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DEVICE FOR MONITORING PENETRATION INTO ANATOMICAL MEMBERS

The present invention relates to the field of the penetration of material, such as bone structures or the like, that exhibit differences in intrinsic physical quantities.

The present invention relates more particularly to a device for monitoring the penetration of a penetrating means into anatomical structures, and especially bone structures, of a living body, said structures having at least two regions of different electrical impedance.

In spinal surgery, for example, when drilling the pedicle, it frequently happens that the vertebral bone cortex is pierced, broken or chipped by the penetrating drill bit. Depending on the authors, 15 to 40% of pedicle screws are thus improperly positioned, with a clinical manifestation (pain, paralysis, hemorrhaging, etc.) in 1 to 2% of the cases and therefore require further intervention.

Surgeons sometimes use equipment such as the following:

- equipment for surgical navigation, which is expensive and cumbersome to implement;

- equipment for monitoring of sensory and/or motor evoked potentials, this being less expensive but also restricting as it requires the presence of a specialist whose mission is solely to carry out this monitoring operation.

As a result, in most cases the operators rely solely on their knowledge of anatomy and their experience in order to accomplish this risky surgical procedure.

The foregoing is also true in the case of other surgical fields.

In the field of drilling bone bodies, the prior art also includes international patent application WO 01/01875.

This patent application discloses a device that uses the ability of nerves and muscles to transmit signals, in order to warn the user when the drilling means comes into contact with a nerve, so as to prevent any lesion of said nerve.

The prior art also teaches the use of impedance measurement in medical devices.

For example, the prior art includes the United States Patent US 4 630 615 which relates to a neural stimulation system that incorporates an apparatus for measuring or determining impedance in which it is desired to manage and determine the changes in impedance in a guide connected to a

cathode implanted into the epidural space of a spinal column. Such a neural stimulation system is typically used when it is desired to block off pain signals that are sent to the brain, which system may also be used for the treatment and/or relief of symptoms involving uncoordinated movements of the spinal column, such as epilepsy, spasticity, cerebral paralysis, etc.

The prior art also includes British Patent Application GB 2 335 990 that relates to a system for mechanical penetration of a needle and for stopping the penetration if a different impedance is detected at the end of the needle.

The object of that system is to inform the user when the end of the needle has definitely reached the desired depth, either using an impedance value or using a change in impedance.

The object of that system is thus absolutely not to prevent a determined depth being reached.

Furthermore, that system requires, for each patient, an experimental determination of the impedance values or of the changes in impedance, as explained on the last page of that application, which absolutely does not allow this system to be adapted for the purpose of preventing a determined depth being reached.

The prior art also includes French Patent Application FR 2 101 911 which relates to an instrument for measuring the length of the root canal of a tooth.

That instrument is used to deduce the length of a hollow body by the subsequent measurement of the distance between two reference marks after these two reference marks have been placed into longitudinal abutment, respectively in the bottom of the tooth canal in the case of the probe, and the crown or the upper edge of the cavity in the case of the rubber piece.

That instrument allows the user to be informed, after having made a cavity, about the depth of this cavity; it does not allow real-time monitoring of the penetration of a penetrating means into anatomical structures.

Another drawback of the techniques of the prior art is that are cumbersome to implement and tend to extend the operation time, thus increasing the associated risks.

The present invention aims to remedy the drawbacks of the prior art by proposing a device that allows real-time monitoring of the penetration of the penetrating means (the drilling means or the like) into the material, by measuring the differences in a physical quantity as the penetration proceeds, so as to allow the user to know where the end of the penetrating means is and thus prevent any lesion.

The physical quantity used is the electrical impedance measurement.

It is important to point out that the use of the electrical impedance measurement may be applied to many different technical fields and not only to the field of drilling bony bodies.

The present invention relates, in its widest sense, to a device for monitoring the penetration of a penetrating means as claimed in claim 1.

This device includes at least:

- at least one impedance meter that can be connected to at least two electrodes, at least one of which is located at a distal end of said penetrating means, said impedance meter continuously measuring the impedance between the two electrodes at least during the penetration; and
- at least one warning device capable of producing a warning signal in the event of a change in impedance being detected by the impedance meter.

In one embodiment, the device further includes an electrostimulator capable of producing a stimulation and able to be connected to at least two electrodes, at least one of which is located at a distal end of said penetrating means.

In this embodiment, at least one electrode able to be connected to an electrostimulator and at least one electrode able to be connected to an impedance meter are preferably connected together. Thus, it is the same electrodes that serve both for delivering the neuromuscular stimulation and for measuring the impedance.

Throughout the text that follows, the term "distal end" is understood to mean, of course, as in the case of any surgical instrument, the end with respect to the handle used for holding the instrument, which is located at the proximal end.

Said warning signal is preferably a visual and/or audible and/or tactile signal.

The neuromuscular stimulation produced by the neuromuscular electrostimulator preferably has a frequency of less than or equal to 10 Hz, a voltage of less than or equal to 4 volts and a pulse of duration of less than or equal to 400 μ s.

In one embodiment, an electrode is formed by a contact surface located at the distal end of said penetrating means and another electrode is formed by a contact surface intended to be positioned on an external surface of the anatomical structures.

In another embodiment, said electrodes are each formed by a contact surface respectively located at the distal end of said penetrating means, said contact surfaces being separated by an insulator.

In one version of this embodiment, the proximal electrode has a contact surface greater in area than the contact surface of the distal electrode.

In one embodiment, at least one distal electrode is formed by a contact surface located on a partial peripheral portion of the distal end of the penetrating means so as to make it possible to detect a change in impedance in a direction approximately perpendicular to the axis of penetration of the penetrating means.

The device according to the invention preferably includes means for rotating said penetration means.

In one version of the invention, the impedance meter, the warning device and optionally the electrostimulator are positioned on a removable electronic card, which includes means for connecting said electrodes, so as to allow the device to be sterilized independently of the electronic part.

The device according to the invention preferably includes, for this purpose, a hollow handle for accommodating said electronic card.

The present invention also relates to:

- a fixed penetrating means, and especially a probe, squared tip, spatula or curette, or
- a penetrating means that can be rotated, and especially a drill screw, drill tap or drill bit for a device according to the invention.

The present invention also relates to an electronic card as defined above for a device according to the invention.

This electronic card is preferably able to be sterilized and, also preferably, is placed in a casing that preserves sterility.

The present invention further relates to a manual or motor-operated drilling instrument, especially for drilling the vertebral pedicle, said instrument including a penetrating means and a device for monitoring the penetration of said penetrating means according to the invention.

Advantageously, the present invention allows the user to be informed in real time of the progression of the penetrating means optionally associated with the drilling instrument.

Also advantageously, the electrode located upstream of the penetration is positioned close to the mechanical

penetration effect and thus makes it possible to obtain a very high sensitivity in detecting a change in impedance.

Advantageously, the invention thus makes it possible to avoid complete transpiercing of the body to be penetrated or pierced, when this is not desired, and in the case of penetration of a bone body, to prevent a lesion of the tissues located beneath the bone body.

The invention will be more clearly understood with the aid of the description, given below purely by way of explanation, of one embodiment of the invention, with reference to the appended figures:

- figure 1 illustrates a partial sectional view of an instrument fitted with a device according to the invention;

- figure 2 illustrates a detailed sectional view of a first embodiment of the penetrating means in the form of a probe;

- figure 3 illustrates a detailed sectional view of a version of the second embodiment of the penetrating means in the form of a probe;

- figure 4 illustrates a detailed sectional view of another version of the second embodiment of the penetrating means in the form of a probe;

- figure 5 illustrates a sectional view of the penetration P of the penetrating means of figure 2;

- figure 6 illustrates a sectional view of the penetration P of the penetrating means of figure 3;
- figure 7 illustrates a sectional view of the penetration P of the penetrating means of figure 4;
- figures 8 and 9 illustrate a front view and top view, respectively, of a penetrating means according to the invention formed by a spatula;
- figures 10 and 11 illustrate a front view and a top view, respectively, of a penetrating means according to the invention formed by a curette;
- figure 12 illustrates a detailed sectional view of a penetrating means according to the invention formed by a drill bit, screw or tap; and
- figure 13 illustrates two examples of the relationship between the measured impedance Z in ohms and the frequency in hertz of an audible signal emitted by the warning device.

The device (1) according to the invention, illustrated in figure 1, is a device for monitoring the penetration of a penetrating means (2) into anatomical structures, and especially bone structures (3) of a living being, said structures having at least two regions of different electrical impedance (Z_1 , Z_2).

For example, the penetrating means (2) makes it possible, itself or combined with a drilling instrument, to drill a hole (20) in said bone structures (3).

A bone body is composed of soft internal tissue (marrow, spongy bone) and hard external tissue (cortex); it is itself surrounded by soft tissues: muscles, tendons, ligaments, blood vessels and nerves.

Owing to these differences in nature, the bone cortex has physical properties different from those of the tissues with which it is contact: it is for this reason that it is also visible in medical images: conventional radiography, scanner, echography, magnetic resonance imaging.

If the instrument used to penetrate the bone cortex is fitted at its distal end with a means for detecting and indicating this difference in physical properties, the operator will therefore immediately have information informing him that he has passed through this cortex or that he is about to do so.

However, it turns out that the bone cortex and the soft tissues also have different impedances.

In a base version, the device (1) according to the invention comprises:

- at least one impedance meter (7) that can also be connected to at least two electrodes, at least one of which

is located at a distal end of said penetrating means (2),
said impedance meter continuously measuring the impedance
between the two electrodes at least during the penetration;
and

- at least one warning device (8) capable of producing
a warning signal in the event of a change in impedance being
detected by the impedance meter (7).

Thus, thanks to the impedance meter (7), it is possible
to monitor the penetration of the detection means associated
with the penetrating means (2) progressively as the latter
penetrates into the bone structures (3).

The way in which the impedance meter or meters (7) are
used to deduce therefrom the position of the associated
detection means constitutes one particular method of
monitoring the penetration of a penetrating means (2)
through a body having at least two regions of different
electrical impedance (Z_1 , Z_2).

The device (1) includes a warning device (8) which can
emit:

- a visual warning signal modulated, for example, by
the use of a flashing warning lamp or a ramp of warning
lamps; and/or

- an audible warning signal frequency-modulated and possibly intensity-modulated, for example by the use of a loudspeaker; and/or

- a tactile warning signal frequency-modulated and possibly intensity-modulated, for example by the use of a vibrator,

providing a warning right from the start of the change in measured impedance and when a threshold of a change in measured impedance is exceeded.

This modulated warning signal is proportional to the change in impedance.

This warning device (8) is preferably positioned on or in the instrument, as may be seen in figure 1.

The device (1) may optionally further include a display means for displaying the change or changes in impedance, which is connected to an impedance meter (7). This display means, formed for example by a display screen, makes it possible to monitor the variation, in the form of curves, of the change in impedance progressively with the penetration of the penetrating means (2).

In one embodiment, the device (1) further includes at least one electrostimulator (4), preferably a neuromuscular stimulator, capable of producing a preferably neuromuscular stimulation and able to be connected to at least two

electrodes (5, 6), at least one of which is located at a distal end of said penetrating means (2).

The neuromuscular stimulation produced by the neuromuscular electrostimulator has:

- a frequency of less than or equal to 10 Hz, preferably around 2.5 Hz;
- a voltage of less than or equal to 4 volts, preferably around 1 volt; and
- a pulse of duration of less than or equal to 400 μ s, preferably around 150 μ s.

In the event of the bone cortex being penetrated by the penetrating means, the distal portion (tip) of the latter comes into contact with the soft tissues located on the outside of the cortical envelope. The stimulation pulses may then propagate easily into these soft tissues of low impedance and stimulate the nerves possibly located near the tip of the penetrating means. Two situations then arise:

- a) if they are motor nerves, they will then cause contractions of the muscle groups with which they are associated, at the rate of the stimulation pulses; these contractions will be detected and recognized, either by an electromyography connected up to the patient beforehand, or clinically by the operator himself in relation to the patient's movements;

b) if they are sensory nerves, a suitable device will be able to detect their stimulation, which is also recognizable by its rate.

In a preferred version of the invention, the electrodes (5, 6) may be connected, using connection terminals (18), both to the electrostimulator (4) and to the impedance meter (7). Thus, it is the same electrodes that serve both for the emission of the neuromuscular stimulation and for the impedance measurement.

The penetrating means (2) of the device (1) may be:

- either fixed, and consisting especially of a probe, a squared tip, a spatula or a curette;
- or capable of being rotated, and consisting especially of a drill screw, a drill tap or a drill bit.

In the latter case, the device (1) then includes drive means (9) for the rotation R of said penetrating means (2).

The drive means (9) consist, for example, of an electric motor capable of rotating the penetrating means (2) and form, in combination with the penetrating means (2), a boring instrument (1) of the borer type.

In the section below, the penetrating means (2) is formed by a probe, but the configurations presented are applicable to any type of penetrating means (2).

In a first embodiment, illustrated in figures 2 and 5, a distal electrode (5) is formed by a contact surface C located at the distal end of said penetrating means (2) and another, proximal electrode (6) is formed by a contact surface C' intended to be positioned on an outer surface of the anatomical structures, including on the operation incision.

The penetrating means (2) has a central portion (15) that is conducting and a peripheral portion (13) that is insulated right to a distal end (14) bared, that is to say not insulated, over a few millimeters. The surface C has an area of less than 10 mm^2 , around 4 mm^2 , and the surface C' has an area of around 20 mm^2 .

Thus, the first pole of the electronic stimulation/measurement device is formed by the distal end of the penetrating means (2) of the instrument and the other pole is formed by a reference connection on the patient.

In a second embodiment, illustrated in figures 3 and 6 on the one hand and 4 and 7 on the other, said electrodes (5, 6) are each formed by a contact surface C, C' respectively, which is located at the distal end of said penetrating means (2), said contact surfaces C, C' being separated by an insulator (12).

In the version illustrated in figures 3 and 6, the penetrating means (2) comprises a conducting central portion (15) and a conducting outer portion (16), said central portion (15) and said outer portion (16) being separated by a cylindrical insulator (12). The two conducting portions each form one pole of the electronic device.

Thus, the outer portion (16) forms a conducting outer tube, hollow at its center, and the central portion (15) forms a conducting inner cylinder, the central (15) and outer (16) portions both emerging at the end of the penetrating means (2) so as to form the two surfaces C and C' that are isolated from each other.

In this version, the proximal electrode (6) has a contact surface C' greater in area than the contact surface C of the distal electrode (5). The surface C has an area of less than 10 mm^2 , around 4 mm^2 , and the surface C' has an area of greater than 100 mm^2 , around 400 mm^2 .

In the version illustrated in figures 4 and 7, the penetrating means (2) comprises an insulating peripheral portion (13) and a noninsulated distal end (14), having two electrodes (5, 6) that are positioned so as to be perpendicular to the axis A of said penetrating means (2) and separated by an insulator (12). The two electrodes (5, 6) each form one pole of the electronic device.

In this version, the electrodes (5, 6) have contact surfaces, C and C' respectively, of approximately the same area, less than 10 mm^2 and around 4 mm^2 . The contact surfaces C, C' are separated by an insulator (12) of thickness less than or equal to 1 mm along an axis A of penetration of said penetrating means (2).

Figures 5, 6 and 7 illustrate one moment during the penetration P of the penetrating means (2), during which a change in a physical quantity, and more particularly a change in electrical impedance, is detected by the impedance meter (7). Such a change occurs especially when the penetrating means (2) leaves the cortex of the bone body, represented by the region Z1, and penetrates a soft surrounding tissue, represented by the region Z2.

In the embodiment that combines an impedance meter with an electrostimulator, the stimulation pulses of the device have a waveform, a voltage and an intensity that are known; it is therefore possible to deduce therefrom the impedance measured by the electrodes associated with the device and in particular by the electrodes placed at the distal portion (the tip) of the penetrating means.

This "local impedance" information can then be converted into signals capable of operating the warning device (8).

The penetrating means (2) may have one pair of electrodes or even several pairs of electrodes.

For each pair of electrodes, at least one electrode is positioned at the distal end (14) of said penetrating means (2).

In one embodiment, at least one distal electrode (5) is formed by a contact surface C located on a partial peripheral portion of the distal end of the penetrating means (2) so as to make it possible to detect a change in impedance in a direction approximately perpendicular to the axis A of penetration of the penetrating means (2). Thus, by rotating the penetrating device (2) and, by observing the warning device (8), it is possible to deduce, from the measured change in impedance thanks to this electrode, the configuration of the distal end of the hole (20).

In the section below, the penetrating means (2) is formed by a drill bit.

The penetrating means (2) is provided, for example, with a helical thread (19) shown in figure 12, or with several helical threads, which are formed along the axis A so as to allow holes (20) to be drilled.

The drill bit comprises a conducting central portion (15) and a conducting helical thread (19), the central portion (15) and the helical thread (19) being separated by a cylindrical insulator (12). The two conducting portions each form one pole of the electronic device.

In this version, the proximal electrode (6) has a contact surface C' greater in area than the contact surface C of the distal electrode (5). The surface C has an area of less than 10 mm^2 , around 4 mm^2 , and the surface C' has an area of greater than 10 mm^2 , around 40 mm^2 . The contact surfaces C, C' are separated by an insulator (12) of thickness less than or equal to 1 mm along an axis A of penetration of said penetrating means (2).

This configuration is also applicable to a screw and especially to a self-drilling screw.

In one embodiment of the invention, the impedance meter (7) and the warning device (8), or the impedance meter (7), the warning device (8) and the electrostimulator (4), are positioned on a removable electronic card (10), visible in figure 1, which includes means for connecting said electrodes (5, 6). Thus, the mechanical part of the device (1) can be sterilized in an autoclave, without the electronic part.

It is also possible to provide for the electronic card (10) to be of one-time use - it is delivered in suitable packaging and is fitted by the surgeon into the instrument that he requires (a probe, squared tip, spatula, curette, screw driver, borer, etc.) when he wishes to monitor the progressive penetration of the associated instrument that he is using. The electronic card (10) is thrown away after the operation, whereas the instrument is sterilized.

It is also possible to produce an electronic card (10) that can be sterilized, especially by chemical action.

The electronic card (10) may also be positioned in a casing that preserves sterility.

To allow the electronic card (10) to be fitted into the instrument, the device (1) preferably has a hollow handle (11) into which the electronic card (10) can be placed. Access to the inside of the hollow handle is gained by removing a plug (19).

The connection terminals (18) allow the electrodes to be connected. They may be positioned around the periphery of the handle (11), in order to connect up one or more electrodes, and in the distal portion of the handle relative to the plug (19), in order to allow the electrode(s) located at the distal end of the penetrating means (2) to be connected.

The electronic stimulation/measurement device positioned on the electronic card (10) measures, during use of the instrument, the electrical impedance between the two poles each formed by one electrode and indicates (in an audible, visual or tactile manner) in real time the values and/or changes in said impedance, in particular in the event of the pedicle cortex being breached.

Figure 13 shows two representations of the relationship between the measured impedance, plotted on the x-axis, and the frequency of an audible signal emitted by the warning device, plotted on the y-axis. This relationship may, for example, be linear, as illustrated by the discontinuous line, or may be stepped. This relationship is obtained with surfaces C and C' about 5 mm² in area.

In order to use the device according to the invention for boring, it may be useful to provide a number, or set, of penetrating means (2), each penetrating means (2) of which has a different diameter.

The invention has been described above by way of example. Of course, a person skilled in the art is capable of producing various alternative embodiments of the invention without thereby departing from the scope of the patent.

CLAIMS

1. A device (1) for monitoring the penetration of a penetrating means (2) into anatomical structures, and especially bone structures (3), of a living body, said structures having at least two regions of different electrical impedance (Z_1 , Z_2), characterized in that it includes at least one impedance meter (7) that can be connected to at least two electrodes, at least one of which is located at a distal end of said penetrating means (2), said impedance meter continuously measuring the impedance between the two electrodes at least during the penetration and at least one warning device (8) capable of producing a warning signal in the event of a change in impedance being detected by the impedance meter (7).

2. The device (1) as claimed in claim 1, characterized in that it includes at least one electrostimulator (4) capable of producing a stimulation and able to be connected to at least two electrodes (5, 6), at least one of which is located at a distal end of said penetrating means (2).

3. The device (1) as claimed in claim 2, characterized in that at least one electrode (5, 6) able to be connected to an electrostimulator (4) and at least one electrode (5, 6) able to be connected to an impedance meter (7) are connected together.

4. The device (1) as claimed in any one of claims 1 to 3, characterized in that said warning signal is a visual and/or audible and/or tactile signal.

5. The device (1) as claimed in any one of claims 1 to 4, characterized in that the neuromuscular stimulation produced by the electrostimulator (4) has a frequency of less than or equal to 10 Hz, a voltage of less than or equal to 4 volts and a pulse of duration of less than or equal to 400 μ s.

6. The device (1) as claimed in any one of claims 1 to 5, characterized in that an electrode (5) is formed by a contact surface C located at the distal end of said penetrating means (2) and in that another electrode (6) is formed by a contact surface C' intended to be positioned on an external surface of the anatomical structures.

7. The device (1) as claimed in any one of claims 1 to 5, characterized in that said electrodes (5, 6) are each formed by a contact surface C, C' respectively located at the distal end of said penetrating means (2), said contact surfaces C, C' being separated by an insulator (12).

8. The device (1) as claimed in claim 7, characterized in that the proximal electrode (6) has a contact surface C' greater in area than the contact surface C of the distal electrode (5).

9. The device (1) as claimed in any one of claims 6 to 8, characterized in that at least one distal electrode (5) is formed by a contact surface C located on a partial peripheral portion of the distal end of the penetrating means (2) so as to make it possible to detect a change in impedance in a direction approximately perpendicular to the axis A of penetration of the penetrating means (2).

10. The device (1) as claimed in any one of claims 1 to 9, characterized in that it includes means (9) for rotating said penetrating means (2).

11. The device (1) as claimed in any one of claims 1 to 10, characterized in that the impedance meter (7), the warning device (8) and optionally the electrostimulator (4) are positioned on a removable electronic card (10), which includes means for connecting said electrodes (5, 6).

12. The device (1) as claimed in claim 11, characterized in that it includes a hollow handle (11) for accommodating said electronic card (10).

13. A fixed penetrating means (2), and especially a probe, squared tip, spatula or curette, or a penetrating means (2) that can be rotated, and especially a drill screw or drill bit, for a device (1) as claimed in any one of claims 1 to 12, characterized in that it includes at least one electrode (5, 6).

14. A manual or motor-operated drilling instrument, especially for drilling the vertebral pedicle, said instrument comprising a penetrating means (2), characterized in that it includes a device (1) for monitoring the penetration of said penetrating means (2) as claimed in any one of claims 1 to 12.

15. An electronic card (10) for a device (1) as claimed in claim 11 or claim 12, which includes means for connecting said electrodes (5, 6).

16. The electronic card (10) as claimed in claim 15, characterized in that it can be sterilized.

17. The electronic card (10) for a device (1) as claimed in claim 15 or claim 16, characterized in that it is placed in a casing that preserves sterility.