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(54) DEVICE FOR REAL-TIME MEASUREMENT OF PARAMETERS OF MECHANICAL STRESS STATE
AND BIOMECHANICAL PROPERTIES OF SOFT BIOLOGICAL TISSUE

VORRICHTUNG ZUR ECHTZEITMESSUNG DER PARAMETER VON MECHANISCHEN
SPANNUNGSZUSTÄNDEM UND BIOMECHANISCHEN EIGENSCHAFTEN VON BIOLOGISCHEM
WEICHGEWEBE

DISPOSITIF DE MESURE EN TEMPS RÉEL DES PARAMÈTRES D’UN ÉTAT DE CONTRAINTE
MÉCANIQUE ET DES PROPRIÉTÉS BIOMÉCANIQUES D’UN TISSU BIOLOGIQUE MOU

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(56) References cited:
WO-A1-2009 056 427
US-A- 4 177 798
US-A- 6 132 385

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FIELD OF THE INVENTION

This invention belongs to the realm of medical technology, it is designed to measure the mechanical stress and biomechanical properties of the parameters of soft biological tissues and to statistically assess their state in real time.

BACKGROUND OF THE INVENTION

The biomechanical properties of soft biological tissue involve its elasticity, dynamical stiffness, creepability, and mechanical stress relaxation time.

In evidence-based medicine, both the parameters characterising the stress of superficial soft biological tissues, for example of skeletal muscle, and its biomechanical properties are used as a supplementary source of information. The said parameters allow specialists to quantitatively determine the extent of pathological processes, and the efficiency of various massage techniques, physiotherapeutic procedures, medication and training programmes, as well as ascertaining the tone of tissues during an operation, and fixing the time of death in forensics.

Until now, many attempts have been made to measure the stress (tone) of soft biological tissues by various methods, but neither has such a device been invented nor such a method found yet that would measure all the variables characterising the abovementioned parameters in a way that is universal and realisable/applicable in daily clinical practice in real time. DE 43 43 612C (Blücher et al) describes a sensor to measure elasticity of biological tissue by monitoring axial displacement of a ring that surrounds a rod to which a known axial force is provided. The measurement involves a static deformation of the tissue.

Tone is defined as the mechanical stress of skeletal muscle with no voluntary contraction of the muscle. If we multiply the numerical value of the skeletal muscle stress by its cross-section area, we get the value of the force by which the tendon of skeletal muscle is pulling the periosteum of the bone.

There are three types of tone:

1) The passive resting tone - a state of skeletal muscle with no contraction in the muscle when the muscle is not balancing force torques on the observed joint axis caused by the force of gravity with its mechanical tension. There is no electromyographic (EMG) signal.

2) The resting tone (relaxation) - a state of mechanical stress (or tension) of skeletal muscle without voluntary contraction with EMG activity due to, for instance, an emotional or pathological condition. Such a state is more variable than the passive resting tone. The muscle force torques in antagonist muscles are balanced.

3) The postural tone is a state of skeletal muscle in which the muscle is balancing the force torques of body segments caused by the force of gravity in order to maintain the equilibrium position. When keeping the position, the muscle tension and stiffness are changing persistently, the variability of which is several times greater than in passive relaxed tone. The state of mechanical tension and stiffness level are also significantly higher.

The tone of the skeletal muscle cannot be decreased at will. The level of the tone depends on intramuscular pressure - the higher the intramuscular pressure, the greater the mechanical tensile stress in the muscle (Vain A. 2006 The Phenomenon of Mechanical Stress Transmission in Skeletal Muscles. Acta Academiae Olympiquae Estoniae, Vol 14, No. 1/2 pp. 38-48). If the intramuscular pressure is high, the outflow of venous blood from the muscle will slow down because the veins have no substantial internal blood pressure and when the intramuscle pressure rises, then the veins' cross-section area will decrease. In the case of passive rest, this causes the situation that skeletal muscles' ability to work is restored slowly. Additionally, the ergonomic efficiency of muscle activity in performing movements will decrease since the moment of force caused by antagonist muscles for turning the part of the body on the axis of the joint increases on account of the work needed to stretch the antagonist muscles. The amount of work A done when stretching the antagonist muscles can be calculated by the following formula:

\[ A = F_{\text{resistance}} \times s \ (J) \]

where \( F_{\text{resistance}} \) - resistant force (N),
\( s \) - extent of stretch (m),

whereas
where \( v \) - speed of stretching (m/s),  
\( f \) - muscle’s natural oscillation frequency (Hz),  
\( D \) - logarithmic decrement of a muscle’s natural oscillation,  
\( m \) - mass of the muscle being stretched (kg).

[0008] It is technically complicated to measure skeletal muscle’s state of mechanical stress. However, there has been revealed a functional connection between a material’s natural oscillation frequency and its mechanical stress, which in the case of short-term measurements makes it possible to characterise the mechanical state of skeletal muscle.  

[0009] The logarithmic decrement of a muscle’s natural oscillation shows how much mechanical energy dissipates during one period of the muscle’s natural oscillation. Hence, the elasticity of skeletal muscle (one of the biomechanical qualities of the muscle) can be characterised via the logarithmic decrement of the muscle’s natural oscillation. Elasticity of soft biological tissue means its ability to restore its former shape after the deforming force is removed. The opposite term to elasticity is plasticity. If an elastic body changes its shape as a result of an impulse transmitted by external forces, then simultaneously mechanical energy of elasticity is stored in the morphological structures of skeletal muscle which possess elasticity properties. When the impulse from the deforming force ends, then the stored mechanical energy will restore the body’s initial shape at a velocity that accords to the value of the logarithmic decrement - very quickly if the value approaches zero, and more slowly if the value is higher. Hence, in a device built to register the parameter characterising elasticity, the effect of oscillation damping must be brought to a minimum.

[0010] In a working muscle, contraction and relaxation alternate. The duration of each may vary. Sometimes it may last only a split second. If the relaxation period is short and the muscle’s logarithmic decrement is big, then the initial shape of skeletal muscle fails to be completely restored, the muscle’s internal pressure falls insufficiently and, as a result, the outflow of venous blood from the muscle is slowed down. The time taken for the muscle’s work capacity to be restored increases, its fatigue also increases, and the danger of a muscle overload trauma becomes a reality.

[0011] Stiffness is a biomechanical property of skeletal muscle which consists in its resistance to any force changing its shape. The property inversely proportional to stiffness is compliance. The unit of measurement of stiffness is N/m. How economical and how accurately coordinated a person’s movements are depends on the stiffness of his/her skeletal muscles. Creepability is a biomechanical property of soft biological tissue to deform permanently under constant stress. The creepability property of liquids has been quantitatively measured (US4534211, Molina O. G. 1985).

[0012] The creepability property of soft biological tissue might be characterised, for example, by the Deborah number \( D_e \). The Deborah number is a quantity whose dimension is 1; this number is used to characterise the viscoelasticity of tissues (or creepability of materials). The latter is expressed as the ratio of relaxation time, \( t_{material} \) representing the intrinsic properties of tissue, and the characteristic time scale of an experiment, or deformation time, \( t_{process} \):

\[
D_e = \frac{t_{material}}{t_{process}}.
\]

[0013] The relaxation property of skeletal muscle tissue is defined as the tissue’s ability to relieve itself of mechanical stress in the case of constant length.


[0015] Various attempts have been made to measure the state of mechanical stress and biomechanical properties of soft biological tissues in vivo. As a result, humanity knows a host of instruments for measuring mechanical stress and stiffness, but no ways have been invented as yet to express creepability and relaxation time of mechanical stress in numerical terms. No such devices or methods are known that would simultaneously measure muscle tone and all the four abovementioned biomechanical properties in real time.

[0016] The principal problem is how to evaluate the state of a person’s skeletal muscles on the basis of measurement data, while the parameters characterising this state are constantly changing due to their involvement in biological processes. Therefore, it is insufficient to represent the state of soft biological tissue by one parameter only, which reflects the level of measurable quantities; considering the aspect of diagnostic information, it is relevant that a characteristic describing the variation of levels be added. For assessment of variation, it is important that the reading of the measuring device be repeated in short-term measuring scales (e.g. measuring after every 1 second). In this case, measuring should be carried out and monitored by measuring software (firmware), in order to collect in a short term a sufficient amount of measurement data for statistical assessment. No such methods of measurement are known as yet in the diagnostics of
 Indeed, both methods and devices are available for numerical characterisation of biological tissues' viscoelasticity (e.g., WO2007144520 Method of measuring Viscoelastic Properties of Biological Tissue Employing an Ultrasonic Transducer, EchoSens S.A., 2006), but neither methods nor devices have been disclosed to date that would separately characterise creepability and relaxation properties of soft biological tissues.

None of the earlier solutions allow measurement to be repeated in a short term because the impact on soft biological tissue tends to change the measurable quantities, the character of the measurements is not standardised, and the impact does not end with a quick release.

Among the known solutions, the method closest to the present invention is the myometer, a device and method for recording of mechanical oscillations in soft biological tissues (US 6 132 385 = EE03374B1, Vain A. 2001). The essence of the myometer lies in causing a short-term effect on soft biological tissue by giving it a mechanical impulse and subsequently recording the tissue's mechanical response by means of an electromechanical sensor (acceleration sensor).

One drawback of this solution of the closest prior art is that while the obtained acceleration graph enables calculation of the tissue's natural oscillation frequency, indicating its state of stress as well as the logarithmic decrement characterising its elasticity and dynamic stiffness, it does not make it possible to determine the parameters describing creepability and relaxation time of mechanical stress. Secondly, the parameters characterising the tissue's state of mechanical stress, elasticity and stiffness are calculated at different moments of the oscillation, which yields varying results since the mass participating in the oscillation process decreases constantly due to dissipation of mechanical energy in the case of damped oscillation.

Resulting from the construction of said device (inclusion of a lever), the impulse may be followed by resonant oscillations of the parts exerting impact. If the size of the device is reduced, then the shoulder of the lever will become so short that it will cause a 'scraping' impact, which may yield incorrect results as the direction of the tissue's deformation changes during stimulation. Another shortcoming is the constructional solution of the above prior art device, in which bending of the signal cable attached to the acceleration sensor during oscillation will bring about dissipation of the energy of impact.

A shortcoming of the cited prior art device is also the feature that the construction of the measuring apparatus involves rotating details, which need fine tuning to minimise resistance caused by mechanical friction. But the greater the resistance, the less sensitive the device.

An additional drawback of the said closest prior art device is that in such cases when the direction of the testing end with respect to the Earth's gravitational field is changed, the pre-pressure exerted by the mass of the testing end on the superficial tissues covering the muscle will decrease. However, preservation of constant pre-pressure is necessary for delivering the impact energy to the muscle and thereby making it oscillate. If the pre-pressure decreases, the role of superficial tissues grows both in recording the muscle's natural oscillation frequency and in the resulting measurements.

Thus, there exists a need for such a device and method that would allow us to measure in real time, simultaneously, quickly and accurately soft biological tissue's mechanical state of stress and parameters characterising its four biomechanical properties: elasticity, dynamic stiffness, creepability and mechanical stress relaxation time, and achieve, irrespectively of the position of the device in the gravitation field, high sensitivity of the device as well as repeatability and reliability of the results.

Disclosures of the invention

The aim of the present invention is to provide a universal device and method for simultaneous measuring, in real time, of parameters characterising the state of mechanical stress, elasticity, dynamic stiffness, creepability and mechanical stress relaxation time of soft biological tissues.

To achieve this aim, a device (myometer) of the invention is provided having the features specified in claim 1. The elastic elements may for example be elastic plates (10 and 11), whose one ends are inflexibly fastened by collet-type coupling (12) to the base (13), and the other ends are inflexibly fastened by collet-type coupling (12) to the movable frame (9). The friction-free element for the signals from the recorder (3) may for example be a flexible flat cable (18). The device is operated by a computer program product stored in the processor memory and comprising portions of the software code adapted to perform the method by stages when the program is running in the processor.

The device's construction and software (computer program) enable the user to achieve repeatability and reliability of the measuring results, allowing simultaneous measurement of the parameters and processing of data as well as making statistically significant judgements in real time.

The technical solution of the construction elements of the current invention makes it easy to assemble the device. Nor will the device need any fine tuning once it has been assembled. There is no need for tuning joints, e.g. the measuring mechanism.
The method for simultaneous measurement of the parameters characterising the biological tissue’s state of mechanical pressure, elasticity, dynamic stiffness, creepability and mechanical stress relaxation time uses the device specified above, and has the features specified in Claim 5. The method has four stages, A, B, C and D.

In Stage B, the parameters of a single external mechanical impulse are chosen, depending on the aims of the diagnostic information, from the following ranges: specific power from the range 0.01-0.2 W/mm², the quick release from the range 0.1-15 ms, and the time for achieving the maximum impulse from the range 1-5 ms.

The measuring series consists of single measurements in which the first measurement starts with stage A and is followed by stages B, C, and D. The next measurement in the series proceeds with repetition of stages B, C, and D until completion of the prescribed number of measurements.

To perform stages A to D and calculate the parameters, specially designed software (firmware) is used, which has been stored in the device’s processor, comprises portions of software code, and has been adapted to perform stages A to D when the device’s firmware is used in the processor. Measuring will be repeated in minimum 1-second intervals for as many times as required for statistical assessment.

By means of the device’s firmware, preliminary processing will then be carried out for statistical assessment; the information obtained will enable us to give reliable answers within a few seconds after the end of the measurement, and the repeatability and reliability of the results will be sufficiently accurate to assess both the current state of the soft biological tissue and the longitudinal trends. The above device and method for measuring soft biological tissue’s state of mechanical stress and parameters of biomechanical properties allow monitoring the object under investigation in the event of different body postures and various levels of gravitation fields, as well as doing it repeatedly, autonomously, portatively, and in a non-disturbing, non-invasive and cost-effective way (cheaply).

DESCRIPTION OF DRAWINGS

Fig. 1 Principal schematic representation of the device.
Fig. 2 Graph of soft biological tissue’s natural oscillation, where:
- \( t_T \) - instant at which the drive of the testing end starts impacting the soft biological tissue mechanically;
- \( t_s \) - the drive of the testing end is switched off;
- \( t_1 \) - the beginning of the mechanical influence of the soft biological tissue on the testing end;
- \( t_2 \) - the end of the restoration of its former shape by the soft biological tissue;
- \( t_1 - t_T \) - duration of the mechanical impact on the soft biological tissue;
- \( t_R - t_1 \) - time taken by the soft biological tissue to restore its former shape after deformation;
- \( a_1 \) - maximum acceleration of deformation of the soft biological tissue;
- \( t_4 - t_1 \) - 1.5 natural oscillation periods;
- a - graph of the acceleration of the testing end;
- v - graph of the velocity of the testing end;
- s - graph of the trajectory of the testing end.

DESCRIPTION OF THE EMBODIMENTS

The device for recording the state of mechanical stress and biomechanical properties of soft biological tissues (Fig. 1) comprises the body 1, with a means at its top holding a processor and controller for monitoring the measuring process and for calculating the parameters (a control means 2), a recorder 3 and a moving frame 9 fastened to an inflexible base 13 by an elastic element, such as elastic plates 10 and 11. The moving frame 9 incorporates a sleeve 14 containing two permanent magnets 15 and 16, whose same-name poles are oriented face to face, while the testing end 4 has been attached to the permanent magnet 16 by means of a cone-shaped end 17 made of either electrical steel or some other suitable material. To the bottom part of the moving frame 9, a acceleration sensor 3 has been inflexibly fastened and to the middle of the frame, a shutter 8.

Above and beneath the shutter 8, the position sensors 6 and 7, respectively, have been inflexibly fastened to the body 1. In the upper and lower parts of the moving frame 9 are located inflexibly fastened stoppers 25 and 26.

The arresting system of the moving frame 9 comprises a drive 20, an actuating screw 21, a slider 22 with a shutter 23 and a means 24 for preventing mechanical damage to the arresting system. Along the axis of movement of the arresting system are placed position sensors 27 (upper), 28 (middle) and 29 (lower), which are inflexibly connected with the body 1.

A solenoid 5 has been inflexibly fastened to the body 1, lying in the middle of the moving frame 9.

When the measuring process is triggered by turn of the switch 31, the solenoid 5 is activated by electric current directed by the signal picked up from the axis of the acceleration sensor 3, depending on how the body 1 is oriented in...
the gravitation field. Constant current in the solenoid 5 gives rise to a constant force affecting the two permanent magnets 15 and 16 located in its magnetic field, as a result of which constant pressure is exerted on the slider 22 by the stopper 25 of the moving frame 9. (This pressure is subsequently conveyed by the testing end 4 to the biological tissue being measured.) Subsequently, the position sensors 6 and 7 of the moving frame 9 are activated, and the slider 22 is positioned by means of the drive 20 and actuating screw 21 from the topmost to the middle position determined by the position sensor 28. As a result, the shutter 8 of the moving frame 9 will expose the light beam proceeding from the position sensor 6 (in the measuring position vis-à-vis the body 1), and cover the light beam proceeding from the position sensor 7 (vis-à-vis the body 1); the testing end 4 will emerge from the opening in the body and the signal lights surrounding the aperture 19 in the testing end will be switched on. Starting from this moment, the device is ready to perform measurements.

Stage A

1) To the testing end of the device (myometer) described above a marker was fastened for marking the area chosen for measurement and for connecting the testing end with the muscle being measured without changing the integrity and function of the biological tissue, i.e., without damaging the tissue, and the testing end was then placed on the surface of the soft tissue to be measured;
2) the device indicated in item 1) was then brought close to the surface being measured until the device’s light or sound signal changed;
3) next, irrespective of the position of the device vis-à-vis the gravitation field, an external influence was exerted on the tissue by the testing end by a force equaling the weight of the testing end mechanism; thus, a static deformation ∆S of the tissue was brought about (Fig. 2);
4) the device was held in the same position (for a prescribed time period) until the light or sound signal changed.

Stage B An external impact was exerted on soft biological tissue by a single constant electrical impulse of the solenoid, which ended with a quick release, while the elastic element of the device was stress-free. The specific power of the impulse was 0.1 W/mm², the quick release lasted 0.1 ms, and the maximum of the impulse was achieved in 3 ms. As a result, the dynamic transformation ∆l was caused on the tissue (Fig.2).

Stage C The mechanical transformation of the tissue was recorded together with the tissue’s subsequent mechanical response in the form of a acceleration graph of the tissue’s natural oscillation. The recordings were performed a certain prescribed number of times within intervals less than 1 sec (Fig.2).

Stage D On the basis of the acceleration graph of the tissue’s natural oscillation, in real time and simultaneously,
the parameters of the measured tissue’s mechanical stress, elasticity, dynamic stiffness and mechanical stress relaxation time were calculated, using the time span on the natural oscillations acceleration graph which consisted of the oscillation period starting with the impact and lasting until its end plus subsequent 1.5 periods of the tissue’s first natural oscillation.

[0046] The natural oscillation diagram, results of measurement and the orientation of the device were stored by means of a computer program in the memory of the device.

[0047] The repeated measurements were carried out after min. 1-second intervals for a sufficient number of times for making statistical estimations. The results were displayed on the LCD screen of the recorder.

[0048] The acceleration curve obtained by measurements made by the device (myometer) described above (Fig. 2) enabled calculation of the natural oscillation $f$ of the oscillating muscle mass (together with the mass of the testing end), which is expressed as the inverse value of the oscillation period $T$

$$f = \frac{1}{T} \text{ [Hz]},$$

dynamic stiffness $C = m_t \cdot a_1 \cdot \Delta l \ [N/m],$
where $m_t$ - is the mass of the moving part in kg,
$a_1$ - acceleration at the time when the testing end is dug deepest in the tissue - m/s$^2$, logarithmic decrement

$$\Theta = \ln(a_1/a_3).$$

[0049] Also, it became possible to calculate, in the myometric method described above, the relaxation time $t_{rel}$ of the tissue, which is expressed by the formula

$$t_{rel} = t_2 - t_1.$$  

The Deborah number characterising the creepability of the tissue was calculated by the following formula:

$$D_\theta = \frac{t_2 - t_1}{t_1 - t_T}.$$  

The results of the measurement are given in Table 1 below.

<table>
<thead>
<tr>
<th>Object</th>
<th>Side of body</th>
<th>Statistics</th>
<th>Frequency [Hz]</th>
<th>Decrement [N/m]</th>
<th>Dynamic stiffness [N/m]</th>
<th>Creepability</th>
<th>Relaxation time [ms]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biceps brahii</td>
<td>Right</td>
<td>Average</td>
<td>13.15</td>
<td>1.17</td>
<td>192</td>
<td>1.36</td>
<td>22.65</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Median</td>
<td>13.14</td>
<td>1.18</td>
<td>193</td>
<td>1.36</td>
<td>22.50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>St-deviation</td>
<td>0.23</td>
<td>0.04</td>
<td>7.9</td>
<td>0.06</td>
<td>0.97</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Var.coeff %</td>
<td>1.76</td>
<td>3.60</td>
<td>4.1</td>
<td>4.36</td>
<td>4.27</td>
</tr>
<tr>
<td></td>
<td>Left</td>
<td>Average</td>
<td>12.93</td>
<td>1.13</td>
<td>180</td>
<td>1.33</td>
<td>22.28</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Median</td>
<td>12.99</td>
<td>1.13</td>
<td>180</td>
<td>1.33</td>
<td>22.20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>St-deviation</td>
<td>0.17</td>
<td>0.02</td>
<td>4.0</td>
<td>0.04</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Var.coeff %</td>
<td>1.32</td>
<td>2.16</td>
<td>2.2</td>
<td>2.73</td>
<td>1.74</td>
</tr>
<tr>
<td>Student t-test (&lt;5%)</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Due to the small values of standard deviation, the differences between the parameters of the right and left side of the body are statistically significant even in the case of small values, which shows the great sensitivity and accuracy of the device. The decrement characterising the elasticity of *tendo calcanei* of the left side of the body has 11.24% variation, calling for the need to repeat the measurement and disclose what causes the instability before appearance of pathological symptoms.
By comparing the measurements performed on the test body by means of the prior art and the device corresponding to the current invention it appeared that the decrement was twice as small when measuring by the device corresponding to the invention, which points at the named device’s substantially higher sensitivity.

Application of the device corresponding to the invention, the method and the computer program enables one to:

- measure simultaneously, in real time, soft biological tissue’s mechanical stress and parameters characterising its four biomechanical properties - elasticity, dynamic stiffness, creepability and mechanical stress relaxation time;
- measure and assess the state of stress and biomechanical properties of soft biological tissue with greater accuracy;
- repeat the measuring procedure within small time intervals, as the parameters for impacting on soft biological tissue by means of a single impulse are chosen so that in the course of measurements they will change neither the stress nor biomechanical properties of the tissue under investigation;
- perform measurements at different angles, maintaining the constant pre-pressure when doing so;
- measure following a prescribed algorithm;
- obtain, owing to good repeatability of measurements, within a short period of investigation, a sufficient number of measurements for statistical evaluation and/or comparison of the state of soft biological tissues with reference values;
- obtain standardised criteria of assessment which are released by the firmware immediately after completion of the measurements;
- raise the sensitivity of the device;
- reduce the user’s influence on the measurements.

The invention is defined by the appended claims.

**Claims**

1. A device for simultaneous measurement of the parameters characterising the mechanical stress, elasticity, dynamic stiffness, and mechanical stress relaxation time of soft biological tissue, comprising a body (1), a control means comprising a processor and controller for managing the measuring process and calculating the parameters (2), a recorder (3), a testing end (4), a movable frame (9) fixed to the testing end (4), and a drive of the testing end (4) comprising a solenoid (5), wherein a shutter (8) is fastened inflexibly to the middle of the movable frame (9), and the body (1) carries position sensors (6, 7) to detect the shutter (8).

<table>
<thead>
<tr>
<th>Device</th>
<th>Statistical parameter</th>
<th>Frequency Hz</th>
<th>Logarithmic decrement</th>
<th>Dynamic stiffness N/m</th>
<th>Creepability</th>
<th>Relaxation time ms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device of the closest prior art</td>
<td>Average</td>
<td>22.12</td>
<td>0.65</td>
<td>500</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>22.1</td>
<td>0.66</td>
<td>501</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>Standard dev.</td>
<td>0.13</td>
<td>0.02</td>
<td>9</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>Var.coeff%</td>
<td>0.59</td>
<td>3.07</td>
<td>1.8</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Device of the current invention</td>
<td>Average</td>
<td>22.98</td>
<td>0.29</td>
<td>391</td>
<td>0.78</td>
<td>9.81</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>23.02</td>
<td>0.29</td>
<td>395</td>
<td>0.78</td>
<td>9.7</td>
</tr>
<tr>
<td></td>
<td>Standard dev.</td>
<td>0.15</td>
<td>0.01</td>
<td>13.28</td>
<td>0.02</td>
<td>0.18</td>
</tr>
<tr>
<td></td>
<td>Var.coeff %</td>
<td>0.64</td>
<td>2.72</td>
<td>3.4</td>
<td>2.78</td>
<td>1.88</td>
</tr>
</tbody>
</table>

Table 2. Statistical indices of the measurements performed on the test body SonarAid130 by the device of the closest prior art and the device corresponding to the invention, (n=30).
shaped tip (17) is fixed self-rigidly to the movable frame (9); so in use an impulse of current may be transmitted to the solenoid (5), to exert a dynamic transformation on the biological tissue (30) which ends with a quick release, after which the biological tissue (30) undergoes a series of free damped oscillations along with the testing end (4), the movable frame (9) and the recorder (3), from which the processor of the control means (2) can calculate the parameters characterising the biological tissue (30); and said device is equipped with an element (18) for communicating the recorder’s (3) signals from the movable frame (9) to the control means (2); and the device includes light and/or sound signals, which are placed around the aperture (19) for the testing end (4), and the device also comprises an arrester system comprising a drive (20), an actuating screw (21), a slider (22) moving on an unmoving base (13), wherein the slider (22) is equipped with a shutter (23) and in the slider (22) is located a means (24) for preventing mechanical injuries to the arrester system, there being stoppers (25, 26) at the extreme positions of the movable frame (9) to engage the slider (22) when the slider is so positioned, and wherein the device also comprises position sensors (27, 28, and 29) to sense the position of the slider (22).

2. A device as claimed in claim 1 wherein the recorder is an acceleration sensor (3).

3. A device as claimed in claim 1 or claim 2 wherein the elastic elements comprise elastic plates (10 and 11) whose one ends are inflexibly fastened to the moving frame (9) and the other ends are inflexibly fastened to a base (13) by means of collet-type coupling (12).

4. A device as claimed in any one of the preceding claims wherein the signal-communicating element is a flexible flat cable (18).

Patentansprüche

1. Vorrichtung zur simultanen Messung der Parameter, die die mechanische Spannung, Elastizität, dynamische Steifigkeit und mechanische Spannungsrelaxationszeit von biologischem Weichgewebe kennzeichnen, umfassend ein Gehäuse (1), ein Steuermittel, das einen Prozessor und eine Steuerung zum Verwalten des Messprozesses und Berechnen der Parameter (2) umfasst, eine Aufzeichnungseinrichtung (3), ein Prüfende (4), einen beweglichen Rahmen (9), der an dem Prüfende (4) festgemacht ist, und einen Antrieb des Prüfendes (4), der eine Magnetspule (5) umfasst, wobei eine Blende (8) unflexibel an der Mitte des beweglichen Rahmens (9) befestigt ist, und das Gehäuse (1) Positionssensoren (6, 7) trägt, um die Blende (8) zu detektieren,

dadurch gekennzeichnet, dass der Antrieb des Prüfendes in Translationsbewegung betrieben werden kann, und der Antrieb die gleiche Richtung wie das Prüfende besitzt, das Prüfende (4) durch eine Öffnung (19) des Gehäuses (1), die mit dem biologischen Weichgewebe in Kontakt anzuordnen ist, hervortreten kann, und die Vorrichtung einen Prüfendmechanismus einschließt, der den beweglichen Rahmen (9) und elastische Elemente (10 und 11) umfasst, um den beweglichen Rahmen (9) an dem Gehäuse (1) zu befestigen, wobei der bewegliche Rahmen (9) eine Buchse (14) mit Dauermagneten (15, 16) enthält, die mit gleichnamigen Polen einander zugewandt ausgerichtet und in der Mitte der Magnetspule (5) angeordnet ist, und wobei eine elektrische stahlkegelförmige Spitze (17) des Prüfendes (4) in dem Anziehungsbereich des Dauermagneten (16) angeordnet ist, der sich näher an dem Prüfende (4) befindet, sodass die kegelförmige Spitze (17) eigensteif an dem beweglichen Rahmen (9) festgemacht ist;
sodass im Gebrauch ein Stromimpuls an die Magnetspule (5) übertragen werden kann, um eine dynamische Transformation auf das biologische Gewebe (30) auszuüben, die mit einem schnellen Loslassen endet, nach dem das biologische Gewebe (30) eine Reihe von freien gedämpften Oszillationen zusammen mit dem Prüfende (4), dem beweglichen Rahmen (9) und der Aufzeichnungseinrichtung (3) durchläuft, aus denen der Prozessor des Steuermittels (2) die Parameter, die das biologische Gewebe (30) kennzeichnen, berechnen kann;

und die Vorrichtung mit einem Element (18) zum Kommunizieren der Signale der Aufzeichnungseinrichtung (3) von dem beweglichen Rahmen (9) an das Steuermittel (2) ausgestattet ist;

und die Vorrichtung Licht- und/oder Tonsignale einschließt, die um die Öffnung (19) für das Prüfende (4) angeordnet sind,

und die Vorrichtung ebenfalls ein Sperrsystem umfasst, das einen Antrieb (20), eine Betätigungsschraube (21), einen Schlitten (22) umfasst, der sich auf einer unbeweglichen Basis (13) bewegt, wobei der Schlitten (22) mit einer Blende (23) ausgestattet ist und sich in dem Schlitten (22) ein Mittel (24) zum Verhindern von mechanischen Schäden an dem Sperrsystem befindet, wobei dort an den Extrempositionen des beweglichen Rahmens (9) Stopper (25, 26) sind, um den Schlitten (22) in Eingriff zu nehmen, wenn der Schlitten so positioniert ist, und
wobei die Vorrichtung ebenfalls Positionssensoren (27, 28, und 29) umfasst, um die Position des Schlittens (22) zu erfassen.

2. Vorrichtung nach Anspruch 1, wobei die Aufzeichnungseinrichtung ein Beschleunigungssensor (3) ist.

3. Vorrichtung nach Anspruch 1 oder Anspruch 2, wobei die elastischen Elemente elastische Platten (10 und 11) umfassen, deren eine Enden unflexibel an dem beweglichen Rahmen (9) befestigt sind und die anderen Enden mittels einer spannhülsenartigen Kopplung (12) unflexibel an einer Basis (13) befestigt sind.

4. Vorrichtung nach einem der vorhergehenden Ansprüche, wobei das signalkommunizierende Element ein flexibles Flachkabel (18) ist.

Revisorungen

1. Dispositif pour la mesure simultanée des paramètres caractérisant la contrainte mécanique, l’élasticité, la rigidité dynamique et le temps de relaxation de contrainte mécanique d’un tissu mou biologique, comprenant un corps (1), un moyen de commande comprenant un processeur et un contrôleur pour gérer le processus de mesure et calculer les paramètres (2), un enregistreur (3), une extrémité d’essai (4), un cadre mobile (9) fixé à l’extrémité d’essai (4) et un entraînement de l’extrémité d’essai (4) comprenant un solénoïde (5), dans lequel un obturateur (8) est fixé de manière inflexible au milieu du cadre mobile (9), et le corps (1) porte les capteurs de position (6, 7) pour détecter l’obturateur (8).

2. Dispositif selon la revendication 1, dans lequel l’enregistreur est un capteur d’accélération (3).

3. Dispositif selon la revendication 1 ou la revendication 2, dans lequel les éléments élastiques comprennent des plaques élastiques (10 et 11) dont des extrémités sont fixées de manière inflexible au cadre mobile (9) et les autres extrémités sont fixées de manière in flexible à une base (13) au moyen d’un couplage de type bague (12).

4. Dispositif selon l’une quelconque des revendications précédentes, dans lequel l’élément de communication de signal est un câble plat flexible (18).
FIG 2
REFERENCES CITED IN THE DESCRIPTION

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