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(54) **Bone fixation system with data logging device**

(57) The fixation system, which is for use in the treatment of a fractured bone, is provided with a data logging device 7 capable of sensing and storing data about at least one physical characteristic of the system, e.g. relative position, strain, pressure or displacement. The data logger may be accommodated within the support bar 4 of an external fixator as shown or may be associated with a plaster of Paris cast or curable resin support. The logger may be provided with means to sense the relative axial displacement of components 6a, 6b of the bar 4 and may count the number of times a certain level of displacement occurs during a given period, such information being relayed via a transducer to the logger memory for subsequent reading.

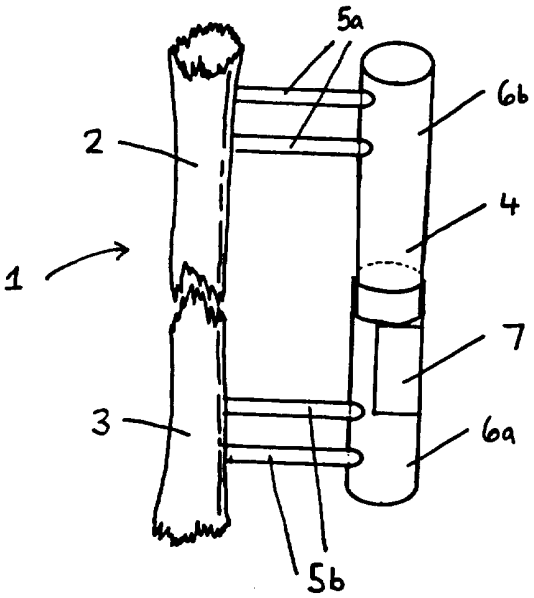

FIGURE 1

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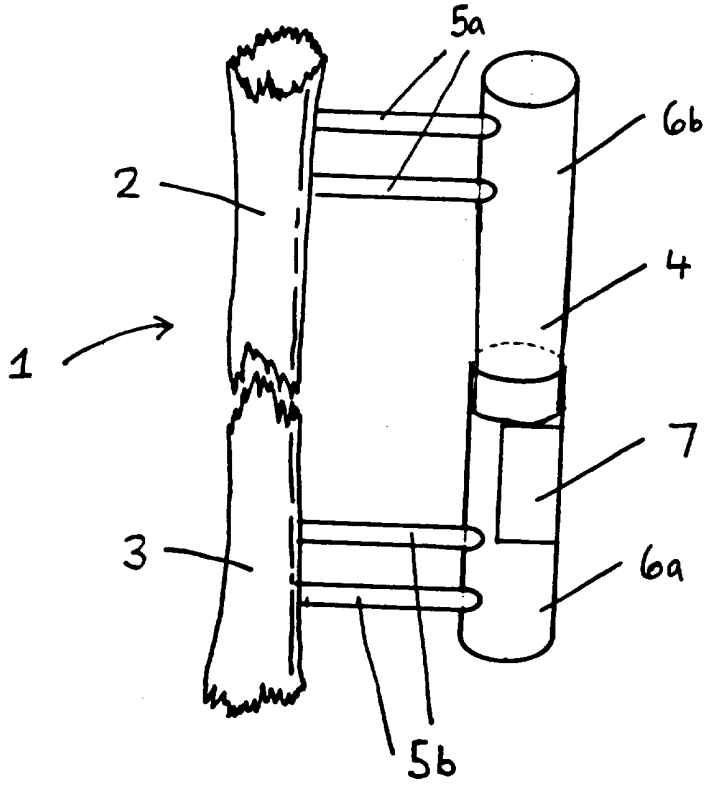

FIGURE 1

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BONE FIXATOR

This invention relates to a bone fixation system. In particular it relates to an external bone fixation system for use in the treatment of fractured bones such as the tibia and a method of monitoring the use of such a bone fixator.

Bone is adept at self-healing, with new bone (callus) formation at the fracture site being able to reunite the fragments of the fractured bone. Medical treatment of fractured bone aims to assist and promote this natural healing.

One method of treatment involves the use of internal fixation whereby an implant (e.g. a bone plate) is directly attached to the bone fragments to rigidly hold them in place whilst healing takes place. Such treatment results in excellent alignment of the bone fragments. Such treatment may not allow relative motion between the two rigidly held bone fragments. Biological research has shown that certain types of callus formation is only triggered and maintained by relative motion of the bone fragments. Rigid fixation of the bone fragments therefore may lead to a reduction in the formation of certain types of callus and therefore to delays in natural healing. Other types of medical treatment such as external supports (e.g. plaster of Paris casts), although allowing relative movement of the bone fragments and thereby promoting good callus formation, may not able to assist in precise and accurate bone fragment realignment. Some external bone fixators have been developed for the treatment of bone fractures which hold the fragments sufficiently rigidly together to allow accurate realignment and yet at the same time allow sufficient relative movement between the bone fragments to promote and not inhibit callus formation. Such external fixators are applied externally to the injured limb and

are attached to the bone fragments by bone pins or screws passing through the soft tissue of the limb into the bone. Bridging the gap between the pins in the two separate fragments is a relatively rigid support mechanism, which holds the fragments in alignment. To promote callus formation the external fixator can be adapted to allow specific and controlled types of movement between the fractured bones. Such movement is generally effected by corresponding movement in the fixator itself, e.g. axial relative movement between components of the fixator can lead to relative axial movement of the fractured bones.

Whilst many bone fixation systems, such as those discussed above, have been developed and some are presently in use clinically, there has been to date no means of accurately obtaining continuous information about their use in practice by patients. Obtaining such information would be of use in the assessment of the usefulness of current designs of bone fixation systems, in the development of future improved designs, and in the assessment of the efficient treatment of fractured bones.

There is therefore a need for means by which the use of a bone fixation system can be monitored, and more particularly by which the use of an external bone fixator, which allows relative movement between fractured bones, can be monitored.

According to the present invention there is provided a bone fixation system for use in the treatment of a fractured bone, which fixation system is provided with a data logging device which is capable of sensing and storing data about at least one physical characteristic of the fixation system.

According to the present invention there is also provided a method of monitoring the use in the treatment of a fractured bone of a bone fixation

system, which method comprises sensing and storing data about at one least one physical characteristic of the fixation system using a data logging device with which the fixation system is provided.

The data logging device may be separable from the fixation system or it may be an integral part thereof. It may, for example, be optionally removably attached to a suitable part of the fixation system. It may be so attached externally or more preferably internally, e.g. within a support bar or limb of the fixation system.

The data logging device must be capable of recording data in a form in which it can be readily used by a computer. In general terms in the data logging device information about the physical characteristic being sensed is fed via a suitable transducer, which converts it into a usable signal, to a memory where it is recorded and stored. The data logging device may at a convenient point in time be suitably connected to a computer for downloading, i.e. reading of the data stored in the memory. The data logging device may be adapted so that it can be downloaded whilst the fixation system is still in use by a patient (i.e. whilst it is still in place on the limb of the patient), alternatively either the data logger alone or the fixation system incorporating the data logger can be removed from the patient and downloaded in isolation.

The data logging device must be portable so as not to hinder the free movement of the patient using the fixation system. It should, therefore, be independently powered, e.g. using suitable batteries.

If sensing or recording of a physical characteristic is to take place at timed intervals the data logging device should be provided with a clock of suitable form.

The data logging device can be adapted to sense any desired characteristic or characteristics. Examples of physical characteristics which may be sensed are relative position, strain, pressure, and displacement. Information regarding displacement of the fixation system or components of the fixation system is particularly useful as it can be analysed to directly relate to bone callus formation and fracture healing. Various aspects of displacement of the fixation system and its components may be monitored using the present invention, e.g. the type of displacement (axial, lateral/medial, posterior/anterior, angular etc.), the degree or extent of displacement, and the frequency of displacement. The present invention could, for example, be used to record the number of times a given (predetermined) level of displacement occurred in a given time interval, e.g. a half hour. Such recording could take place continuously throughout the day and could provide information as to how regularly the fixation system or one or more of its components was displaced. As in certain cases displacement in the fixation system is directly related to displacement of the fractured bones such information could be used to investigate the amount or type of relative movement occurring at the fracture site. Little displacement would be expected initially whilst the affected limb was too painful to move. Displacement should increase as the patient began to use the limb more but the fractured bones were still relatively mobile. Displacement frequency should decrease again with time as callus formation increased and "knitted" the bones back together preventing relative movement. Information on displacement frequency could therefore show how healing was progressing. The logged information could show, for example, that an observed patient was not moving enough

to promote healing.

The data logging device or the fixation system could be provided with indicator means which indicated when a certain event or condition, as measured by the data logger, had occurred. It could show, for example whether given levels of displacement had occurred. This could motivate patients to move more if certain targets of displacement were not reached as shown by the indicator.

The present invention may, for example, be used with any suitable bone fixation system. It could for example be used with an internal fixation system but more preferably it is used with an external bone fixation system. Suitable external fixation systems include external supports, such as a plaster of paris cast or curable resin support or any type of external bone fixator. It may, for example, be used with an external bone fixator which allows relative movement between the bone fragments. One such fixator is the Orthofix™ external fixator, e.g. as described in EP-A-0011258. In such a fixator the support bar or mechanism is formed by telescopic elements, so that the distance between the pin or set of pins attached to one of the bone fragments to the pin or set of pins attached to the other bone fragment can be varied. Such distance variation allows for forced axial movement of the bone fragments relative to each other.

Another fixator which is particularly preferred for use in the present invention allows relative angular movement of the fractured bones, e.g. as described in British Patent Application No. 9420188.6. (filed 6th October 1994). Such a fixator allows controlled angular motion of the bone fragments with respect to each other around the bone fracture site. In more detail such an external fixator comprises:

means of attachment to a first bone fragment of

the fractured bone;

means of attachment to a second bone fragment of the fractured bone;

and a rigid support bar extending between the two means of attachment, which support bar comprises first and second relatively movable elements each of which is movably mounted so as to be capable of angular motion in one plane, with the plane in which the second element moves being substantially orthogonal to the plane in which the first element moves, which first and second elements are coupled together in such a way as to allow simultaneous angular movement of the support bar in the two substantially orthogonal planes.

In a preferred embodiment of such a fixator the first member is pivotally mounted on a third member by means of a pivot pin about which it is able to pivot and the second member is provided with one or more projections which are received within one or more arc-shaped slot on the third member. For a compact design one of the first or second members may take the form of an open housing into which the other member may be received. If present the third or coupling member may also be received within the housing. The dimensions of the housing may be used to limit the degree of freedom of movement of the movable member mounted within it.

The means of attachment of the fixation system to or around the bone fragments may take any suitable form such as that used conventionally for the type of fixation system in question. It is usual for external fixators to be fixed to the bone fragments by percutaneous or transcutaneous pins or screws, i.e. pins or screws which transect the skin. Such bone pins or screws may either be transfixion pins, i.e. ones which pass completely through the bone and limb and emerge on the other side, or half pins which fasten into the bone and do not emerge therefrom. If

transfixion pins are used a fixator can be attached on either end of the pins, i.e. a fixator can be attached on either side of the limb (bilateral). If half pins are used only one fixator will be attached on only one side of the limb (unilateral). The fixator may be attached to the bone fragments by any suitable number of pins, e.g. one, two or more. It is preferred that three pins are used to attach to each bone fragment as this number leads to good stress reduction at the bone interface and would allow for the removal of one pin if necessary, leaving two for sufficient stability. If only two pins were used and one was required to be removed, further operation may be required for the insertion of another pin to ensure stability. The fixator should have means of attachment, for example clamps, able to fixedly attach to the bone pins or screws. Such means may be integral with or separate from the fixator itself.

The fixation system and its data logging device may be made of any suitable material, such as those used conventionally in orthopaedic and prosthetic components. Such materials are those which are corrosion resistant, cleanable and sterilisable. The material is preferably and where possible X-ray transparent or translucent to allow X-rays of the fracture to be carried out whilst the fixation system is in place. Carbon fibre composites are suitable materials that would be X-ray translucent.

The material chosen for the data logging device may be such as to reduce its weight to a minimum, e.g. cast aluminium high strength alloys could be used.

The present invention is advantageous as it will allow the use of bone fixation systems, including those which allow relative movement of fractured bones, to be monitored and assessed. This will provide information useful in the assessment of current designs of fixation

systems, in the development of future improved designs and in the assessment of the efficient treatment of fractured bones, e.g. to predict optimum fracture healing time. The invention will allow monitoring of the fracture over a period of weeks even months.

For a better understanding of the present invention and to show how the same may be put into effect reference will now be made, by way of example, to the accompanying drawing, in which:-

Figure 1 is a schematic view of an external fixator attached to a fractured bone.

In Figure 1, which is schematic only, a fractured bone 1 is shown, which has been broken into an upper fragment 2 and a lower fragment 3. Support is given to the fractured bone by an external fixator 4. The fixator 4 is in the form of rigid support bar extending substantially parallel to the longitudinal axis of the bone (or as close to parallel thereto as is possible). It is attached to the upper and lower fragments 2 and 3 by two pairs of bone pins 5a, 5b which extend in parallel to each other and substantially perpendicularly to the longitudinal axis of the bone 1.

In this embodiment the support bar 4 is divided into a first (lower) component 6a and a second (upper) component 6b, which fits and slides within the first component 6a. The telescoping of the two components 6a, 6b, i.e. their relative axial movement, leads to corresponding relative axial movement between the bone fragments 2 and 3.

The data logger 7 is accommodated (out of the patient's sight) within the support bar 4. It is provided with means by which it senses the relative axial displacement of the components 6a, 6b of the support bar 4. It may count the number of times a certain level of axial displacement occurs during a given period, e.g. 30 minutes. That information may

then be relayed via a transducer to the memory of the data logger for recording and storing for subsequent reading.

CLAIMS

1. A bone fixation system for use in the treatment of a fractured bone, which fixation system is provided with a data logging device which is capable of sensing and storing data about at least one physical characteristic of the fixation system.

2. A method of monitoring the use in the treatment of a fractured bone of a bone fixation system, which method comprises sensing and storing data about at one least one physical characteristic of the fixation system using a data logging device with which the fixation system is provided.

3. A system or method according to claim 1 or 2, wherein the data logging device is adapted to sense one or more of the following characteristics: relative position, strain, pressure, and displacement.

4. A system according to claim 1, 2 or 3, wherein the data logger is adapted to sense the type of displacement (axial, lateral/medial, posterior/anterior, angular etc.), the degree or extent of displacement, or the frequency of displacement.

5. A system or method according to any preceding claim, wherein the data logging device or the fixation system is provided with indicator means which indicates when a certain event or condition, as measured by the data logger, has occurred.

6. A system or method according to any preceding claim, wherein the bone fixation system is an external bone fixation system.

7. A system or method according to claim 6, wherein the external fixation system is an external support, such as a plaster of paris cast or curable resin support, or a type of external bone fixator.

8. A system or method according to claim 7, wherein the bone fixation system is an external bone fixator which allows relative movement between the bone

fragments.

9. A system or method according to claim 8, wherein the bone fixator allows controlled angular motion of the bone fragments with respect to each other around the bone fracture site.

10. A system or method according to claim 9, wherein the external fixator comprises:

means of attachment to a first bone fragment of the fractured bone;

means of attachment to a second bone fragment of the fractured bone;

and a rigid support bar extending between the two means of attachment, which support bar comprises first and second relatively movable elements each of which is movably mounted so as to be capable of angular motion in one plane, with the plane in which the second element moves being substantially orthogonal to the plane in which the first element moves, which first and second elements are coupled together in such a way as to allow simultaneous angular movement of the support bar in the two substantially orthogonal planes.

11. A system or method according to claim 10, wherein the first member is pivotally mounted on a third member by means of a pivot pin about which it is able to pivot and the second member is provided with one or more projections which are received within one or more arc-shaped slot on the third member.

12. A system or method according to claim 11, wherein one of the first or second members takes the form of an open housing into which the other member may be received.

13. A bone fixation system or method of monitoring a bone fixation system substantially as hereinbefore described with reference to and as illustrated in the accompanying drawing.

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Patents Act 1977
Examiner's report to the Comptroller under Section 17
(The Search report)

Application number
GB 9508828.2

Relevant Technical Fields

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(ii) Int Cl (Ed.6) A61B 17/58; A61F 5/04, 13/04

Search Examiner
L V THOMAS

Date of completion of Search
26 JULY 1995

Databases (see below)
(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

(ii) ONLINE: WPI

Documents considered relevant following a search in respect of Claims :-
1 TO 13

Categories of documents

X: Document indicating lack of novelty or of inventive step.

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A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages		Relevant to claim(s)
X	EP 0450423 A1	(CLASBRUMMEL) see WPI Abstract Accession No. 91-296844/41 and Figures 1, 9	1 to 4, 6 to 8
X	EP 0135394 A2	(UNIVERSITY OF STRATHCLYDE) see page 1 line 29 to page 2 line 29, page 3 lines 11 to 20 and Figure 2	1 to 3, 6 to 8
X	WO 94/16651 A1	(GULLICHSEN) see page 1 lines 1 to 9, page 4 lines 15 to 20 and page 5 lines 6 to 26	1 to 3, 6, 7
X	US 4141349	(ORY ET AL) see column 1 lines 36 to 53, column 2 lines 32 to 61 and column 3 lines 24 to 51	1 to 3

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).