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(54) SYSTEM FOR NORMALIZING IMPLANT STRAIN READINGS TO ASSESS BONE HEALING

SYSTEM ZUR NORMALISIERUNG VON IMPLANTATSBELASTUNGSMESSUNGEN ZUR BEURTEILUNG DER KNOCHENHEILUNG

SYSTÈME DE NORMALISATION DE RELEVÉS DE DÉFORMATION D'IMPLANT POUR ÉVALUER LA CICATRISATION OSSEUSE

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Description

FIELD OF THE INVENTION

[0001] The present invention relates to a system for tracking the progress of bone healing and, in particular, systems that calculate a ratio of strain at multiple locations along an implant and/or a bone

BACKGROUND

[0002] Strain gages can be placed on orthopedic implants to track the progress of bone healing. Upon initial implantation, the implants are expected to experience higher levels of strain which decrease during healing as the bone begins to share more of the load with the implant. Currently, however, implant strain values need to be assessed with a known load applied to the bone in order to evaluate bone healing. A system for tracking the healing process of a bone, including a bone plate with a plurality of strain gages is known from US 2006/0052782 A1. An intramedullary nail having strain sensors is disclosed in US 2008/0300597 A1.

SUMMARY OF THE INVENTION

[0003] The present invention is directed to a system as defined in claim 1, comprising an implant configured for attachment to a bone and a first sensor measuring a strain on a first portion of the implant, the first portion of the implant being configured to be mechanically coupled to a weakened portion of a bone when the implant is coupled to the bone in a target position in combination with a second sensor measuring strain in a non-weakened portion of the bone.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004]

FIG. 1 shows a perspective view of a system according to a first exemplary embodiment of the present invention;

FIG. 2 shows a perspective view of a system according to a second exemplary embodiment of the present invention;

FIG. 3 shows a perspective view of a system according to a third exemplary embodiment of the present invention;

FIG. 4 shows a side view of a bone fixation element of the system of FIG. 3; and

FIG. 5 shows a perspective view of a system according to a fourth exemplary embodiment of the present invention.

DETAILED DESCRIPTION

[0005] The present invention may be further understood with reference to the following description and the appended drawings, wherein like elements are referred to with the same reference numerals. The exemplary embodiment of the present invention relate to a system for tracking the progress of bone healing. In particular, the exemplary embodiments describe systems that calculate a ratio of strain at multiple locations along an implant and/or a bone. An exemplary embodiment of the system may include a first sensor on a surface of the implant adapted to be positioned at a location proximate a weakened portion of the bone. Strain on the implant at this location will be affected by the strength or stiffness of the weakened bone and the load placed on the bone by the patient. A second sensor may be placed on the implant at a location in which strain measured by the second sensor is affected only by the load placed on the bone such that the measured strain is substantially unchanged by the bone healing process. Thus, a ratio between the strains measured by the first and second sensors provides information corresponding to bone healing, regardless of the load on the bone. It will be understood by those of skill in the art that although the exemplary embodiment specifically describe tracking the healing progress of a leg bone, the present invention may be used to track the progress of healing of any load bearing bone. It will also be understood by those of skill in the art that although the exemplary embodiments specifically show and describe two sensors, the present invention may include additional sensors along different areas of the bone to determine ratios corresponding to the bone healing progress of the different areas. In addition, although exemplary embodiments show a bone plate, the present invention may be used with any other fixation element such as, for example, screws, intramedullary devices, external fixators, spine fixation implants and prosthetics.

[0006] As shown in Fig. 1, a system 100 according to a first exemplary embodiment of the invention comprises an implant 102 (e.g., a bone plate) and first and second sensors 104, 106, respectively. The implant 102 is configured for fixation over a target portion of a bone 108 to, for example, fix a fracture 110 or to support a weakened portion of the bone 108. The first and second sensors 104, 106 are mounted along a surface 114 of the implant 102 such that the first and second sensors 104, 106 may be mechanically coupled to the bone 108. Although the surface 114 is shown as facing away from the bone 108 when the implant 102 is fixed to the bone 108 in a desired location, it will be understood by those of skill in the art that the sensors 104, 106 may be mounted along any surface of the implant 102. For example, the sensors 104, 106 may also be mounted on a surface of the implant 102 facing the bone 108 or a surface on a side of the implant 102. The first and second sensors 104, 106, respectively, are positioned on the implant 102 so that, when the implant is in a desired position on the bone 108,

the first sensor 104 is located over a site of the fracture 110 while the second sensor 106 is separated from the fracture 110 over a healthy (i.e., solid) portion 112 of the bone 108 to measure levels of strain and/or load on the implant 102, at these positions along the implant 102. The second sensor 106 should be isolated between two screws locked in a healthy portion 112 of the bone 108 to measure a load on the bone 108.

[0007] The sensors 104, 106 in this embodiment may be passively powered MEMs sensors that are used to measure strain and include an interface for wireless connection to a data collection device as would be understood by those skilled in the art. In another embodiment, the sensors 104, 106 may be powered chips that are connected to a printed circuit board (PCB). This permits strain on the implant 102 to be measured and transmitted to the data collection device for further processing without physically accessing the sensors 104, 106. It will be understood by those of skill in the art that the strain measurements detected by the sensors 104, 106 are not required to represent actual strain values, but may include any signal that changes based on changing strains of their substrates. For example, the MEMS sensors 104, 106 may be RF devices that deform when a strain is placed thereon, resulting in a frequency shift caused by a change in capacitance of the sensors 104, 106 such that the frequency shift corresponds to a change in strain. As would be understood by those skilled in the art, an external device may be employed to wirelessly provide a signal to the sensors 104, 106. Changes in a returned signal may then be measured to determine a level of strain to which the sensor is subject. A ratio of the strain measured by the first sensor 104 to the strain measured by the second sensor 106 may then be determined by a physician or other professional to track healing progress. Alternatively, the ratio may be determined by a processing device that may also store the strain measurements and the determined ratios (e.g., in an internal memory or on an external storage device) so that changes in the ratio may be reviewed to more fully understand the progression of the healing over time.

[0008] It will be understood by those of skill in the art that when the bone 108 is initially broken or fractured, strain on the implant 102 at the location of the fracture 110 will vary based on changing mechanical properties of the bone 108 during the healing process and the load placed on the bone 108 (e.g., the weight that the patient places on the leg) while the strain measured in the healthy portion 112 varies based only on the load placed on the bone 108. Thus, taking a ratio of the strains measured by the two sensors 104, 106 normalizes the effects of the load on the sensors 104, 106 providing data corresponding to the stiffness of the bone 108 at the fracture site 110. The ratio of the measurements from the first sensor 104 to the measurements from the second sensor 106 during the healing process should trend in a decreasing pattern over time, whereas a lack of healing would show no recognizable trend over time.

[0009] As shown in Fig. 2, a system 200 according to a second exemplary embodiment of the invention is substantially similar to the system 100, including an implant 202 and at least two sensors 204, 206. However, rather than both sensors 204, 206 being positioned on the implant 202, the first sensor 204 is located on a surface 214 of the implant 202 in a position corresponding to a fracture of a bone 208, while the second sensor 206 is placed directly on a solid portion 212 of the bone 208, outside a perimeter of the implant 202. Thus, the first sensor 204 measures strain on the implant 202 at a position corresponding to the site of the fracture 210 while the second sensor 206 measures strain on the solid portion 212 of the bone 208. Similarly to the system 100, a ratio between the strains measured by the first and second sensors 204, 206 is determined and tracked to study the progress of healing in the bone 208. As indicated above, the ratio of the strain measurements from the first sensor 204 to the strain measurements from the second sensor 206 trend in a decreasing pattern as the bone 208 heals, whereas a lack of healing will show no recognizable trend over time.

[0010] As shown in Figs. 3 - 4, a system 300 according to a third exemplary embodiment of the invention is substantially similar to the system 200, comprising an implant 302 and at least two sensors 304, 306. Similarly to the first sensor 204, the first sensor 304 is placed on a surface 314 of the implant 302 in a location corresponding to a position of a fracture 310 of a bone 308 (when the implant 302 is mounted on the bone 308 in a desired position) to measure strain on the implant 302 at the position of the fracture 310 while the second sensor 306 is placed directly on a solid portion 312 of the bone 308. However, rather than being placed on an exterior surface of the bone 308, the second sensor 306 is placed within the solid portion 312 via, for example, a bone fixation element 316 (e.g., screw).

[0011] The second sensor 306 may be attached adjacent to a proximal end 318 of the bone fixation element 316 such that when the bone fixation element 316 is inserted into the solid portion 312 of the bone, the second sensor 306 contacts a cortical wall of the bone 308. The second sensor 306 may be printed or mounted around a portion of the bone fixation element 316 to measure deformation of the bone 308 which is directly related to strain on the bone 308. The ratio of the measurements from the first sensor 304 to those of the second sensor 306 may then be determined to track healing progress in the same manner described above.

[0012] As shown in Fig. 5, a system 400 according to a fourth exemplary embodiment of the invention is substantially similar to the system 100, comprising an implant 402 and first and second sensors 404, 406, respectively, both of which are mounted on the implant 402. Similarly to the first sensor 104, the first sensor 404 is located on the implant 402 in a position which, when the implant 402 is in the desired position, corresponds to the location of a fracture 410 so that the first sensor 404 measures strain

on the implant 402 at a position corresponding to the site of the fracture 410. The second sensor 406 is positioned on a portion 420 of the implant 402 having greater flexibility than the portion of the implant 402 on which the first sensor 404 is mounted. For example, the portion 420 may be made more flexible than other portions of the implant 402 by reducing a width (i.e., an extent of the implant 402 across a bone facing surface thereof in a direction perpendicular to a longitudinal axis of the implant 402) and/or a thickness of the portion 420 (i.e., a distance between the bone facing surface and a surface thereof which faces away from the bone) as compared to remaining portions of the implant 402. In a preferred embodiment, the flexible portion 420 is adjacent to an end 422 of the implant 402 so that the second sensor 406 is separated from the fracture 410 by a distance great enough to ensure that the underlying portion 412 of the bone 408 is solid.

[0013] The second sensor 406 on the flexible portion 420 of the implant 402 is fixed to the solid portion 412 of the bone 408 via, for example, locking screws inserted in holes 424 on opposing sides thereof. The second sensor 406 measures strain on a portion of the implant 402 corresponding to the solid portion 412 of the bone 408 so that measurements from the second sensor 406 may be used to normalize measurements from the first sensor. Similarly to the placement of a sensor directly in or on a bone, as described in conjunction with systems 200 and 300, placing the second sensor 406 on a more flexible portion 420 of the implant 402 between two locked screws permits a more accurate measurement of the strain on the underlying solid portion 412 of the bone 408, as compared to the results from placing the second sensor 406 on a stiffer portion of the implant 402. The ratio of the measurements from the first sensor 404 to the measurements from the second sensor 406 during the healing process should trend in a pattern indicating an increasing stiffness of the bone 408 over time, whereas a lack of healing should show no recognizable trend over time.

It will be understood by those of skill in the art that other mechanisms may be employed for normalizing measurements of strain on a portion of an implant which, when mounted on a bone in a target location, corresponds to a position of a fracture or other weakened portion of that bone.

It will be apparent to those skilled in the art that various modifications and variations can be made in the structure and the methodology of the present invention, without departing from the scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of this invention provided that they come within the scope of the appended claims.

Claims

1. A system (100 - 400) for tracking a bone healing progress, comprising:

an implant (102 - 402) configured for fixing a fracture (110 - 410) of a bone (108 - 408) including a first sensor (104 - 404) configured for measuring a first strain when mounted thereon at a position which, when the implant (102 - 402) is mounted on the bone (108 - 408) in a target position, is mechanically coupled to a fracture (110 - 410) of the bone (108 - 408); and

a second sensor (106 - 406) configured for measuring a second strain on a portion of the bone (108 - 408) separated from the fracture (110 - 410),

characterized in that the system is configured to calculate a ratio of the first strain to the second strain so as to normalize an effect of loads on the bone (108 - 408) and indicate an increased stiffness as the fracture (110 - 410) heals.

2. The system of claim 1, wherein
the first sensor (104 - 404) is located on the implant (102 - 402) for measuring the first strain; and
the second sensor (106 - 406) is located on the implant (102 - 402) or on the bone (108 - 408) for measuring the second strain.

3. The system of claim 1 or 2, wherein the implant (102 - 402) is a plate configured to be coupled to a bone overlying a fracture site.

4. The system of any one of claims 1 to 3, wherein the second sensor (206; 306) is configured to be coupled directly to a non-weakened portion of the bone.

5. The system of any one of claims 1 to 4, wherein the second sensor (306) is mounted to a portion of a bone fixation element (316) which, when in an operative position, is inserted into a non-weakened portion of the bone so that the second sensor (306) contacts a cortical wall of the non-weakened portion of the bone.

6. The system of claim 5, wherein the second sensor (306) extends about a circumference of a proximal portion of the bone fixation element (316).

7. The system of any one of claims 1 to 4, further comprising:

a bone fixation element (316), the second sensor (306) being mounted at a proximal end thereof so that, when the bone fixation element (316) is inserted into the bone to a desired position, the second sensor (306) contacts a cortical wall of the bone.

8. The system of any one of claims 1 to 4, wherein the

implant (402) includes a flexible portion (420) and a rigid portion, a bending stiffness of the rigid portion being greater than that of the flexible portion (420), the second sensor (406) being mounted on the flexible portion (420) while the first sensor (404) is mounted on the rigid portion.

9. The system of claim 8, further comprising:

first and second locking screws which, when the implant (402) is coupled to the bone in a target configuration, are inserted through openings (424) in the implant (402) on opposing sides of the flexible portion (420).

10. The system of any one of claims 1 to 9, wherein the first and second sensors (104 - 404, 106 - 406) provide data to an external data gathering unit wirelessly.

11. The system of claim 10, wherein the first and second sensors (104 - 404, 106 - 406) are one of MEMs sensors and powered chips connected to printed circuit boards.

Patentansprüche

1. System (100 - 400) zum Verfolgen eines Knochenheilungsprozesses, umfassend:

ein Implantat (102 - 402), das eingerichtet ist zum Fixieren einer Fraktur (110 - 410) eines Knochens (108 - 408), enthaltend einen ersten Sensor (104 - 404), der eingerichtet ist zum Messen einer ersten Spannung, wenn er daran an einer Position angebracht ist, welche, wenn das Implantat (102 - 402) an dem Knochen (108 - 408) in einer Zielposition angebracht ist, mechanisch an eine Fraktur (110 - 410) des Knochens (108 - 408) gekoppelt ist; und
einen zweiten Sensor (106 - 406), der eingerichtet ist zum Messen einer zweiten Spannung auf einen Teil des Knochens (108 - 408), der von der Fraktur (110 - 410) getrennt ist,
dadurch gekennzeichnet, dass das System eingerichtet ist, ein Verhältnis der ersten Spannung zur zweiten Spannung zu berechnen, um einen Effekt von Belastungen auf den Knochen (108 - 408) zu normalisieren und eine erhöhte Steifigkeit anzuzeigen, wenn die Fraktur (110 - 410) heilt.

2. System nach Anspruch 1, wobei
der erste Sensor (104 - 404) auf dem Implantat (102 - 402) zum Messen der ersten Spannung angeordnet ist; und
der zweite Sensor (106 - 406) auf dem Implantat (102 - 402) oder auf dem Knochen (108 - 408) zum Messen der zweiten Spannung angeordnet ist.

3. System nach Anspruch 1 oder 2, wobei das Implantat (102 - 402) eine Platte ist, die eingerichtet ist, an einen Knochen über einer Frakturstelle liegend gekoppelt zu werden.

4. System nach einem der Ansprüche 1 bis 3, wobei der zweite Sensor (206; 306) eingerichtet ist, direkt an einen nicht geschwächten Teil des Knochens gekoppelt zu werden.

5. System nach einem der Ansprüche 1 bis 4, wobei der zweite Sensor (306) an einem Teil eines Knochenfixierelements (316) angebracht ist, welches, wenn es in einer Betriebsposition ist, in einen nicht geschwächten Teil des Knochens eingeführt ist, so dass der zweite Sensor (306) eine Kortikaliswand des nicht geschwächten Teils des Knochens kontaktiert.

6. System nach Anspruch 5, wobei sich der zweite Sensor (306) um einen Umfang eines proximalen Teils des Knochenfixierelements (316) herum erstreckt.

7. System nach einem der Ansprüche 1 bis 4, des Weiteren umfassend:

ein Knochenfixierelement (316), wobei der zweite Sensor (306) an einem proximalen Ende davon angebracht ist, so dass, wenn das Knochenfixierelement (316) in den Knochen bis zu einer gewünschten Position eingeführt ist, der zweite Sensor (306) eine Kortikaliswand des Knochens kontaktiert.

8. System nach einem der Ansprüche 1 bis 4, wobei das Implantat (402) einen flexiblen Teil (420) und einen festen Teil enthält, wobei eine Biegesteifigkeit des festen Teils größer ist als die des flexiblen Teils (420), wobei der zweite Sensor (406) an dem flexiblen Teil (420) angebracht ist, während der erste Sensor (404) an dem festen Teil angebracht ist.

9. System nach Anspruch 8, des Weiteren umfassend:

eine erste und zweite Verriegelungsschraube, welche, wenn das Implantat (402) an den Knochen in einer Zielkonfiguration gekoppelt ist, durch Öffnungen (424) in dem Implantat (402) auf gegenüberliegenden Seiten des flexiblen Teils (420) eingeführt sind.

10. System nach einem der Ansprüche 1 bis 9, wobei der erste und zweite Sensor (104 - 404, 106 - 406) Daten an eine externe Datensammeleinheit drahtlos bereitstellen.

11. System nach Anspruch 10, wobei der erste und zweite Sensor (104 - 404, 106 - 406) entweder MEMS Sensoren oder mit Leiterplatten verbundene angetriebene Chips sind.

Revendications

1. Système (100-400), destiné à suivre un processus de cicatrisation osseuse, comprenant :

un implant (102-402) configuré pour fixer une fracture (110-410) d'un os (108-408) incluant un premier capteur (104-404) configuré pour mesurer une première déformation lorsqu'il est monté sur celui-ci en une position qui, lorsque l'implant (102-402) est monté sur l'os (108-408) dans une position cible, est couplée par voie mécanique à une fracture (110-410) de l'os (108-408), et
un second implant (106-406) configuré pour mesurer une seconde déformation sur une partie de l'os (108-408) séparée de la fracture (110-410),
caractérisé en ce que le système est configuré pour calculer un rapport entre la première déformation et la seconde déformation, de manière à normaliser un effet de charges sur l'os (108-408) et indiquer une rigidité accrue au fur et à mesure de la cicatrisation de la fracture (110-410).

2. Système selon la revendication 1, dans lequel
le premier capteur (104-404) se situe sur l'implant (102-402) en vue de mesurer la première déformation, et
le second capteur (106-406) se situe sur l'implant (102-402) ou sur l'os (108-408) en vue de mesurer la seconde déformation.

3. Système selon la revendication 1 ou 2, dans lequel l'implant (102-402) est une plaque configurée pour être couplée avec un os sus-jacent à un site de fracture.

4. Système selon l'une quelconque des revendications 1 à 3, dans lequel le second capteur (206; 306) est configuré pour être couplé directement à une partie non affaiblie de l'os.

5. Système selon l'une quelconque des revendications 1 à 4, dans lequel le second capteur (306) est monté sur une partie d'un élément de fixation osseuse (316) qui, en position de fonctionnement, est introduit dans une partie non affaiblie de l'os, de sorte que le second capteur (306) est en contact avec une paroi corticale de la partie non affaiblie de l'os.

6. Système selon la revendication 5, dans lequel le second capteur (306) s'étend autour d'une circonférence d'une partie proximale de l'élément de fixation osseuse (316).

7. Système selon l'une quelconque des revendications 1 à 4, comprenant en outre :

un élément de fixation osseuse (316), le second capteur (306) étant monté au niveau d'une extrémité proximale de celui-ci, de telle sorte que, lorsque l'élément de fixation osseuse (316) est introduit dans l'os sur une position souhaitée, le second capteur (306) est en contact avec une paroi corticale de l'os.

8. Système selon l'une quelconque des revendications 1 à 4, dans lequel l'implant (402) inclut une partie flexible (420) et une partie rigide, une rigidité de flexion de la partie rigide étant supérieure à celle de la partie flexible (420), le second capteur (406) étant monté sur la partie flexible (420) tandis que le premier capteur (404) est monté sur la partie rigide.

9. Système selon la revendication 8, comprenant en outre :

des première et seconde vis de blocage qui, lorsque l'implant (402) est couplé à l'os dans une configuration cible, sont introduites à travers des ouvertures (424) dans l'implant (402) dans des côtés opposés de la partie flexible (420).

10. Système selon l'une quelconque des revendications 1 à 9, dans lequel les premier et second capteurs (104-404, 106-406) fournissent des données à une unité de collecte de données externe de manière sans fil.

11. Système selon la revendication 10, dans lequel les premier et second capteurs (104-404, 106-406) sont un parmi des capteurs MEM et des puces à énergie connectées à des cartes de circuit imprimé.

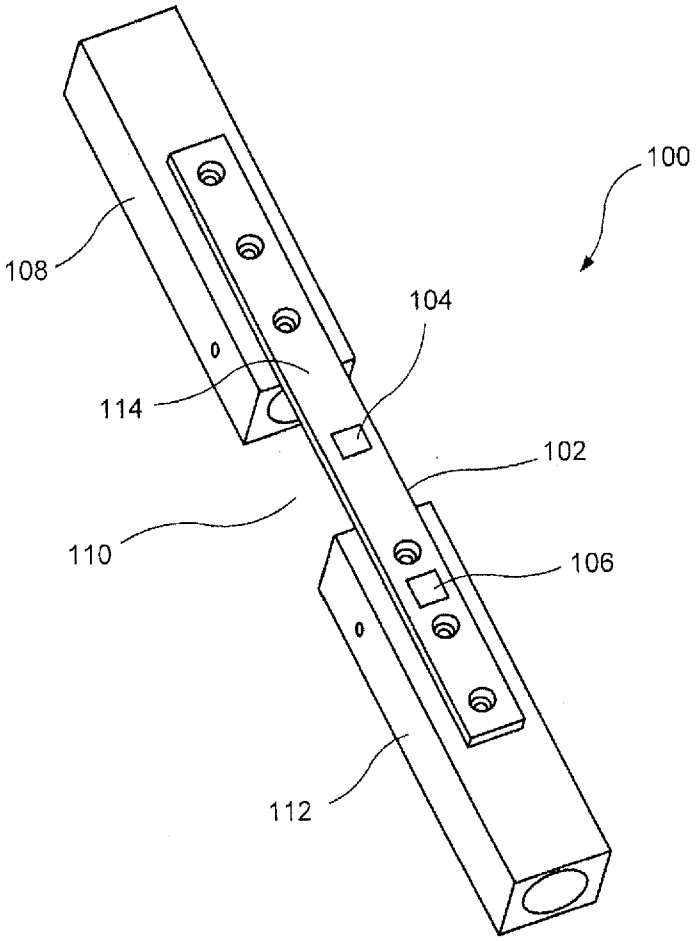

FIG. 1

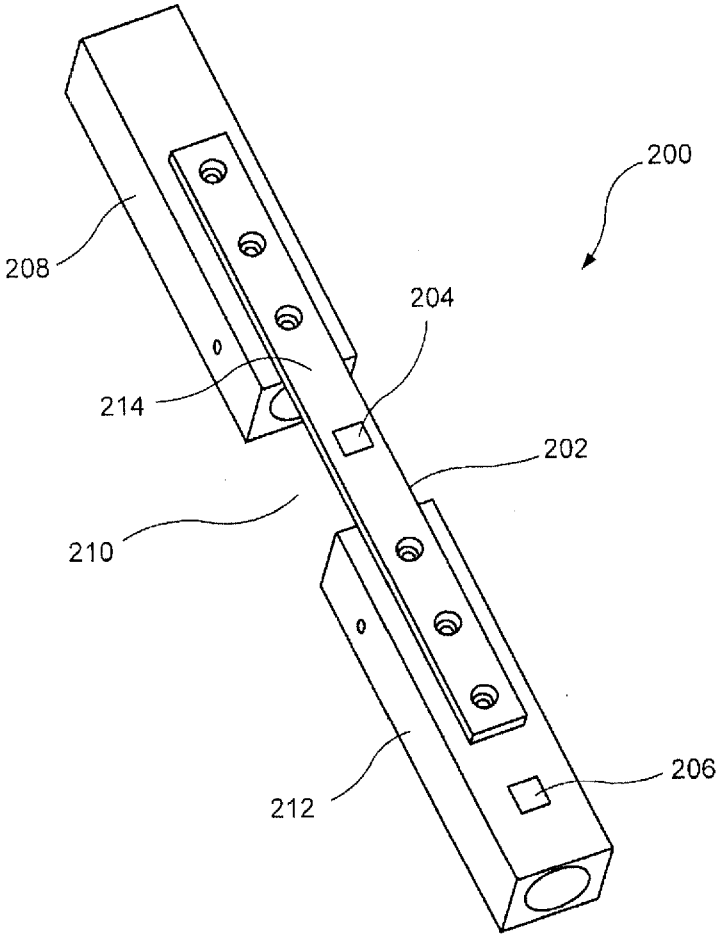

FIG. 2

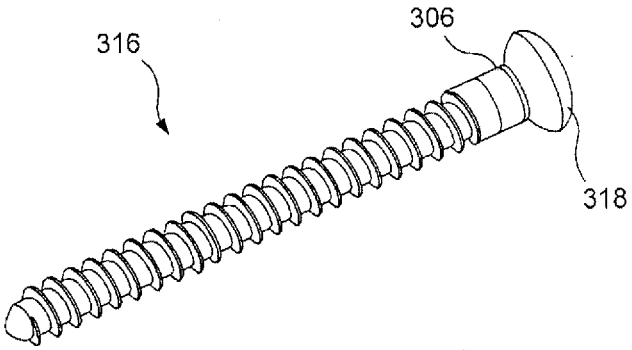

FIG. 4

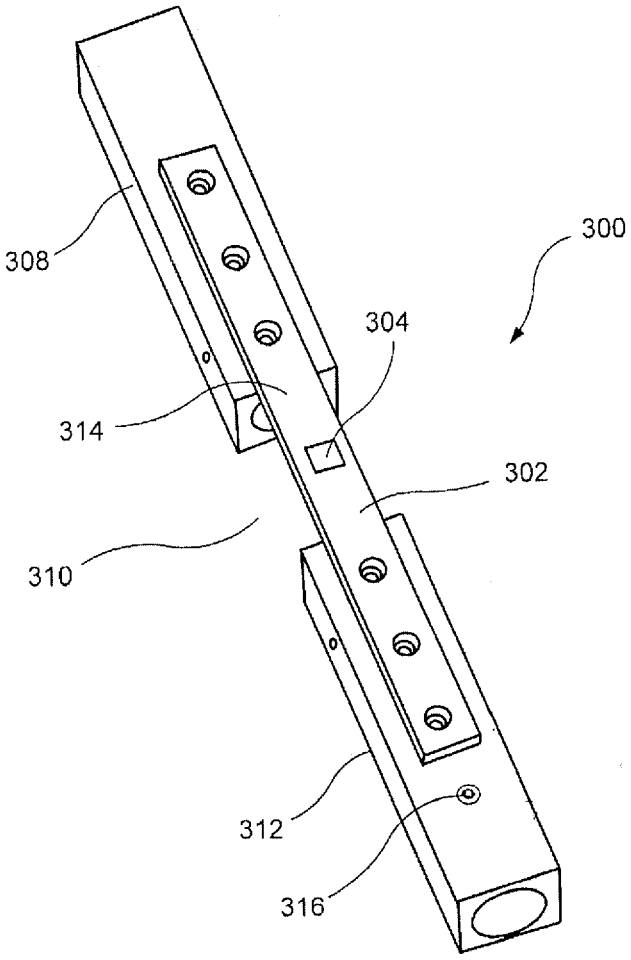

FIG. 3

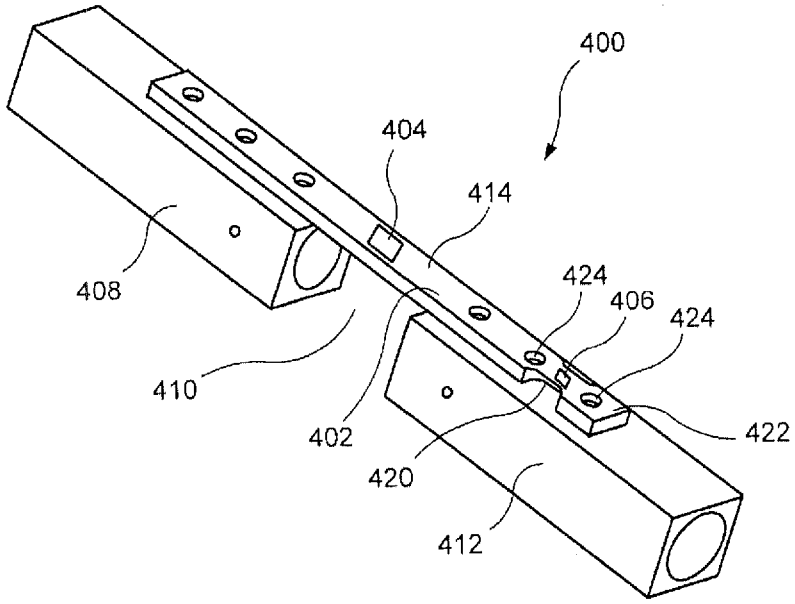

FIG. 5

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于归一化植入物应变读数以评估骨愈合的系统		
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摘要(译)

一种用于治疗活体内骨骼的装置，包括（a）包括配置用于附接到骨骼的植入物；（b）测量植入物的第一部分上的应变的第一传感器，植入物的第一部分被配置成当植入物在目标位置与骨骼结合时机械地连接到骨骼的弱化部分；（c）第二传感器测量骨的非弱化部分的应变。

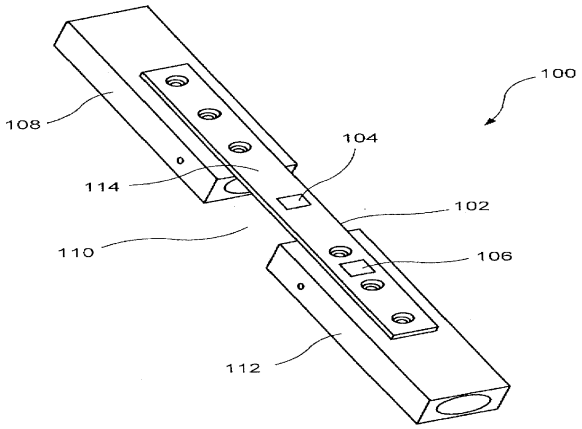

FIG. 1