the patient has access to the type of "real time," continuous, objective, prosthesis performance measurements that they might otherwise like to have.

[0011] The present invention discloses novel total and partial knee replacements which overcome many of the difficulties of previous knee prostheses, methods for constructing and monitoring these novel knee replacements, and further provides other related advantages.

SUMMARY

[0012] Briefly stated, full and partial knee prostheses are disclosed with a number of sensors to monitor the integrity and efficaciousness of the artificial knee joint within the patient. The sensors may be positioned on the outer surface of the prosthetic knee, on the inner surfaces of the prosthetic knee, within the prosthetic material (stainless steel, titanium, cobalt chromium, polyurethane, high molecular weight polyurethane, ceramics, etc.) itself, between the various components that comprise the prosthetic knee, the screws and/or fastening hardware (if present) used to secure the prosthesis in place, within the bone cement (e.g., PMMA, or PMMA and MMA copolymer blends) used to secure the knee (if present), and/or within the tissues surrounding the prosthesis. Within certain examples, the sensors are of the type that are passive and thus do not require their own power supply.

[0013] In one aspect, the present disclosure refers to knee replacement prosthesis (10) comprising a tibial component, said tibial component including a tibial plate (5) and a tibial stem (2); characterised in that the knee replacement prosthesis (10) comprises a plurality of sensors (22, 27, and/or 28) within the tibial stem wherein at least one sensor is an accelerometer (27) that detects acceleration, tilt, vibration, shock and/or rotation. Disclosed herein are assemblies for positioning and placement within a patient an implant comprising a total or partial knee prosthesis; and one or more sensors positioned on, in, or around the prosthesis, and/or within the bone cement and/or bone screws or anchors utilized to attach the prosthesis. In another aspect, the present disclosure refers to a non-surgical method comprising: obtaining acceleration data from accelerometers positioned within said tibial stem as disclosed herein located in-situ in the knee of a patient; storing the acceleration data in a memory located in the knee replacement prosthesis; and transferring the acceleration data from said memory in the knee replacement prosthesis to a memory in a location outside the knee replacement prosthesis. In yet another aspect, the present disclosure refers to a kit comprising the knee replacement prosthesis as disclosed herein, further comprising bone cement and/or bone screws comprising one or more sensors. In a further aspect, the

present disclosure refers to a non-surgical method for detecting and/or recording an event in a subject with a knee replacement prosthesis as described herein, comprising the step of interrogating at a desired point in time the activity of one or more sensors within the knee replacement prosthesis, and recording said activity. In another aspect, the present disclosure refers to a method for imaging a knee replacement prosthesis as disclosed herein, comprising the steps of (a) detecting the location of one or more sensors in a knee replacement prosthesis as disclosed herein; and (b) visually displaying the location of said one or more sensors, such that an image of the knee replacement prosthesis is created. In another aspect, the present disclosure refers to a non-surgical method of monitoring a knee replacement prosthesis within a subject, comprising: transmitting a wireless electrical signal from a location outside the subject's body to a location inside the subject's body; receiving the signal at a sensor positioned on a knee replacement described herein located inside the body; powering the sensor using the received signal; sensing data at the sensor; and outputting the sensed data from the sensor to a receiving unit located outside of the subject's body. Also disclosed herein are medical devices comprising at least one of: a tibial component, patellar prosthesis, or femoral component, and one or more sensors. For purpose of clarity, the one or more sensors may be purposely placed at specific locations on the knee replacement prosthesis, medical device, and/or bone screw or anchor, and/or randomly dispersed across, upon and within the knee replacement prosthesis, medical device, bone screw or anchor, and bone cement. Hence, use of the terms or phrases "are placed", "appear" or "utilized" should not be deemed to require specific placement, unless a specific placement is required.

[0014] Within various examples the sensor can be positioned on an outer surface of the prosthetic knee, on an inner surface of the prosthetic knee, within the materials used to construct the prosthetic knee, between the various components that make up the prosthetic knee, the screws and/or fastening hardware (if present) used to secure the prosthesis in place, on or in the bone cement used to secure the prosthetic knee, on or in the tissues surrounding the prosthetic knee (typically bone or bone marrow, but also muscle, ligament, tendon, joint capsule and/or synovial compartment), or any combination of these. Representative examples of sensors suitable for use within the present invention include accelerometers (acceleration, tilt, vibration, shock and rotation sensors), pressure sensors, contact sensors, position sensors, chemical microsensors, tissue metabolic sensors, mechanical stress sensors and temperature sensors. Within particularly preferred examples the sensor is a wireless sensor, or a sensor connected to a wireless microprocessor.

[0015] Within further examples a plurality of the aforementioned sensors are positioned on, within, or around (bone cement, bone screws or tissue) the prosthetic knee, and within preferred examples, the prosthetic knee can contain more than one type of sensor (e.g., one or more of, or any combination of the following: acceleration sensors, tilt sensors, vibration sensors, shock sensors, rotation sensors, pressure sensors, contact sensors, position sensors, chemical microsensors, tissue metabolic sensors, and mechanical stress sensors).

[0016] According to various examples, sensors are placed at different locations in a replacement knee joint in order to monitor the operation, movement, medical imaging (both prosthesis and surrounding tissues), function, wear, performance, potential side effects, medical status of the patient and the medical status of the artificial knee and its interface with the live tissue of the patient. Live, continuous, *in situ*, monitoring of patient activity, patient function, prosthesis activity, prosthesis function, prosthesis performance, prosthesis and joint alignment, patellar tracking, prosthesis and joint forces and mechanical stresses, prosthesis and surrounding tissue anatomy (imaging), mechanical and physical integrity of the prosthesis, patellar tracking and potential side effects is disclosed. In addition, information is available on many aspects of the knee replacement prosthesis and its interaction with the patient's own body tissues, including clinically important measurements not currently available through physical examination, medical imaging and diagnostic medical studies.

[0017] According to one example, the sensors provide evaluation data on the range of motion (ROM) of the knee. Currently, ROM is usually measured clinically by the physician passively moving the knee joint through a full range of motion during physical examination and recording the results (degrees of flexion, extension, anterior/posterior stability and medial/lateral stability; see, e.g., Figure 4). Motion sensors and accelerometers can be used to accurately determine the full ROM of the prosthetic knee joint both during physical examination and during normal daily activities between visits. Similarly, motion sensors and accelerometers can be used to accurately measure any anterior/posterior or medial/lateral instability (including full, partial or subclinical dislocation) of the prosthetic knee joint both during physical examination and during normal daily activities between visits. Additionally, motion sensors and accelerometers can be used to accurately measure any improper tracking of the patella and/or patellar instability (including full, partial or subclinical subluxation) during physical examination and during normal daily activities between visits.

[0018] According to one example, contact sensors are provided between the prosthesis and the surrounding bone, between the screws and/or fastening hardware (if present) and the surrounding bone, between the prosthesis and the surrounding bone cement (if present), and/or between the bone cement (if present) and the surrounding bone in order to measure bone erosion and loosening around the implant. In other examples, vibration sensors are disclosed to detect the vibration between the prosthesis and the surrounding bone, between the screws and/or fastening hardware (if present) and the surrounding bone, between the prosthesis and the surrounding bone cement, between the bone cement and the surrounding bone as an early indicator of motion and loosening. In other examples, strain gauges are disclosed to detect the strain between the prosthesis and the surrounding bone, between the screws and/or fastening hardware (if present) and the surrounding bone, between the prosthesis and the surrounding bone cement, between the bone cement and the surrounding bone, and also the strain which is exerted on the various portions of the prosthesis. Sudden increases in strain may indicate that too much stress is being placed on the replacement prosthesis, which may increase damage to the body. For example, a gradual, long-term decrease in strain may cause bone reabsorption around the implant, leading to loosening of the prosthesis or fractures in the bone surrounding the prosthesis, while a gradual, long-term increase in strain may lead to microfractures of the prosthesis materials themselves.

[0019] According to other examples, accelerometers are disclosed which detect vibration, shock, tilt and rotation. According to other examples, sensors for measuring surface wear, such as contact or pressure sensors, may be embedded at different depths within the femoral articular surface, the tibial articular surface, and/or the patellar articular surface in order to monitor articular surface erosion. In other examples, position sensors, as well as other types of sensors, are disclosed which indicate the range of motion and monitor for partial (or complete) femoral-tibial knee dislocation or subluxation in actual use over a period of time, improper tracking of the patella and/or subluxation of the patellar-femoral joint, or movement between the interconnected components of the prosthesis (and the anchoring hardware) itself.

[0020] Within further examples, the artificial knee (total or partial) can contain sensors at specified densities in specific locations. For example, the artificial knee can have a density of sensors of greater than one, two, three, four, five, six, seven, eight, nine, or ten sensors (e.g., acceleration sensors, tilt sensors, vibration sensors, shock sensors, rotation sensors, pressure sensors, contact sensors, position sensors, chemical microsensors, tissue metabolic sensors, and mechanical stress sensors, or any combination of these) per square centimeter

of the device. Within other examples, the artificial knee (total or partial) can have a density of sensors of greater than one, two, three, four, five, six, seven, eight, nine, or ten sensors (e.g., acceleration sensors, tilt sensors, vibration sensors, shock sensors, rotation sensors, pressure sensors, contact sensors, position sensors, chemical microsensors, tissue metabolic sensors, and mechanical stress sensors, or any combination of these) per cubic centimeter of the device. Within related examples, the sensors (e.g., acceleration sensors, tilt sensors, vibration sensors, shock sensors, rotation sensors, pressure sensors, contact sensors, position sensors, chemical microsensors, tissue metabolic sensors, and mechanical stress sensors) can be positioned at particular locations on, within, or around the artificial knee, including for example, the femoral component (medial, lateral or both) , the tibial plate, the tibial stem (if present), the tibial lining, the prosthetic patellar lining, within portions of the device which are to be connected (e.g., the connecting segments of the tibial cup and the tibial lining), the screws and/or fastening hardware (if present) used to secure the prosthesis in place, and around the artificial knee (on or in the bone cement used to secure the prosthetic knee, on or in the tissues surrounding the prosthetic knee - typically bone or bone marrow, but also muscle, ligament, tendon, joint capsule and/or synovial compartment).

[0021] Within certain examples, the total or partial knee prosthesis is disclosed with a specific unique identifying number, and within further examples, each of the sensors on, in or around the prosthetic knee each have either a specific unique identification number, or a group identification number (e.g., an identification number that identifies the sensor as an acceleration sensor, a tilt sensor, a vibration sensor, a shock sensor, a rotation sensor, a pressure sensor, a contact sensor, a position sensor, a chemical microsensor, a tissue metabolic sensor, or a mechanical stress sensor). Within yet further examples, the specific unique identification number or group identification number is specifically associated with a position on, in or around the prosthetic knee.

[0022] Within other examples methods are disclosed for monitoring an implanted total or partial knee prosthesis comprising the steps of transmitting a wireless electrical signal from a location outside the body to a location inside the body; receiving the signal at a sensor positioned on, in or around an artificial knee located inside the body; powering the sensor using the received signal; sensing data at the sensor; and outputting the sensed data from the sensor to a receiving unit located outside of the body.

[0023] Within other examples methods are disclosed for imaging a knee replacement or medical device as disclosed herein, comprising the steps of (a) detecting the location of one or more sensors in a knee replacement or medical device; and (b) visually displaying the

location of said one or more sensors, such that an image of the knee replacement or medical device is created. Within various examples, the step of detecting may be done over time, and the visual display may thus show positional movement over time. Within certain examples the image which is displayed is a two or three-dimensional image. Within preferred examples the various images may be collected and displayed in a time-sequence (e.g., as a moving image or 'movie-like' image).

[0024] The imaging techniques disclosed herein may be utilized for a wide variety of purposes. For example, within one example, the imaging techniques may be utilized during a surgical procedure in order to ensure proper placement and working of the knee replacement or medical device. Within other example, the imaging techniques may be utilized post-operatively in order to examine the knee replacement or medical device, and/or to compare operation and/or movement of the device over time.

[0025] The integrity of the partial or total knee prosthesis can be wirelessly interrogated and the results reported on a regular basis. This permits the health of the patient to be checked on a regular basis or at any time as desired by the patient and/or physician. Furthermore, the prosthesis can be wirelessly interrogated when signaled by the patient to do so (via an external signaling/triggering device) as part of "event recording" – i.e. when the patient experiences a particular event (e.g. pain, injury, instability, etc.) she/he signals/triggers the device to obtain a simultaneous reading in order to allow the comparison of subjective/symptomatic data to objective/sensor data. Matching event recording data with sensor data can be used as part of an effort to better understand the underlying cause or specific triggers of a patient's particular symptoms. Hence, within various examples methods are disclosed for detecting and/or recording an event in a subject with one of the total or partial knee replacements disclosed herein, comprising the interrogating at a desired point in time Hence, within one example methods are disclosed for detecting and/or recording an event in a subject with a knee replacement or medical device as disclosed herein, comprising the step of interrogating at a desired point in time the activity of one or more sensors within the knee replacement or medical device, and recording said activity. Within various examples, they may be accomplished by the subject and/or by a health care professional. Within related examples, the step of recording may be performed with one or more wired devices, or, wireless devices that can be carried, or worn (e.g., a cellphone, watch, wristband, and/or glasses). Within further examples, the worn devices (e.g. cellphone, watch, wristband and/or glasses may have sufficient processing power and memory to be able to carry out further data collection and analysis.

[0026] Within further examples, each of the sensors contains a signal-receiving circuit and a signal output circuit. The signal-receiving circuit receives an interrogation signal that includes both power and data collection request components. Using the power from the interrogation signal, the sensor powers up the parts of the circuitry needed to conduct the sensing, carries out the sensing, and then outputs the data to the interrogation module. The interrogation module acts under control of a control unit which contains the appropriate I/O circuitry, memory, a controller in the form of a microprocessor, and other circuitry in order to drive the interrogation module. Within yet other examples the sensor (e.g., an acceleration sensor, a tilt sensor, a vibration sensor, a shock sensor, a rotation sensor, a pressure sensor, a contact sensor, a position sensor, a chemical microsensor, a tissue metabolic sensor, or a mechanical stress sensor) are constructed such that they may readily be incorporated into or otherwise mechanically attached to the knee prosthesis (e.g., by way of a an opening or other appendage that provides permanent attachment of the sensor to the knee prosthesis) and/or readily incorporated into the bone cement or the tissues that surround the knee prosthesis.

[0027] Within yet other examples methods devices are disclosed suitable for transmitting a wireless electrical signal from a location outside the body to a location inside the body; receiving the signal at one of the aforementioned sensors positioned on, in or around a prosthetic knee located inside the body; powering the sensor using the received signal; sensing data at the sensor; and outputting the sensed data from the sensor to a receiving unit located outside of the body. Within certain examples the receiving unit can provide an analysis of the signal provided by the sensor.

[0028] The data collected by the sensors can be stored in a memory located within the femoral component, the tibial plate and/or the tibial stem. During a visit to the physician, the data can be downloaded via a wireless sensor, and the doctor is able to obtain data representative of real-time performance of the prosthesis.

[0029] The advantages obtained include more accurate monitoring of the prosthesis and permitting medical reporting of accurate, *in situ*¸ data that will contribute to the health of the patient. The details of one or more embodiments are set forth in the description below. Other features, objects and advantages will be apparent from the

CLAIMS

What is claimed is:

1. A knee replacement prosthesis (10) comprising:

a tibial component, said tibial component including a tibial plate (5) and a tibial stem (2); characterised in that the knee replacement prosthesis (10) comprises a plurality of sensors (22, 27, and/or 28) within the tibial stem wherein at least one sensor is an accelerometer (27) that detects acceleration, tilt, vibration, shock and/or rotation.

2. The knee replacement prosthesis according to claim 1 further comprising a sensor selected from the group consisting of pressure sensors (22), contact sensors (22), position sensors (28), chemical microsensors, tissue metabolic sensors, mechanical stress sensors and temperature sensors.

3. The knee replacement prosthesis according to any one of claims 1 to 2 further comprising:

an electronic processor positioned upon and/or inside the tibial component that is electrically coupled to sensors.

4. The knee replacement prosthesis of claim 3 wherein the electric coupling is a wireless coupling.

5. The knee replacement prosthesis of claim 4 further including:

a memory coupled to the electronic processor and positioned upon and/or inside the tibial component.

6. The knee replacement prosthesis according to any one of claims 1 to 5 wherein said plurality of sensors are positioned within said tibial stem at a density of greater than 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or 20 sensors per square centimeter.

7. The knee replacement prosthesis according to any one of claims 1 to 5 wherein said plurality of sensors are positioned within said tibial stem at a density of greater than 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or 20 sensors per cubic centimeter.

8. A non-surgical method comprising:

obtaining acceleration data from accelerometers positioned within said tibial stem of claims 1 to 7 located in-situ in the knee of a patient;

storing the acceleration data in a memory located in the knee replacement prosthesis; and

transferring the acceleration data from said memory in the knee replacement prosthesis to a memory in a location outside the knee replacement prosthesis.

9. A kit comprising the knee replacement prosthesis according to any one of claims 1 to 7, further comprising bone cement and/or bone screws comprising one or more sensors.

10. A non-surgical method for detecting and/or recording an event in a subject with a knee replacement prosthesis as provided in any one of claims 1 to 7, comprising the step of interrogating at a desired point in time the activity of one or more sensors within the knee replacement prosthesis, and recording said activity.

11. The method according to claim 10 wherein the step of interrogating is performed by a subject which has an implanted knee replacement.

12. The method according to claim 11 wherein said recording is performed on a wearable device.

13. The method according to any one of claims 11 or 12, wherein said recording is provided to a health care provider.

14. A method for imaging a knee replacement prosthesis according to any one of claims 1 to 7, comprising the steps of

(a) detecting the location of one or more sensors in a knee replacement prosthesis according to any one of claims 1 to 7; and

(b) visually displaying the location of said one or more sensors, such that an image of the knee replacement prosthesis is created.

15. The method according to claim 14 wherein the step of detecting occurs over time.

16. The method according to claim 15, wherein said visual display shows changes in the positions of said sensors over time.

17. The method according to any one of claims 14 to 16 wherein said visual display is a three-dimensional image of said knee replacement prosthesis.

18. A non-surgical method of monitoring a knee replacement prosthesis within a subject, comprising:

transmitting a wireless electrical signal from a location outside the subject's body to a location inside the subject's body;

receiving the signal at a sensor positioned on a knee replacement according to any one of claims 1 to 7 located inside the body;

powering the sensor using the received signal;

sensing data at the sensor; and

outputting the sensed data from the sensor to a receiving unit located outside of the subject's body.

19. The method according to claim 18 wherein said receiving unit is a watch, wrist band, cell phone or glasses.

20. The method according to claims 18 or 19 wherein said receiving unit is located within a subject's residence or office.

21. The method according to any one of claims 18 to 20 wherein said sensed data is provided to a health care provider.

22. The method according to any one of claims 18 to 21 wherein said sensed data is posted to one or more websites.