(54) Title: DEVICE AND METHOD FOR THE NON-INVASIVE MEASUREMENT OF STATE OF TENSION, BIOMECHAN-
ICAL AND VISCOELASTIC PROPERTIES OF SURFACES OF SOFT BIOLOGICAL TISSUES

Fig.1.
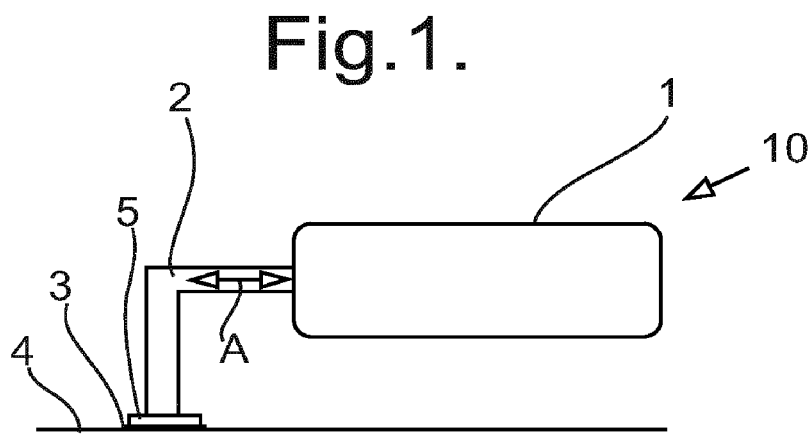
(57) Abstract: Device and method for the non-invasive measurement of state of tension, biomechanical and viscoelastic properties
of surfaces of soft biological tissues A device (10) for measurement of biomechanical and viscoelastic properties of a surface (4) of a
soft biological tissue with elastic properties includes a housing (1) comprising electronic, digital and mechanical elements and
sensors, and also a testing end (2). The elements within the housing (1) can subject the testing end (2) to a mechanical impulse force
(13), and can sense (15) the movement (A) of the testing end (2). The testing end (2) has a contact surface (5) which can be adhered
(3) to the surface (4) of the soft biological tissue, and subjected to a mechanical force in a direction parallel to the surface (4).

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Device and method for the non-invasive measurement of state of tension, biomechanical and viscoelastic properties of surfaces of soft biological tissues

Field of invention

The present invention relates to the field of medical diagnostic technologies, more precisely to the field of methods and devices for measurement of biomechanical and viscoelastic properties of biological surfaces, including but not limited to the skin.

Background of the invention

Human skin provides the body with a flexible barrier to the exterior environment through a highly integrated layered structure consisting of epidermis, dermis and subcutaneous tissues. Each layer has its own specific structure and functions. Mechanical behavior of the human skin is complex and well known to exhibit nonlinear and time-dependent mechanical behavior.

Soft biological tissues can be characterized by the state of tension, biomechanical and viscoelastic properties. Many attempts have been made to measure the biomechanical and viscoelastic properties of surfaces of soft biological tissues, for example human skin. The principal problem is how to evaluate human skin objectively, and to obtain numerical values, non-invasively, painlessly, quickly, and cost effectively, without causing the changes of the tissue being measured.

The US patent application US2011/0319792A1 describes a testing device for measuring biomechanical properties of skin for use by a surgeon, which has a force measurement device measuring the applied force, and a displacement measurement device measuring corresponding induced movement at a set of locations. The described testing device is not entirely satisfactory for the following reasons:

- Long duration of measurement process, which may influence the numerical value of the measured parameter;
- Only one parameter is measured, which is insufficient for objective characterization of the soft biological tissue;
- The measurement process requires use of a flexible articulated arm which is a restricting factor as regards its ease of use, making the measurement process complicated and requiring long preparation;
- The flexible articulated arm may allow measurements to be made only at certain angles of the measurement surface to the gravity vector;

The solution is difficult to use objectively in micro- or zero gravity, which is essential for manned space flight missions.

Brief description of the invention

The aim of the present invention is to provide a solution for measuring surfaces of soft biological tissue with elastic properties, including but not limited to the skin, in real time, at any angle of orientation of the surface to the gravitation field, non-invasively, painlessly, quickly, cost effectively and without causing changes to the tissue being measured.

According to the present invention there is therefore provided a device for measurement of biomechanical and viscoelastic properties of a surface of a soft biological tissue with elastic properties, the device comprising a housing comprising electronic, digital and mechanical elements and sensors, characterized in that the device also comprises a testing end with a contact surface which can be adhered to the surface of the soft biological tissue, and subjected to a mechanical force in a direction parallel to the surface.

According to a preferred embodiment, the device is for measurement of biomechanical and viscoelastic properties of skin of a soft biological tissue with elastic properties and comprises a housing comprising electronic, digital and mechanical elements with at least one sensor; a testing end with a contact surface which can be adhered to the surface of the skin of the soft biological tissue, and subjected to a mechanical force by an actuator along an axis of movement in a direction parallel to the surface of the skin; and comprising an accelerometer arranged to record the acceleration of the testing end; the testing end being shaped such that the contact surface extends in a plane that is parallel to the axis of movement of the testing end; wherein the actuator is arranged to subject the testing end to a force such that the skin is subjected to a pre-set tension, and then to apply a brief mechanical impulse, while continuing to apply the pre-tension force; and wherein after the application of the brief mechanical impulse the resulting damped natural oscillation is recorded with data from the accelerometer; and a signal processing unit to calculate properties of the skin from the data from the accelerometer during the damped natural oscillation.

The electronic, digital and mechanical elements and sensors are adapted to subject the testing end to a mechanical impulse in a direction parallel to the surface, and also to measure the displacement of the testing end that results from the mechanical impulse. The displacement may be determined from measurements of acceleration. The mechanical impulse is applied after application of a preset pre-tension to the surface of the soft biological

tissue, which ensures that the mechanical impulse is applied while the surface is under tension and can therefore undergo oscillation. The mechanical impulse is applied parallel to the surface so that deeper layers of the biological tissue are not significantly involved in the oscillation.

The contact surface may be of area at least 20 mm^2, and preferably at least 50 mm^2, and may be circular or oval, although other shapes are possible. For example it may be a circular plate of diameter 8 mm (area 50.2 mm^2) or of diameter 10 mm (area 78.5 mm^2), or of diameter 12 mm (area 113 mm^2). If the contact surface is too small, or if it has corners, then the mechanical impulse may generate excessively high local stresses; but if the contact surface is too large, then it prevents the device from being used to measure skin properties over a small area.

The electronic, digital and mechanical elements may optionally include a gravitational sensor, and a feedback circuit to ensure that the preset pre-tension and the

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mechanical impulse have values which are unaffected by the orientation of the housing relative to the gravitational field.

5   An important advantage of the present method and technical solution is that the mechanical impulse and subsequent registration of the tissue response is very short (less than 400 ms) so it doesn't influence the numerical values of the parameters being measured. The present invention lies in the design of testing end and in the combination of said testing end with a device (for example myometer myotonpro™ www.myoton.com or similar devices) for subjecting an elastic biological surface to a short-term external
10 mechanical impulse with quick release under constant pre-tension where the response to the impulse is subsequently registered by an accelerometer in the form of acceleration curve. In the present invention the mechanical impulse is applied parallel to the surface of the soft biological tissue. Deeper layers of soft biological tissues (eg superficial skeletal muscles) are not involved in the oscillation.

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The device's construction and its firmware enable it to achieve repeatable and reliable measuring results. The device being used in this invention and its original testing end was designed for measuring deeper layers of soft biological tissues (eg. Superficial skeletal muscles and muscle tendons) but was not suitable for measuring of surfaces of
20 soft biological tissues eg. Human skin.

The present invention comprises the testing end which makes possible to measure surfaces of soft biological tissues without involving deeper layers. The testing end is easy to attach to the device. In order to conduct the measurements with the present invention
25 the device doesn't need any calibration or different settings.

The device has been designed for the non-invasive measurement of superficial soft biological tissue. The device may comprise a gravity-compensating system for its mechanism which allows it to take measurements at different angles (0° to 360°) to the
30 Earth's gravitational field as well as in zero gravity, reproducibly and repeatedly, independently, portably, non-invasively and painlessly, cost-effectively, and quickly.

From the measured acceleration curve the device calculates the following parameters.
35 **State of tension:**
1. F - Natural oscillation frequency [Hz];

Biomechanical properties:

2. D - Logarithmic Decrement of natural oscillation, characterizing Elasticity;

3. S - Dynamic Stiffness [N/m];

Viscoelastic properties:

4. C - Creep (Deborah number), calculated as the ratio of mechanical stress relaxation time to the deformation time;

5. R - Mechanical Stress Relaxation Time [ms].

The present invention also provides a method of measuring biomechanical and viscoelastic properties of a surface of a soft biological tissue with elastic properties, using a device comprising a housing comprising electronic, digital and mechanical elements and sensors, and a testing end with a contact surface which can be adhered to the surface of the soft biological tissue, the method comprising adhering the contact surface of the testing end to the surface of the soft biological tissue, and subjecting the testing end to a mechanical force in a direction parallel to the surface while monitoring the resulting acceleration of the testing end.

The method of measuring comprises the recording of the damped natural oscillation of soft biological tissue in the form of an acceleration graph and the subsequent simultaneous computation of the above given parameters associated with the tissue being measured. The method of present invention is objective, safe, non-invasive, painless, quickly applicable and cost-effective.

According to a preferred embodiment, the method measures the biochemical and viscoelastic properties of skin of a soft biological tissue with elastic properties, using a device comprising a housing comprising electronic, digital and mechanical elements and sensors, and a testing end with a contact surface which can be adhered to the surface of the skin of the soft biological tissue, and which is movable by an actuator along an axis parallel to the surface of the skin, the testing end being shaped such that the contact surface extends in a plane that is parallel to the axis of movement of the testing end, the method comprising the following steps:

- placing the contact surface of the testing end on the measurement point on the surface being measured;

- adhering the contact surface to the surface of the soft biological tissue;

- subjecting the measurement point on the surface to a preset pre-tension in the direction of the axis;

- then subjecting the testing end to a brief mechanical impulse in the direction of the axis with quick release under constant pre-tension;

- registering, with an accelerometer, an acceleration curve of the testing end during a damped natural oscillation in response to the mechanical impulse;
- performing signal processing on signals representing the acceleration during the damped natural oscillation; and thereby
- computing values of the biomechanical and viscoelastic properties of the skin.

The measuring process of the surfaces of soft biological tissues with elastic properties comprises the following steps:

1 . Constant longitudinal pre-tension is applied to the surface being measured. Constant pre-tension is necessary to achieve consistent and repeatable surface longitudinal oscillation at different angles to the gravity vector.

2. After pre-tension the longitudinal mechanical impulse with quick-release is exerted by the device at constant mechanical force.

3. The surface responds to the exterior mechanical impulse by a damped natural oscillation. The co-oscillation of the surface and testing end are recorded by an accelerometer in the form of an acceleration graph.

4. From the raw signal obtained above in step 3, the low and high frequencies that are not characteristic to the soft biological tissue's natural oscillation are then filtered out.

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5. On the basis of the processed oscillation signal, numerical values describing state of tension of the surface being measured as well as its biomechanical and viscoelastic properties are then calculated.

5   The longitudinal mechanical impulse exerted to the surface is of short duration and involves minimal mechanical force, hence it does not cause residual mechanical deformation nor neurological reaction of the subcutaneous tissues being evaluated.

Definitions of parameters

10   STATE OF TENSION

F – Oscillation Frequency [Hz] indicates the state of intrinsic tension of the tissue.

BIOMECHANICAL PROPERTIES

D – Logarithmic Decrement of a natural oscillation indicates the elasticity of tissue being measured, as it corresponds to the dissipation of mechanical energy in the tissue during a

15   damped oscillation. Elasticity is the biomechanical property that characterizes the ability of the tissue to recover its initial shape after removal of the force or deformation; if the material were perfectly elastic, with no dissipation of energy, the decrement would be zero, and the larger the decrement then the less elastic is the material.

S – Dynamic Stiffness [N/m] is the biomechanical property that characterizes the tissue's

20   ability to resist a force of deformation. The term dynamic stiffness originates from the dynamic measurement method. The inverse of stiffness is compliance.

VISCO-ELASTIC PROPERTIES

C – Creep is the gradual elongation over time when placed under a constant tensile stress. This can be characterised by calculating the ratio of the mechanical stress relaxation time

25   and the time to cause maximum deformation.

R – Mechanical Stress Relaxation Time [ms] is the time taken for the tissue that has been deformed to return to its initial shape after removal of the force of deformation.

Brief description of the drawings

30   The present invention is explained more precisely with references to the accompanying drawings, where

Fig 1 shows a general schematic view of the device of the present invention;

Fig 2 shows a schematic view of components within the device of figure 1; and

Fig 3 shows a schematic view of a different mode of use of the device of figure 2.

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Detailed description of the invention

Referring to figure 1, a device 10 according to the present invention comprises an L-shaped testing end 2, a contact substance 3, and a body or housing 1 containing electronic, digital and mechanical elements and means, including sensors for governing the

5   measuring process and for calculating parameters of a surface 4 of a soft biological tissue with elastic properties. The testing end 2 defines a contact surface 5 which is held parallel to the surface 4, and is also parallel to the direction of the mechanical impulse, indicated by the arrow A.

10 The contact substance 3 may be a double-sided adhesive tape, for example in the form of a circular patch, or alternatively may be a skin adhesive. If the contact substance 3 is a circular patch of double-sided adhesive tape, it may be of slightly larger diameter than the contact surface 5. For example the contact surface 5 may be a circle of diameter 10 mm, while the circular patch of double-sided adhesive tape may be of diameter 12 mm.

15 This ensures that it is not necessary to locate the contact surface 5 exactly concentric with the circular patch.

Referring now to figure 2, this shows schematically the components within the housing 1. Within the housing 1 the end of the testing end 2 is fixed to the end of an

20 actuator shaft 12. The actuator shaft 12 is supported so it is free to move axially without friction, as indicated by the arrow A. For example the actuator shaft 12 may be supported by leaf springs (not shown). The other end of the actuator shaft 12 is provided with a non-contact electromagnetic force actuator 13 which can provide a controlled force axially to the actuator shaft 12. The force provided by the actuator 13 is controlled by a control circuit 14.

25 An accelerometer 15 is mounted on the actuator shaft 12, and signals from the accelerometer 15 are provided to a signal analysis unit 16. In this example the signal analysis unit 16 is connected to a digital display 17.

Hence, referring again to figure 1, once the contact surface 5 has been adhered to

30 the surface 4, the force actuator 13 is actuated initially to provide a preset pre-tension to the surface 4. Once the surface 4 has been subjected to this pre-tension, the force actuator 13 is arranged to apply a brief mechanical impulse, while continuing to apply the pre-tension force to the actuator shaft 12. The mechanical impulse has a duration less than 25 ms, for example 10 ms or 15 ms. Hence the actuator shaft 12, along with the testing end 2,

35 is then free to oscillate along with the portion of the surface 4 which is adhered to the

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contact surface 5. After application of this mechanical impulse, the damped oscillation is monitored for up to 400 ms.

For connecting the measurement point on the surface 4 with the testing end 2, the
5   contact substance 3 is attached either to the contact surface 5 or to the surface 4. The contact surface 5 of the testing end 2 is in touch with the surface 4 through contact substance 3, which enables firm connection between the testing end 2 and the surface 4 being measured.

10   To conduct the measurement, the testing end 2 is placed on the surface 4 being measured, the longitudinal mechanical impulse is applied, and the subsequent natural oscillation is recorded in the form of an acceleration curve with the data from the accelerometer 15. The natural oscillation of the surface 4 is registered by the accelerometer 15, and the device 10 hence measures the state of tension, biomechanical
15   and viscoelastic properties.

The method for determining the biomechanical and viscoelastic properties of human skin, where human skin constitutes the surface 4, comprises the following steps.

20   The testing end 2 is placed at the measurement point on the surface 4 being measured. The device 10 is moved towards to the measurement point until the correct position of the measurement mechanism in the device 10 and required pre-tension is achieved. As soon as the correct position is achieved, the device 10 subjects the surface 4 to a longitudinal mechanical impulse of preset force. After the mechanical impulse the
25   device 10 records the surface response in the form of an acceleration curve.

The parameters of state of tension, biomechanical and viscoelastic properties are then simultaneously calculated by the signal processing unit 16. The results may be displayed on a LCD screen of the digital display 17 of the device 10. Additionally or
30   alternatively the data may be transmitted to an external device such as a portable computer.

Referring now to figure 3 there is shown an alternative way of measuring some properties of the surface 4 of a soft biological tissue, for example human skin, without
35   involving deeper layers below the surface. This uses a device 20 which incorporates the housing 1 as described above, but in this case it is connected to a straight testing end 22.

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The testing end 22 defines a contact surface 5 which is connected and adhered to the surface 4 by a contact substance 3, in the same way as described above in relation to figure 1.

5   In use of the device 20, the contact surface 5 is adhered to the surface 4, and the electromagnetic force actuator 13 provides a quick mechanical impulse pulling the contact surface 5 away from the soft biological tissue, as indicated by the arrow B, and so deforming the surface 4 (as shown). The data from the accelerometer 15 can then be used to determine the displacement of the surface 4 from its original position, from which the
10   elasticity of the surface can be deduced.

        The preferred mode of operation is with the surface 4 horizontal, as shown in figures 1 and 3, and with the device 10 or 20 above the surface 4. Where it is necessary to take measurements on surfaces 4 that are not horizontal, it is desirable to ensure that the
15   pre-tension force and the mechanical impulse force are not altered as a result of the effect of gravity. Referring now to figure 2, the accelerometer 15 is arranged to measure the acceleration of the actuator shaft 12 (and so the testing end 2 or 22) parallel to the axis of the actuator shaft 12. Consequently, if the housing 1 is inclined from the horizontal, the accelerometer 15 provides a signal indicative of the angle of tilt of the housing 1 from the
20   horizontal. As indicated by the broken line 18 the signals from the accelerometer 15 may be fed back to the control circuit 14, in order to compensate for this inclination from the horizontal.

Claims

1.   A device for measurement of biomechanical and viscoelastic properties of skin of a soft biological tissue with elastic properties, the device comprising a housing comprising electronic, digital and mechanical elements with at least one sensor; a testing end with a contact surface which can be adhered to the surface of the skin of the soft biological tissue, and subjected to a mechanical force by an actuator along an axis of movement in a direction parallel to the surface of the skin; and an accelerometer arranged to record the acceleration of the testing end; the testing end being shaped such that the contact surface extends in a plane that is parallel to the axis of movement of the testing end; wherein the actuator is arranged to subject the testing end to a force such that the skin is subjected to a pre-set tension, and then to apply a brief mechanical impulse, while continuing to apply the pre-tension force; and wherein after the application of the brief mechanical impulse the resulting damped natural oscillation is recorded with data from the accelerometer; and a signal processing unit to calculate properties of the skin from the data from the accelerometer during the damped natural oscillation.

2.   A device as claimed in claim 1 wherein the contact surface is of area at least 20 mm².

3.   A device as claimed in claim 2 wherein the contact surface is of area at the least 50 mm².

4.   A device as claimed in any one of the preceding claims wherein the contact surface is circular or oval.

5.   A device as claimed in any one of the preceding claims wherein the testing end is L-shaped.

6.   A device as claimed in any one of the preceding claims also including a gravitational sensor and a feedback circuit to ensure operation of the device is unaffected by the orientation of the housing relative to the gravitational field.

7.   A device as claimed in claim 6 wherein the accelerometer is arranged to provide a signal indicative of the orientation of the housing relative to the gravitational field, and wherein signals from the accelerometer are fed to a control circuit of the actuator, so enabling the pre-tension force and the mechanical impulse force to be compensated for the inclination from the horizontal.

8. A method of measuring biomechanical and viscoelastic properties of skin of a soft biological tissue with elastic properties, using a device comprising a housing comprising electronic, digital and mechanical elements and sensors, and a testing end with a contact surface which can be adhered to the surface of the skin of the soft biological tissue, and which is movable by an actuator along an axis parallel to the surface of the skin, the testing end being shaped such that the contact surface extends in a plane that is parallel to the axis of movement of the testing end, the method
comprising the following steps:
- placing the contact surface of the testing end on the measurement point on the surface being measured;
- adhering the contact surface to the surface of the soft biological tissue;
- subjecting the measurement point on the surface to a preset pre-tension in the direction of the axis;
- then subjecting the testing end to a brief mechanical impulse in the direction of the axis with quick release under constant pre-tension;
- registering, with an accelerometer, an acceleration curve of the testing end during a damped natural oscillation in response to the mechanical impulse;
- performing signal processing on signals representing the acceleration during the damped natural oscillation; and thereby
- computing values of the biomechanical and viscoelastic properties of the skin.

9. A method as claimed in claim 8 wherein the mechanical impulse has a duration less than 25 ms.

10. A method as claimed in claim 8 or claim 9 wherein the damped natural oscillation is monitored for up to 400 ms.

11. A method as claimed in any one of claims 8 to 10, wherein the signal processing step comprises filtering out low and high frequencies that are not characteristic of the natural oscillation.

12. A method as claimed in any one of claims 8 to 11, wherein the electronic, digital and mechanical elements and sensors include a gravitational sensor, and a feedback circuit, such that the preset pre-tension and the mechanical impulse have values which are unaffected by the orientation of the housing relative to the gravitational field.

13. A method as claimed in claim 12 wherein the accelerometer is arranged to provide a signal indicative of the orientation of the housing relative to the gravitational field, and wherein signals from the accelerometer are fed to a control circuit of the actuator, so

enabling the pre-tension force and the mechanical impulse force to be compensated for the inclination from the horizontal.
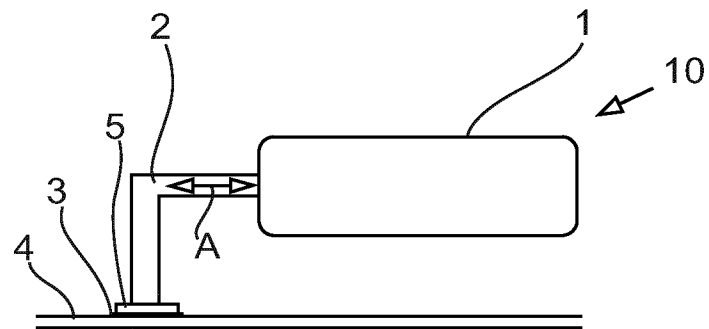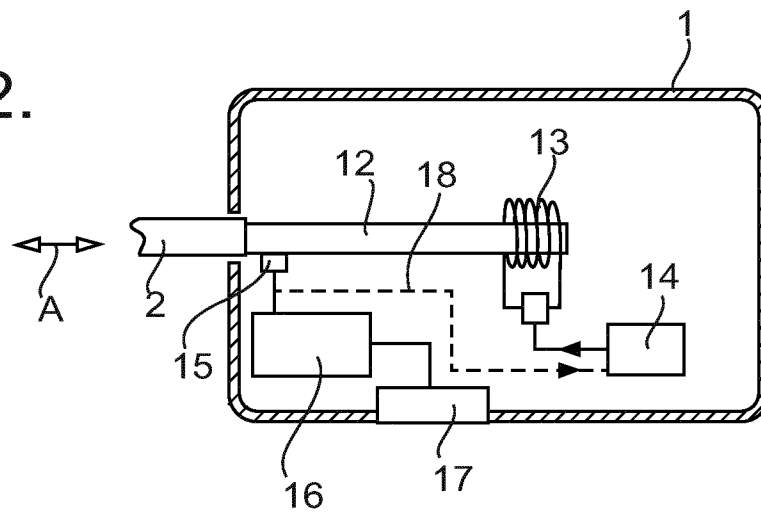
Fig.1.

Fig.2.

Fig.3.