within the bone cement (e.g., PMMA, or PMMA and MMA copolymer blends) used to secure the hip (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 the present disclosure assemblies are provided for positioning and placement within a patient an implant comprising a total or partial hip prosthesis; and a sensor positioned on, in, or around the prosthesis. Within various examples the sensor can be positioned on an outer surface of the prosthetic hip, on an inner surface of the prosthetic hip, within the materials used to construct the prosthetic hip, between the various components that make up the prosthetic hip, on or in the bone cement used to secure the prosthetic hip, on or in the tissues surrounding the prosthetic hip (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 disclosure 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.

[0014] Within further examples a plurality of the aforementioned sensors are positioned on, within, or around (bone cement or tissue) the prosthetic hip, and within preferred examples, the prosthetic hip 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).

[0015] According to various examples, sensors are placed at different locations in a replacement hip joint in order to monitor the operation, movement, function, wear, performance, potential side effects and medical status of the artificial hip 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, and potential side effects is provided. In addition, information is available on many aspects of the hip 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.

[0016] According to one example the sensors provide evaluation data on the range of motion (ROM) of the hip. Currently, ROM is usually measured clinically by the physician passively moving the hip joint through a full range of motion during physical examination and recording the results (degrees of flexion, extension, abduction, adduction, external rotation, internal rotation and rotation in flexion). Motion sensors and accelerometers can be used to accurately determine the full ROM of the prosthetic hip joint both during physical examination and during normal daily activities between visits.

[0017] According to one example, contact sensors are provided between the prosthesis and the surrounding bone, between the prosthesis and the surrounding bone cement, and/or between the bone cement and the surrounding bone in order to measure bone erosion and loosening around the implant. In other examples, strain gauges are provided to detect the strain between the prosthesis 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.

[0018] According to other examples, accelerometers are provided 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 head, the acetabulum, and/or the acetabular cup in order to monitor articular surface erosion. In other examples, position sensors, as well as other types of sensors, are provided which indicate the range of motion and monitor for partial (or complete) hip dislocation in actual use over a period of time.

[0019] Within further examples, the artificial hip (total or partial) can contain sensors at specified densities in specific locations. For example, the artificial

hip 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 hip (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 hip, including for example, the femoral stem, the femoral neck, the femoral head, the acetabular cup, the acetabular lining, within portions of the device which are to be connected (e.g., the connecting segments of the femoral stem, femoral neck and femoral head; the connecting segments of the acetabular cup and the acetabular lining), and around the artificial hip (on or in the bone cement used to secure the prosthetic hip, on or in the tissues surrounding the prosthetic hip - typically bone or bone marrow, but also muscle, ligament, tendon, joint capsule and/or synovial compartment).

[0020] Within certain examples of the disclosure, the total or partial hip prosthesis is provided with a specific unique identifying number, and within further examples, each of the sensors on, in or around the prosthetic hip 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 hip.

[0021] In the present disclosure methods are provided for monitoring an implanted total or partial hip 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 hip 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.

[0022] The integrity of the partial or total hip 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.

[0023] 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 hip prosthesis (e.g., by way of a an opening or other appendage that provides permanent attachment of the sensor to the hip prosthesis) and/or readily incorporated into the bone cement or the tissues that surround the hip prosthesis.

[0023a] In one aspect, the present disclosure refers to a hip replacement prosthesis comprising a femoral stem, a femoral head, or an acetabular assembly, and one or more sensors coupled to said femoral stem, femoral head, or acetabular assembly, wherein the hip prosthesis further comprises a memory to store data collected

by the one or more sensors and positioned in the femoral stem, characterized in that said one or more sensors comprises one or more accelerometers.

[0024] In the present disclosure methods devices are provided 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 hip 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.

[0025] The data collected by the sensors can be stored in a memory located within the femoral 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.

[0025a] In another aspect, the present disclosure refers to a method of transferring data comprising a) obtaining contact data from the one or more sensors of the prosthesis as described herein; b) storing the data in the memory at a storage site within the prosthesis; and c) transferring the data from the memory to a location outside of the storage site, particularly wherein the prosthesis is implanted within a subject, and the data is transferred to a site outside of the subject, particularly wherein said data is transferred to a watch, wrist band, cell phone or glasses; or to a residence or an office; or a health care provider.

[0025b] In another aspect, the present disclosure refers to a method for detecting degradation in the hip replacement prosthesis as described herein, provided to a patient, comprising the step of detecting a change in the one or more sensors of the hip prosthesis, and thus determining degradation of the hip prosthesis, particularly wherein said sensor is capable of detecting one or more physiological and or locational parameters.

[0026] 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 examples are set forth in the description below. Other features, objects and advantages will be apparent from the description, the drawings, and the claims. In addition, the disclosures of all patents and patent applications referenced herein are incorporated by reference in their entirety.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Figure 1 is an isometric view of a total hip replacement.

[0028] Figure 2 is an exploded view of the total hip replacement of Figure 1.

[0029] Figure 3 shows the total hip replacement within the pelvis of a patient.

[0030] Figure 4 is an exploded view of a total hip having sensors thereon according to various embodiments as described herein.

[0031] Figure 5 illustrates the embodiment of Figure 4 after the hip has been replaced showing contact locations with the bones of the patient.

[0032] Figure 6A is an exploded view of the acetabular cup, a liner, and the femoral having various sensors thereon according to the various embodiments described herein. Figure 6B is an illustration of the incorporation of strain gauges in a variety of locations.

[0033] Figure 7A is a side view of the femoral implant with the ball attached.

[0034] Figure 7B is an enlarged side view of the femoral implant with various sensors and a power generation segment.

[0035] Figure 8A is a top side view of an acetabular cup having various sensors according to the embodiments described herein.

CLAIMS

What is claimed is:

1. A hip replacement prosthesis comprising

a femoral stem,

a femoral head, or

an acetabular assembly, and one or more

sensors coupled to said femoral stem, femoral head or the acetabular assembly, wherein the hip replacement prosthesis further comprises a memory to store data collected by the one or more sensors and positioned in the femoral stem, characterized in that said one or more sensors comprises one or more accelerometers.

2. The hip replacement prosthesis according to claim 1 wherein said one or more sensors further comprises sensors selected from the group consisting of gyroscopes, pressure sensors, contact sensors, position sensors, chemical microsensors, tissue metabolic sensors, mechanical stress sensors and temperature sensors.

3. The hip replacement prosthesis according to claim 1 or 2, further including:

an electronic processor positioned inside the femoral stem that is electrically coupled to the one or more sensors, optionally wherein the electric coupling is a wireless coupling, wherein the memory is coupled to the electronic processor and positioned inside the femoral stem.

4. The hip replacement prosthesis according to any one of claims 1 to 3, wherein the one or more sensors are placed within the prosthesis.

5. The hip replacement prosthesis of claim 1 wherein said one or more sensors further comprises contact sensors positioned between the femoral head and the acetabular assembly, or on the outer surface of the acetabular assembly.

6. The hip replacement prosthesis of claim 1 wherein said one or more sensors further comprises a plurality of strain sensors positioned between the femoral head the acetabular assembly, or wherein the acetabular assembly includes an acetabular shell and an acetabular liner and said one or more sensors further comprises strain sensors positioned between the acetabular liner and the acetabular shell.

7. The hip replacement prosthesis of claim 1 wherein said one or more sensors further comprises gyroscopes, and the accelerometers or gyroscopes are positioned on the femoral stem.

8. A method of transferring data comprising

a) obtaining data from the one or more sensors of the prosthesis according to any one of claims 1 to 7;

b) storing the data in the memory at a storage site within the prosthesis; and

c) transferring the data from the memory to a location outside of the storage site,

particularly wherein the prosthesis is implanted within a subject, and the data is transferred to a site outside of the subject, particularly wherein said data is transferred to a watch, wrist band, cell phone or glasses; or to a residence or an office; or a health care provider.

9. The method according to claim 8 comprising:

obtaining contact data from contact sensors positioned between the femoral head and the acetabular assembly of the prosthesis according to claim 5 located in situ in the hip of the patient;

storing the contact data in the memory, the memory being located in the femoral stem that is coupled to the femoral head; and

transferring the data from the memory to a location outside the femoral stem.

10. The method according to claim 8 comprising:

obtaining strain data from strain sensors positioned between the femoral head and the acetabular assembly of the hip replacement prosthesis according to claim 6 located in the hip of a patient;

storing the strain data in the memory, the memory being located in a femoral stem that is coupled to the femoral head; and

transferring the strain data from the memory to a location outside the femoral stem.

11. The method according to claim 8, comprising:

obtaining contact data from a contact sensor positioned between the acetabular assembly of the prosthesis according to any one of claims 2-7 and a pelvis bone of the patient;

storing the contact data in the memory, the memory being located in the femoral stem; and

transferring the contact data from the memory in the femoral stem to a memory in a location outside of the femoral stem.

12. The method according to claim8 comprising:

obtaining acceleration data from the accelerometer or gyroscope positioned on the femoral stem of the prosthesis according to claim 7 located in situ in a hip of a patient;

storing the acceleration data in the memory, the memory being located in the femoral stem that is coupled to the femoral head; and

transferring the acceleration data from the memory in the femoral stem to a memory in a location outside the femoral stem.

13. The method according to any one of claims 8 to 12, further comprising the step of analyzing the data.

14. The method according to any one of claims 8 to 13, wherein said data is plotted to enable visualization of change over time, or plotted to provide a two or three-dimensional image, or plotted to provide a moving two or three-dimensional image, and/or wherein said data is utilized to determine a range of motion of a subject with said hip prosthesis, or to determine or predict any deficiencies or malfunctions of the hip prosthesis.

15. A method for detecting degradation in the hip replacement prosthesis according to any one of claims 1 to 7, provided to a patient comprising the step of detecting a change in the one or more sensors of the hip prosthesis, and thus determining degradation of the hip implant prosthesis, particularly wherein said sensor is capable of detecting one or more physiological and or locational parameters.