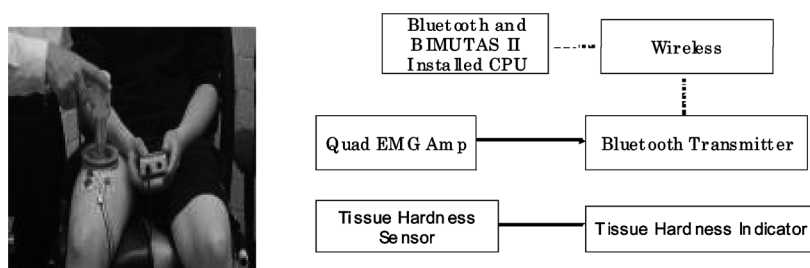


Fig. 2. Block diagram of the experiment and location of the measuring device. Tissue hardness and muscle strength were measured with the subject seated on a chair with the hip joint at 90 degrees, the knee bent at 60 degrees, and the trunk vertical. The pelvis and upper body were fixed by a belt.

assumed to represent the tissue hardness value. The timing of the end of measurement depends on the examiner's subjective judgment. With another type of meter, the examiner pushes the sensor down on to the tissue; the hardness is determined by the depth at which the instrument reaches a certain pressure level^{9,10}.

The new tissue hardness meter has two built-in pressure sensors (PS-1 and PS-2) (Fig. 1, right). As the examiner applies increasing pressure to the measurement head from the start of measurement, the value indicated by the outer circumferential sensor (Fig. 1, PS-2=RFs: repulsion force from skin) increases. When the PS-2 pressure reaches a constant value (30 N), the value at PS-1 is assumed to be the hardness of the tissue (Fig. 1, RFt: repulsion force from tissue). The timing of the end of the measurement is thus constant and objective. To achieve high data reliability, five values are recorded at 20-ms intervals; and the average of five values is assumed to represent the hardness of the tissue.

The subject's pelvis and upper body were fixed by a belt to the muscle power measuring chair. The hip joint was set to 90 degrees and the knee joint to 60 degrees flexion, with the trunk vertical.

The instrument's measuring head was placed in the center of the thigh, on the long axis of the femur 22 cm above the proximal edge of the patella (Fig. 2). The load was changed to measure muscle strength under seven scenarios: no muscle contraction with no load and isometric contractions under loads of 10, 20, 30, 40, or 60 lbs, or at maximum muscle contraction. Three measurements were made during each contraction, and the measured values were averaged and used to represent tissue hardness.

A prototypical dynamometer (Accelerated Care

Plus) was used to identify muscle strength values with the subject seated in the same position as described above.

The measurement head was placed over the anterior surface of the tibia 2 inches above the lateral malleolus. Subjects were directed to kick against the dynamometer plate during isometric contractions at 10, 20, 30, 40, or 60 lbs or at maximum muscle strength. Muscle strength was adjusted by the subject observing the numerical values on the dynamometer display, and the output was maintained for 10 s when it had reached the target values. The interval between measurements was always more than 1 min.

The following conditions were used in electromyography of the rectus femoris muscle: equilibrium input method, input resistance 100 MΩ or above, frequency response DC 500 Hz, fixed amplification rate 1000 times, CMMR -95 db or above, and amplifier with a polarization voltage-proof of ± 500 mV. The instrument used was custom-made by Holonic Co.

The electrodes were pretreated to a skin impedance of less than 5 kΩ using an impedance meter custom-designed by ME Co. They were placed on the right rectus femoris muscle at 3-cm intervals (1: 12 cm above the proximal edge of the patella; 2: on the central line of the femur; and 3: at the intersection of 1 and 2).

The electromyograph was connected to a Bluetooth transmitter (103×59×27 mm, 126 g, analog-to-digital translation, 12-bit resolution, MSP430FG439; Texas Instruments, USA; sampling frequency 1 ms, sending mode Bluetooth Class 2, sending and receiving frequency 2.4 GHz, MES-01 and Holonic Co.)

Data were transmitted to a notebook computer equipped with a Bluetooth receiver (Hagiwara

HNT-UB03; Hagiwara Sys-Com) after analog-to-digital conversion with 12-bit quantization (Fig. 2).

The signal sent to the computer was fed into an all-round system for analysis of the living body (BIMUTASII H0504011; Kissei Comtech) at a sampling frequency of 1 kHz, using software for collecting communication information (HolonBio HOL-01; Holonic Co.) and a waveform viewing program (VitalTracer D20071120; Kissei Comtech) (Fig. 2).

Measurement start and end times were identified by the elevated position of the examiner's pushbutton (pressure sensor); the data were picked up within 5 s of these times. The data were subjected to band pass (10–250 Hz) and band stop (49.5–50.5 Hz) processing.

The muscle potential data were subjected to integration processing after rectification of all waves, and the three trial integrated values were also averaged.

Reliability was examined by calculation of interclass correlation coefficients (ICC) for the three measurement values in the 14 subjects at the time of no load and during muscle output; SPSS16.0 for Windows was used for the statistical analysis.

Spearman's correlation coefficient was used to examine the relationship among change in muscle output, muscle hardness, and the integrated value of muscle potential. The Friedman test was used to test the validity of the muscle hardness changes in each subject against the electromyographic muscle output changes. The Wilcoxon test was used for multiple comparison afterwards. The significance level was set at less than 5%.

Fifteen healthy adult males who provided their informed consent were the algometer test subjects (average age 24.6, range 20–29 years old; average weight, 63.9 ± 8.6 kg; average height 170.9 ± 5.6 cm).

Two kinds of algometer were used for pressure pain evaluation: the new algometer and an algometer made by J-TECH Co. The new algometer was the same device used as a tissue hardness meter in the first experiment with minor adjustments. To make the conversion to an algometer the stability board at the tip of the tissue hardness meter is removed. The outside cylinder of the tissue hardness meter, i.e. PS-2 (Fig. 1) is slid back and locked open, to expose the central rod, PS-1. A patient hand-switch is installed, and the meter is switched to the algometer setting. This process makes algometer measurements possible.

The units of measurement can be chosen from among pounds, kilograms, and newtons by a switch (N was used as the unit in this experiment). In both the new algometer and J-TECH Co.'s algometer, the rod at the center is pushed to the point at which pain is elicited from body pressure, and the pressure on the rod at that time is considered to indicate the pain value.

The difference between the two devices is that the new algometer uses a switch pressed by the patient to identify the end of measurement, whereas measurement by the J-TECH algometer is ended by the examiner when the patient calls out or raises his/her hand as a signal.

For measurements, the subjects placed their arms on the table while sitting in a chair in a relaxed position with the forearms pronated. The measurement sites were both edges of the cubital fossa and immediately in front of the lateral humeral epicondyle. On the right side, the pain threshold (the pressure in newtons at which the subject feels an unpleasant sense of pain) was measured three times. On the left side, the degree of pain tolerance (the pressure immediately before the unpleasant sensation is felt; i.e. the pressure at which the patient feels the pain could not be continuously endured and that if it were to continue they would receive a traumatic wound) was measured three times.

The endpoint of the measurements with the new algometer is identified by the subject pushing a switch held in the hand on the side not being tested. With the J-TECH algometer, the end is identified by the subject raising a hand and/or giving an oral signal. At the same time as we measured the pain threshold and pain tolerance, subjective pain was investigated using a visual analog scale (VAS). A 100-mm line was drawn as a VAS, and the extent of pain felt by the subject was marked on the line, with the left end "painless" and the right end the "worst pain".

Statistical analysis was performed with SPSS16.0 for Windows using ICCs for each set of three measurements made by the new algometer and the J-TECH algometer. The three mean values obtained with each device were compared by the paired *t*-test, and the relationship between the degree of pain tolerance, pain threshold, and VAS was estimated using Spearman's correlation coefficient. The significance level was assumed to be less than 5%.

Table 1. ICCs of three measurements of tissue hardness

Load	No load	10 lb	20 lb	30 lb	40 lb	60 lb	Max
ICC	0.944	0.926	0.932	0.955	0.863	0.892	0.92
Hardness (lb)	2.09 ± 0.19	2.53 ± 0.27	2.75 ± 0.31	2.92 ± 0.29	3.04 ± 0.3	3.24 ± 0.34	3.41 ± 0.43
I-EMG (mv/v)		1.6 ± 0.9	2.0 ± 1.1	2.2 ± 1.2	2.3 ± 1.3	2.3 ± 1.3	2.5 ± 1.3

Table 2. Mean threshold and tolerance values obtained with the two algometers, together with ICCs and correlation coefficients for VAS

	ACP (N)	J-TECH (N)	ACP (ICC)	J-TECH (ICC)	ACP-VAS (r)	J-TECH-VAS (r)
Threshold	20.9 ± 1.6	24.2 ± 3.0	0.946	0.895	0.139	0.251
Tolerance	51.7 ± 4.5	56.2 ± 3.2	0.943	0.988	0.545	0.496

The purpose and content of the research in terms of benefit, risk, protection of personal information, refusal, and withdrawal of participation were explained to the subjects, and signed participation agreements were obtained. The study also received approval (No: AP00610232) from the Ethical Review Board of Shiroyama Hospital, which is managed by the Hachioji Health Cooperative.

RESULTS

The interclass correlation coefficients (ICCs) of the three soft tissue hardness measurements are shown in Table 1. The range of ICCs across the various muscle outputs was 0.863–0.955; it was highly significant ($p < 0.01$).

The validity of the tissue hardness measurements at the time of muscle output changes was examined. The validity of the measurement were demonstrated by the results of the Friedman test and then the Wilcoxon test, since the values rose significantly ($p < 0.01$) from no load to maximum muscle output for each subject.

Spearman's test showed a significant correlation between muscle output change and tissue hardness change (Table 1) ($r = 0.778$, $p < 0.01$). Significant correlations were also found between muscle strength change and I-EMG change ($r = 0.89$, $p < 0.01$) (Table 1), and between soft tissue hardness and integrated electromyogram values ($r = 0.652$, $p < 0.01$).

The ICCs of both pain threshold and degree of tolerance with the new algometer were high (0.946 and 0.943; $p < 0.01$, respectively). The ICCs with the J-TECH algometer were also high (0.895 and 0.988; $p < 0.01$). With the new algometer the pain threshold occurred at a significantly lower pressure (ACP, 51.7 ± 4.5 N; J-TECH, 56.2 ± 3.2 N; $p < 0.05$)

(Table 2).

The Spearman correlation analysis revealed significant relationships ($p < 0.05$) between VAS and degree of pain tolerance (ACP, $r = 0.545$; J-TECH, $r = 0.496$) for both algometers. There were no significant correlations for pain threshold (Table 2).

DISCUSSION

Soft tissue hardness measurement is an important clue to muscle induration and muscle tension status. Causes of pain and limitations of range of joint motion can be examined from this information. Furthermore, information can be obtained on convulsion, spasm, tumors, muscle fatigue, and neurological disease. Currently, measurement of soft tissue hardness in clinical practice often relies on subjective methods such as palpation. Moreover, methods that use equipment have various pros and cons in terms of reliability, reproducibility, and validity. Fischer^{9,10} reported on the reliability of measuring the depth of a sensor pushed under a constant pressure. Yano et al.²⁰ and Arokoski et al.¹⁸ reported that it is possible to measure muscle hardness from the surface of the body.

Two pressure sensors (PS-1 and PS-2) are built into the new tissue hardness meter (Fig. 1, right). When pressure is placed on the measurement head at the beginning of measurement by tester, the reading obtained by the outer circumferential sensor (PS-2) rises. When the PS-2 pressure reaches a certain level (30 N), the pressure at PS-1 is measured. The decision regarding the measurement is externalized by assuming that the PS-1 value obtained represents tissue hardness.

The ICC range was 0.863–0.955 when muscle hardness was measured three times at the time of

muscle output change. Therefore, the reliability of our method of calculating the mean values of three measurements was high. Also the validity of the measurement was confirmed by the load-related change in the muscle hardness. Output rose significantly ($p < 0.01$) from no load, to the time of muscle contractions in all subjects, as shown by the results of the Freedman and Wilcoxon tests. We assumed that this was due to the objectivity of the measurement, which was made possible by the use of two sensors for the measurement, as described above. A discoid tissue stability board 7.5 cm in diameter (area in $\text{cm}^2 = 3.75 \times 3.75 \times 3.14$), which was used by Fischer^{9,10}, was adapted for use on the sensor tip for the soft tissue hardness measurement.

This stability board is considered to place the same consistent pressure on the skin and on a constant area of tissue right under the skin at the time of soft tissue hardness measurement. Thus, any skin or soft tissue diffusion and escape phenomena that may occur when the sensor is pushed into the skin are suppressed, decreasing the chance that the tip of the sensor will measure bone hardness instead in the early stages of measurement.

The reliability and validity of measurements by this new soft tissue hardness meter are therefore high. Muscle induration (spasm), muscle tonus (spasticity or rigidity and flaccidity) and edema can be evaluated objectively by using this soft tissue hardness meter.

There were significant correlations between changes in muscle strength and soft tissue hardness, muscle strength and integrated electromyograms of the quadriceps, and integrated electromyograms and soft tissue hardness.

Muscle strength is determined by motor unit recruitment and the firing frequency of motor neurons. Integrated electromyograms increase linearly²¹ as muscle constriction increases, and at around 80% of maximum voluntary contraction there is a relative increase in mean electromyogram reading over muscle strength²²⁻²⁴. Our results generally agree with the results of these previous experiments.

In light of these findings and our results, it is possible that quantitative alterations in muscle contraction can be evaluated by measuring muscle hardness at the time of maximum muscle output and at rest. Moreover, examination of the relationship between muscle hardness at the time of muscle output change and electromyogram frequency at the

same time suggests that muscle hardness measurement can be used for qualitative evaluation of the muscle.

Pain is an important sense for the living body because it defends the body from noxious stimuli. Humans take intentional or unconscious action to protect their tissues from internal and external noxious stimuli. In diseases and injuries that are accompanied by pain, in many cases the pain itself will cause functional lesions. It is therefore important to capture the pain objectively, quantitatively, and qualitatively as much as possible. However, because pain is to some extent subjective and it is difficult to measure it directly. Current method, therefore, focus on measuring pain through subjective evaluation. Such methods are used to measure the pain threshold to determine whether or not the subject perceives pain when a painful stimulus of a certain amount is given, or the degree of pain tolerance at a time when the pain cannot be endured.

Stimuli that induce a sense of pain include mechanical, chemical, electrical, and optical (heat). We chose to use pressure stimulus derived from mechanical energy. Keele²⁵, Fischer¹⁴, and Jensen et al.²⁶ have reported on the reliability of measuring pressure pain by pressure stimulus. In creating our new device we attempted to increase the reliability of measurement.

With previous instruments, an examiner has recognized a voice or hand signal given by the subject showing that they felt pain; the examiner then ended the measurement. We found a problem with the time lag between the signals and the end of the measurement. The existence of this examiner-dependent time lag can cause scattering of measurement values. Our improvement to pain measurement is that a switch is used directly by the subject to end the stimulus, and the ICCs of both pain threshold and tolerance degree were high with the new improved algometer. The ICCs for the J-TECH algometer were also high; reliable measurements were possible with both algometers (Table 2). However, with the new algometer the pain threshold occurred at a significantly lower pressure. Thus, measurement with the new algometer ended at lower pressures.

VAS and degree of pain tolerance were significantly correlated for both algometers. However, the correlation coefficient of the new algometer was higher, because the switch used by

the subject eliminated the reaction time of an examiner. The resulting suppression of the scattering of measurement values yielded highly accurate measurements.

The new device can be used as a tissue hardness meter or as an algometer with minor adjustments. Pain and hardness in the soft tissues (e.g. muscles) of the human body are closely related. It is therefore epoch-making that we are able to measure both with the same piece of equipment.

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