SUMMARY

[0014] Briefly stated, embodiments of the present disclosure relate to intelligent implants, systems including intelligent implants, methods of using the implants/systems to do at least one of detect, locate, quantify and/or characterize problems associated with the implant, and methods and devices to address the problems that have been identified. As provided in more detail below, embodiments of the present disclosure provide medical devices coupled to a sensor, and systems including such devices, which can generate data as well as analysis based on that data, which may be used to identify and/or address problems associated with the implanted medical device. In one embodiment the medical device is an artificial joint (TJA) and the data is kinematic data reflecting movement of the artificial joint. Problems that may be identified include incorrect placement of the TJA device, incorrect alignment of the device, unanticipated degradation or wear of the device, instability of the device (and the associated joint), and undesired movement of the device. Also provided are medical devices coupled to a sensor, and devices and methods to address problems that have been identified with an implanted medical device.

[0015] Embodiments of the medical device coupled to a sensor may be referred to as an intelligent implant, where the intelligent implant will include a sensor that can detect and/or measure the functioning of the implant and/or the immediate environment around the implant and/or the activity/movement of the implant as well as the activity and movement of the patient. The implant may alternatively be referred to herein as a prosthesis, where an intelligent implant and an intelligent prosthesis have the same meaning. In one embodiment, the coupling of the sensor to the medical device, e.g., to the prosthesis/implant, is to have the sensor located entirely within the medical device such that the sensor is totally enclosed by the exterior surface of the medical device, so that no part of the sensor physically contacts any tissue of a patient into whom the medical device has been implanted. In embodiments of the present disclosure, reference herein to a medical device, or to an implant or a prosthesis may be understood to be a reference to an intelligent medical device or implant/prosthesis having a sensor that is located entirely within the medical device or implant/prosthesis as disclosed herein. In embodiments of the present disclosure, reference herein to a medical device, or to an implant or a prosthesis having a sensor is to be understood to be a reference to an intelligent medical device or implant/prosthesis wherein the sensor is located entirely within the medical device or implant/prosthesis. In embodiments of the present disclosure, reference herein to a medical device, or an implant/prosthesis having a sensor is to be understood to be a reference to an intelligent medical device or implant/prosthesis wherein

the sensor is one accelerometer or more than one accelerometer (e.g., two, three, four, five, six, seven, etc. accelerometers) located entirely within the medical device or implant/prosthesis. In embodiments of the present disclosure, reference herein to a medical device, or an implant/prosthesis having a sensor is to be understood to be a reference to an intelligent medical device or implant/prosthesis wherein the sensor is one or more accelerometers (e.g., two, three, four, five, six, seven, etc. accelerometers) located entirely within a tibial extension of the medical device, implant/prosthesis, such that the medical device or implant/prosthesis is, e.g. a component of a TKA.

[0016] Embodiments of the systems will include the intelligent implant and one or more of a memory that stores data from that detection and/or measuring, an antenna that transmits that data; a base station that receives the data generated by the sensor and may transmit the data and/or analyzed data to a cloud-based location; a cloud-based location where data may be stored and analyzed, and analyzed data may be stored and/or further analyzed; and a receiving station that receives output from the cloud-based location, where that receiving station may be accessed, e.g., by a health care professional or an insurance company or the manufacturer of the implant, and the output may identify the status of the implant and/or the functioning of the implant and/or the status of the patient who has received the implant, and may also provide recommendations for addressing any concerns raised by analysis of the original data.

[0017] For example, instability in the total joint arthroplasty (e.g. TKA, THA and TSA) hardware may lead to bone erosion and accelerated fatigue of the implant components. Left untreated or uncorrected, bone erosion and accelerated fatigue will typically lead to pain and inflammation. By the time pain and inflammation prompt a total joint arthroplasty (TJA) patient to seek medical care, the extent of bone erosion and TJA fatigue may leave the health care professional with only one-choice: a highly invasive and expensive surgery with reduced probability of “successful” outcome. Embodiments of the present disclosure provide devices, systems and methods which provide that the instability in the TJA hardware can be detected early before bone erosion and implant fatigue damage. This instability can be detected, quantified and characterized, and the results communicated to a health care provider to allow for early treatment and/or more effective treatment of the problem, i.e., the health care provider may take advantage of corrective treatments that are far less invasive, less expensive, and more likely to succeed. Embodiments of the present disclosure also provide devices and/or methods to address the instability problem.

[0018] Embodiments of the present disclosure refers to TJA (total joint arthroplasty) which term includes reference to the surgery and associated implanted hardware such as a TJA prosthesis of the

present disclosure. Features of methods, devices and systems of embodiments of the present disclosure may be illustrated herein by reference to a specific intelligent TJA prosthesis, however, the disclosure should be understood to apply to any one or more TJA prosthesis, including a TKA (total knee arthroscopy) prosthesis, such as a TKI (total knee implant) which may also be referred to as a TKA system; a TSA (total shoulder arthroscopy) prosthesis, such as a TSI (total shoulder implant) which may also be referred to as a TSI system; and a THA (total hip arthroscopy) prosthesis, such as a THI (total hip implant) which may also be referred to as a THA system. In one embodiment the TJA prosthesis is an intelligent TJA, also referred to as an intelligent TJA prosthesis, having at least one sensor at disclosed herein.

[0019] This Brief Summary has been provided to introduce certain concepts in a simplified form that are further described in detail below in the Detailed Description. Except where otherwise expressly stated, this Brief Summary is not intended to identify key or essential features of the claimed subject matter, nor is it intended to limit the scope of the claimed subject matter.

[0020] The following are some exemplary aspects and embodiments of the present disclosure:

Disclosed herein is a tibial insert for an implantable knee prosthesis, comprising a tibial insert that is 1, 2, 3, 4, 5, 6, 7, 8, 9, or, 10 mm thicker on the medial side of the implant, as compared to the lateral side.

Disclosed herein is a tibial insert for an implantable knee prosthesis, comprising a tibial insert that is 1, 2, 3, 4, 5, 6, 7, 8, 9, or, 10 mm thicker on the lateral side of the implant, as compared to the medial side.

Disclosed herein is a tibial insert for an implantable knee prosthesis, comprising a tibial insert that is 1, 2, 3, 4, 5, 6, 7, 8, 9, or, 10 mm thicker on the anterior side of the implant, as compared to the posterior side.

Disclosed herein is a tibial insert for an implantable knee prosthesis, comprising a tibial insert that is 1, 2, 3, 4, 5, 6, 7, 8, 9, or, 10 mm thicker on the posterior side of the implant, as compared to the anterior side.

Disclosed herein is a tibial insert / articular spacer / for an implantable knee prosthesis, comprising a tibial insert that is 1, 2, 3, 4, 5, 6, 7, 8, 9, or, 10 mm thicker on the medial, lateral, anterior and/or posterior side of the implant.

In the above disclosed tibial insert, the tibial insert is composed of polyethylene, or polyetheretherketone (PEEK).

In the above disclosed tibial insert, the tibial insert is customized to a patient.

In the above disclosed tibial insert, wherein said insert is manufactured by 3-D printing, or, by molding.

According to a first aspect of the present disclosure, there is provided an implantable medical device, comprising: a circuit configured to be fixedly attached to an implantable prosthetic device; a power component; and a device configured to uncouple the circuit from the power component.

According to a second aspect of the present disclosure, there is provided an implantable medical device, comprising: a circuit configured to be fixedly attached to an implantable prosthetic device; a battery; and a fuse coupled between the circuit and the battery.

According to a third aspect of the present disclosure, there is provided a method, comprising electrically opening a fuse that is disposed between a circuit and a battery, at least the fuse and the circuit being disposed on an implanted prosthetic device.

Disclosed herein is an implantable medical device, comprising: at least one sensor configured to generate a sensor signal; and a control circuit configured to cause the at least one sensor to generate the sensor signal at a frequency that is related to a telemedicine code.

Disclosed herein is an implantable medical device, comprising: at least one sensor configured to generate a sensor signal; and a control circuit configured to cause the at least one sensor to generate the sensor signal at a frequency that allows a doctor to qualify for payment under a telemedicine insurance code.

Disclosed herein is an implantable medical device, comprising: at least one sensor configured to generate a sensor signal; and a control circuit configured to cause the at least one sensor to generate the sensor signal at a frequency that allows a doctor to qualify for full payment under a telemedicine insurance code.

Disclosed herein is a method, comprising, generating a sensor signal that is related to an implanted medical device at a frequency that allows a doctor to qualify for payment available under a telemedicine insurance code.

Disclosed herein is a method, comprising, generating a sensor signal that is related to an implanted medical device at a frequency that allows a doctor to qualify for full payment available under a telemedicine insurance code.

Disclosed herein is an implantable prosthesis, comprising: a housing; and an implantable circuit disposed in the housing and configured to generate at least one first signal representative of a movement; to determine whether the signal meets at least one first criterion; and to send the signal to a remote location in response to determining that the signal meets the at least one first criterion.

Disclosed herein is a base station, comprising: a housing; and a base-station circuit disposed in the housing and configured to receive, from an implantable prosthesis, at least first signal representative of a movement; to send the at least one first signal to a destination; to receive at least one second signal from a source; and to send the at least one second signal to the implantable prosthesis.

According to a fourth aspect of the present disclosure, there is provided a method, comprising opening a fuse disposed on an implantable prosthesis between a power source and an implantable circuit in response to a current through the fuse exceeding an overcurrent threshold.

According to a fifth aspect of the present disclosure, there is provided a method, comprising opening a fuse disposed on an implantable prosthesis between a power source and an implantable circuit in response to a current through the fuse exceeding an overcurrent threshold for at least a threshold time.

According to a sixth aspect of the present disclosure, there is provided a method, comprising opening a fuse disposed on an implantable prosthesis between a power source and an implantable circuit in response to a voltage across the fuse exceeding an overvoltage threshold.

According to a seventh aspect of the present disclosure, there is provided a method, comprising opening a fuse disposed on an implantable prosthesis between a power source and an implantable circuit in response to a voltage across the fuse exceeding an overvoltage threshold for at least a threshold time.

According to an eighth aspect of the present disclosure, there is provided a method, comprising opening a fuse disposed on an implantable prosthesis between a power source and an implantable circuit in response to a temperature exceeds an overtemperature threshold.

According to a ninth aspect of the present disclosure, there is provided a method, comprising opening a fuse disposed on an implantable prosthesis between a power source and an implantable circuit in response to a temperature exceeding an overtemperature threshold for at least a threshold length of time.

Disclosed herein is a method, comprising: generating a sensor signal in response to a movement of a subject in which a prosthesis is implanted; and transmitting the sensor signal to a remote location.

Disclosed herein is a method, comprising: generating a sensor signal in response to a movement of a subject in which a prosthesis is implanted; sampling the sensor signal; and transmitting the samples to a remote location.

Disclosed herein is a method, comprising: generating a sensor signal in response to a movement of a subject in which a prosthesis is implanted; determining whether the sensor signal represents a qualified event; and transmitting the signal to a remote location in response to determining that the sensor signal represents a qualified event.

Disclosed herein is a method, comprising: generating a sensor signal in response to a movement of a subject in which a prosthesis is implanted; receiving a polling signal from a remote location; and transmitting the sensor signal to the remote location in response to the polling signal.

Disclosed herein is a method, comprising: generating a sensor signal in response to a movement of a subject in which a prosthesis is implanted; generating a message that includes the sensor signal or data representative of the sensor signal; and transmitting the message to a remote location.

Disclosed herein is a method, comprising: generating a sensor signal in response to a movement of a subject in which a prosthesis is implanted; generating a data packet that includes the sensor signal or data representative of the sensor signal; and transmitting the data packet to a remote location.

Disclosed herein is a method, comprising: generating a sensor signal in response to a movement of a subject in which a prosthesis is implanted; encrypting at least a portion of the sensor signal or data representative of the sensor signal; and transmitting the encrypted sensor signal to a remote location.

Disclosed herein is a method, comprising: generating a sensor signal in response to a movement of a subject in which a prosthesis is implanted; encoding at least a portion of the sensor signal or data representative of the sensor signal; and transmitting the encoded sensor signal to a remote location.

Disclosed herein is a method, comprising: generating a sensor signal in response to a movement of a subject in which a prosthesis is implanted; transmitting the sensor signal to a remote location; and entering an implantable circuit associated with the prosthesis into a lower-power mode after transmitting the sensor signal.

Disclosed herein is a method, comprising: generating a first sensor signal in response to a movement of a subject in which a prosthesis is implanted; transmitting the first sensor signal to a remote location; entering at least one component of an implantable circuit associated with the prosthesis into a lower-power mode after transmitting the sensor signal; and generating a second sensor signal in response to a movement of the subject after an elapse of a low-power-mode time for which the implantable circuit is configured.

Disclosed herein is a method, comprising: receiving a sensor signal from a prosthesis implanted in a subject; and transmitting the received sensor signal to a destination.

Disclosed herein is a method, comprising: sending an inquiry to a prosthesis implanted in a subject, receiving a sensor signal from a prosthesis after sending the inquiry; and transmitting the received sensor signal to a destination.

Disclosed herein is a method, comprising: receiving a sensor signal and at least one identifier from a prosthesis implanted in a subject; determining whether the identifier is correct; and transmitting the received sensor signal to a destination in response to determining that the identifier is correct.

Disclosed herein is a method, comprising: receiving a message including a sensor signal from a prosthesis implanted in a subject; decrypting at least a portion of the message; and transmitting the decrypted message to a destination.

Disclosed herein is a method, comprising: receiving a message including a sensor signal from a prosthesis implanted in a subject; decoding at least a portion of the message; and transmitting the decoded message to a destination.

Disclosed herein is a method, comprising: receiving a message including a sensor signal from a prosthesis implanted in a subject; encoding at least a portion of the message; and transmitting the encoded message to a destination.

Disclosed herein is a method, comprising: receiving a message including a sensor signal from a prosthesis implanted in a subject; encrypting at least a portion of the message; and transmitting the encrypted message to a destination.

Disclosed herein is a method, comprising: receiving a data packet including a sensor signal from a prosthesis implanted in a subject; decrypting at least a portion of the data packet; and transmitting the decrypted data packet to a destination.

Disclosed herein is a method, comprising: receiving a data packet including a sensor signal from a prosthesis implanted in a subject; decoding at least a portion of the data packet; and transmitting the decoded data packet to a destination.

Disclosed herein is a method, comprising: receiving a data packet including a sensor signal from a prosthesis implanted in a subject; encoding at least a portion of the data packet; and transmitting the encoded data packet to a destination.

Disclosed herein is a method, comprising: receiving a data packet including a sensor signal from a prosthesis implanted in a subject; encrypting at least a portion of the data packet; and transmitting the encrypted data packet to a destination.

Disclosed herein is a method, comprising: receiving a sensor signal from a prosthesis implanted in a subject; decrypting at least a portion of the sensor signal; and transmitting the decrypted sensor signal to a destination.

Disclosed herein is a method, comprising: receiving a sensor signal from a prosthesis implanted in a subject; decoding at least a portion of the sensor signal; and transmitting the decoded sensor signal to a destination.

Disclosed herein is a method, comprising: receiving a sensor signal from a prosthesis implanted in a subject; encoding at least a portion of the sensor signal; and transmitting the encoded sensor signal to a destination.

Disclosed herein is a method, comprising: receiving a sensor signal from a prosthesis implanted in a subject; encrypting at least a portion of the sensor signal; and transmitting the encrypted sensor signal to a destination.

Disclosed herein is an implantable circuit for an implantable prosthesis.

Disclosed herein is an implantable prosthesis including an implantable circuit.

According to a tenth aspect of the present disclosure, there is provided an implantable prosthesis including a fuse.

Disclosed herein is a base station for communication with an implantable prosthesis.

Disclosed herein is a monitoring-session-data collection, analysis, and status-reporting system implemented as a component of one or more computer systems, each computer system having one or more processors, one or more memories, one or more network connections, and access to one or more mass-storage devices, the one or more the monitoring-session-data collection, data-analysis, and status-reporting system comprising: a monitoring-session-data-receiving component that receives monitoring-session-data, including acceleration data generated by sensors within or proximal to a prosthesis attached or implanted within a patient, from an external monitoring-session-data source and that stores the received monitoring-session-data in one or more of the one or more memories and one or more mass-storage devices; a monitoring-session-data-processing component that prepares the monitoring-session-data for processing, determines component trajectories representing motion modes and additional metric values from the monitoring-session-data; and a monitoring-session-data-analysis component that determines a prosthesis status and a patient status from the motion modes and additional metric values, distributes the determined prosthesis status and patient status to target computer systems through the network connections, and when indicated by the determined prosthesis status and patient

status, distributes one or more alarms and events to target computer systems through the network connections.

In an embodiment of the above disclosed monitoring-session-data collection, analysis, and status-reporting system, the monitoring-session-data includes: a patient identifier; a device identifier; a timestamp; device-configuration data; and an ordered set of data.

In an embodiment of the above disclosed monitoring-session-data collection, analysis, and status-reporting system, the ordered set of data comprises one of: a time sequence of data vectors, each data vector including numerical values related to linear-accelerations with respect to three coordinate axes of an internal device coordinate system; and a time sequence of data vectors, each data vector including numerical values related to linear-accelerations with respect to three coordinate axes of a first internal device coordinate system and including numerical values related to angular velocities, numerical values related to angular velocities relative to the first internal device coordinate system or to a second internal device coordinate system.

In an embodiment of the above disclosed monitoring-session-data collection, analysis, and status-reporting system, the monitoring-session-data-processing component prepares the monitoring-session-data for processing by: receiving a time sequence of data vectors, each data vector including three numerical values related to linear-accelerations in the directions of three coordinate axes of a first internal device coordinate system and including three numerical values related to angular velocities about each axis of the first or a second internal device coordinate system; when rescaling of the data-vector sequence is needed, rescaling the numerical values of the data vectors; when normalization of the data-vector sequence is needed, normalizing the numerical values of the data vectors; when transformation of one or more of the numerical values related to linear-acceleration and the numerical values related to angular velocities is needed to relate the numerical values related to linear-acceleration and the numerical values related to angular velocities to a common internal coordinate system, transforming one or more of the numerical values related to linear-acceleration and the numerical values related to angular velocities to relate to the common internal coordinate system; and when the time sequence of data vectors needs to be synchronized with respect to a fixed-interval time sequence, synchronizing the data vectors with respect to a fixed-interval time sequence.

In an embodiment of the above disclosed monitoring-session-data collection, analysis, and status-reporting system, the monitoring-session-data-processing component determines component trajectories representing motion modes and additional metric values from the monitoring-session-data by: orienting the prepared monitoring-session-data, comprising data vectors, each data vector

including three numerical values related to linear-accelerations in the directions of three coordinate axes of an internal device coordinate system and including three numerical values related to angular velocities about each axis of the internal device coordinate system, with respect to a natural coordinate system; bandpass filtering the oriented data vectors to obtain a set of data vectors for each of multiple frequencies, including a normal-motion frequency; determining, from the data vectors for each of the non-normal-motion frequencies, a spatial amplitude in each of the coordinate-axis directions of the natural coordinate system; determining, from a basis trajectory for the patient and the data vectors for the normal-motion frequency, a spatial amplitude in each of the coordinate-axis directions of the natural coordinate system; and determining, from the basis trajectory for the patient and the data vectors for the normal-motion frequency, current normal-motion characteristics.

In an embodiment of the above disclosed monitoring-session-data collection, analysis, and status-reporting system, determining, from the data vectors for a frequency, a spatial amplitude in each of the coordinate-axis directions of the natural coordinate system further comprises: generating a spatial trajectory from the data vectors; projecting the spatial frequency onto each of the coordinate axes; and determining the lengths of the protections of the spatial frequency onto each of the coordinate axes.

In an embodiment of the above disclosed monitoring-session-data collection, analysis, and status-reporting system, the monitoring-session-data-analysis component determines a prosthesis status and a patient status from the motion modes and additional metric values by: submitting the motion modes and additional metric values to a decision tree that generates a diagnosis-and-suggestions report; and packaging the diagnosis-and-suggestions report together with amplitudes generated for the motion modes, metrics generated from a normal-motion-frequency trajectory and a base trajectory, and additional metric values to generate one or both of an output report and output data values that characterize the prosthesis status and the patient status.

In an embodiment of the above disclosed monitoring-session-data collection, analysis, and status-reporting system, the monitoring-session-data-analysis component wherein the one or more alarms and events distributed to target computer systems include: an alarm that notifies a medical practitioner or medical facility of the need, by the patient, of immediate assistance or intervention; and an event that indicates additional services and/or equipment needed by the patient that may be handled by various external computer systems to automatically provide the additional services and/or equipment to the patient or inform the patient of the additional services and/or equipment

and provide the patient with information regarding procurement of the additional services and/or equipment.

Disclosed herein is a method, carried out by a monitoring-session-data collection, analysis, and status-reporting system implemented as a component of one or more computer systems, each computer system having one or more processors, one or more memories, one or more network connections, and access to one or more mass-storage devices, the method comprising: receiving monitoring-session-data, including acceleration data generated by sensors within or proximal to a prosthesis attached or implanted within a patient, from an external monitoring-session-data source; storing the received monitoring-session-data in one or more of the one or more memories and one or more mass-storage devices; determining a prosthesis status and a patient status from the motion modes and additional metric values, distributing the determined prosthesis status and patient status to target computer systems through the network connections, and when indicated by the determined prosthesis status and patient status, distributing one or more alarms and events to target computer systems through the network connections.

In an embodiment of the above disclosed method, determining a prosthesis status and a patient status from the motion modes and additional metric values further comprises: preparing the monitoring-session-data for processing, determines component trajectories representing motion modes and additional metric values from the monitoring-session-data; submitting the motion modes and additional metric values to a decision tree that generates a diagnosis-and-suggestions report; and packaging the diagnosis-and-suggestions report together with amplitudes generated for the motion modes, metrics generated from a normal-motion-frequency trajectory and a base trajectory, and additional metric values to generate one or both of an output report and output data values that characterize the prosthesis status and the patient status.

In an embodiment of the above disclosed method, preparing the monitoring-session-data for processing further comprises receiving a time sequence of data vectors, each data vector including three numerical values related to linear-accelerations in the directions of three coordinate axes of a first internal device coordinate system and including three numerical values related to angular velocities about each axis of the first or a second internal device coordinate system; when rescaling of the data-vector sequence is needed, rescaling the numerical values of the data vectors; when normalization of the data-vector sequence is needed, normalizing the numerical values of the data vectors; when transformation of one or more of the numerical values related to linear-acceleration and the numerical values related to angular velocities is needed to relate the numerical values related to linear-acceleration and the numerical values related to angular velocities to a

common internal coordinate system, transforming one or more of the numerical values related to linear-acceleration and the numerical values related to angular velocities to relate to the common internal coordinate system; and when the time sequence of data vectors needs to be synchronized with respect to a fixed-interval time sequence, synchronizing the data vectors with respect to a fixed-interval time sequence.

In an embodiment of the above disclosed method, determining component trajectories representing motion modes and additional metric values from the monitoring-session-data by: orienting the prepared monitoring-session-data, comprising data vectors, each data vector including three numerical values related to linear-accelerations in the directions of three coordinate axes of an internal device coordinate system and including three numerical values related to angular velocities about each axis of the internal device coordinate system, with respect to a natural coordinate system; bandpass filtering the oriented data vectors to obtain a set of data vectors for each of multiple frequencies, including a normal-motion frequency; determining, from the data vectors for each of the non-normal-motion frequencies, a spatial amplitude in each of the coordinate-axis directions of the natural coordinate system; determining, from a basis trajectory for the patient and the data vectors for the normal-motion frequency, a spatial amplitude in each of the coordinate-axis directions of the natural coordinate system; and determining, from the basis trajectory for the patient and the data vectors for the normal-motion frequency, current normal-motion characteristics.

In an embodiment of the above disclosed method, determining, from the data vectors for a frequency, a spatial amplitude in each of the coordinate-axis directions of the natural coordinate system further comprises: generating a spatial trajectory from the data vectors; projecting the spatial frequency onto each of the coordinate axes; and determining the lengths of the protections of the spatial frequency onto each of the coordinate axes.

In an embodiment of the above disclosed method, determining a prosthesis status and a patient status from the motion modes and additional metric values further comprises: submitting the motion modes and additional metric values to a decision tree that generates a diagnosis-and-suggestions report; and packaging the diagnosis-and-suggestions report together with amplitudes generated for the motion modes, metrics generated from a normal-motion-frequency trajectory and a base trajectory, and additional metric values to generate one or both of an output report and output data values that characterize the prosthesis status and the patient status.

In an embodiment of the above disclosed method, the one or more alarms and events distributed to target computer systems include: an alarm that notifies a medical practitioner or

medical facility of the need, by the patient, of immediate assistance or intervention; and an event that indicates additional services and/or equipment needed by the patient that may be handled by various external computer systems to automatically provide the additional services and/or equipment to the patient or inform the patient of the additional services and/or equipment and provide the patient with information regarding procurement of the additional services and/or equipment.

Disclosed herein is a physical data-storage device encoded with computer instructions that, when executed by one or more processors within one or more computer systems of a monitoring-session-data collection, analysis, and status-reporting system, each computer system having one or more processors, one or more memories, one or more network connections, and access to one or more mass-storage devices, control the monitoring-session-data collection, analysis, and status-reporting system to: receive monitoring-session-data, including acceleration data generated by sensors within or proximal to a prosthesis attached or implanted within a patient, from an external monitoring-session-data source.

Disclosed herein is a method for determining joint loosening in a patient having an implanted artificial joint, comprising a) analyzing movement of an implanted artificial joint, and b) comparing said movement vs. previous / standardized norms.

Disclosed herein is a method for determining loosening of an implanted prosthesis in a patient having the implanted prosthesis, comprising: a) obtaining a standardized norm of movement by analyzing movement of an implanted prosthesis during one or more first monitoring sessions, b) obtaining a current description of movement by analyzing movement of an implanted prosthesis during one or more second monitoring sessions that occur subsequent to the one or more first monitoring sessions; and c) comparing said current description of movement to said standardized norm of movement, to thereby identify loosening of an implanted prothesis in a patient having the implanted prosthesis.

Disclosed herein is a method for identifying a clinical or subclinical condition associated with an implant in a patient, the method comprising:

a. monitoring a first motion of the implant during a first monitoring session using a sensor which is directly coupled to the implant, to provide a first monitoring-session data for the first motion;
b. monitoring a second motion of the implant during a second monitoring session using the sensor, to provide a second monitoring-session-data for the second motion; and

c. comparing the first monitoring-session data or a product thereof to the second monitoring-session-data or a product thereof, to provide a comparison that is indicative of a clinical or subclinical condition associated with the implant.

In an embodiment of the above disclosed method, the clinical or subclinical condition is a loosening of the implant (motion of prosthesis within the surrounding bone or cement, e.g., the implant becomes separated from the host bone due, e.g., to periprosthetic lucency or periprosthetic osteolysis).

In an embodiment of the above disclosed method, the clinical or subclinical condition is a malalignment (sub-optimal positioning of a prosthetic component) or a realignment of the implant (change in alignment of prosthetic component).

In an embodiment of the above disclosed method, the clinical or subclinical condition is deformation (wear) of the implant.

In an embodiment of the above disclosed method, the patient is asymptomatic for the condition, and the comparison of the first and second data or products thereof indicate that the condition has occurred between the first and second monitoring sessions.

In an embodiment of the above disclosed method, the patient is asymptomatic for loosening of the implant, and the comparison of the first and second data or products thereof indicate that the implant has loosened between the first and second monitoring sessions.

In an embodiment of the above disclosed method, the patient is asymptomatic for realignment of the implant, and comparison of the first and second data or products thereof indicate that the implant has changed alignment between the first and second monitoring sessions.

In an embodiment of the above disclosed method, the patient is asymptomatic for deformation of the implant, and comparison of the first and second data or products thereof indicate that the implant has deformed between the first and second monitoring sessions.

Disclosed herein is method for treating a clinical or subclinical condition associated with an implant in a patient, comprising:

a. identifying an implant in a patient, where the implant has a clinical or subclinical condition; and

b. attaching corrective external bracing to patient to restore proper alignment and/or enhanced stability to the implant.

In an embodiment of the above disclosed method, the corrective external bracing has been specifically tailored to the patient and the subclinical condition.

Disclosed herein is a method for treating a clinical or subclinical condition associated with an implant in a patient, comprising:

a. identifying an implant in a patient, where the implant has a clinical or subclinical condition; and

b. contacting the implant with a fixation system to retard progression of the subclinical condition.

In an embodiment of the above disclosed method, the fixation system comprises hardware selected from a K-wire, pin, screw, plate and intramedullary device.

In an embodiment of the above disclosed method, a screw is located through a bone that holds the implant, where a terminus of the screw pushes against a surface of the implant to retard movement of the implant, where a screw is selected from one, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen, seventeen, eighteen, nineteen and twenty screws.

In an embodiment of the above disclosed method, the fixation system comprises bone cement.

Disclosed herein is a method for treating a clinical or subclinical condition associated with an implant in a patient, comprising:

a. identifying an implant in a patient, where the implant has a clinical or subclinical condition; and

b. contacting the implant with a tamp, where the contacting changes a location of the implant within the patient; and optionally

c. applying a cement around the implant having the changed location.

In an embodiment of the above disclosed, the subclinical condition is a realignment of the implant.

Disclosed herein is a method for treating a clinical or subclinical condition associated with an implant in a patient, comprising:

a. identifying an implant in a patient, where the implant has a clinical or subclinical condition; and

b. implanting an insert adjacent to a component of the implant, where the insert modifies forces acting on the component of the implant.

In an embodiment of the above disclosed method, the insert is a tibial insert.

In an embodiment of the above disclosed method, the insert is a tibial insert having (i) a lateral side with a minimum thickness and (ii) a medial side with a minimum thickness that is non-identical to the minimum thickness of the lateral side.

Disclosed herein is a method for treating a clinical or subclinical condition associated with an implant in a patient, comprising:

a. identifying an implant in a patient, where the implant has a clinical or subclinical condition; and

b. delivering a pro-osteointegration agent to a location surrounding the implant.

In an embodiment of the above disclosed method, the pro-osteointegration agent is selected from autologous bone graft, xenograph bone graft, synthetic bone graft, bone pastes, bone growth factor, and growth factor.

Disclosed herein is a method for treating a clinical or subclinical condition associated with an implant in a patient, comprising:

a. identifying an implant in a patient, where the implant has a clinical or subclinical condition; and

b. delivering an anti-bacterial agent to a location surrounding the implant.

In an embodiment of the above disclosed method, the anti-bacterial agent is compounded in a sustained release form.

In an embodiment of the above disclosed method, the implant is an intelligent implant.

In an embodiment of the above disclosed method, the implant is selected from a knee implant, a hip implant and a shoulder implant.

In an embodiment of the above disclosed method, the product of the monitoring-session data comprises a motion mode.

In an embodiment of the above disclosed method, the product of the monitoring-session data comprises a motion mode, and a status of the implant is determined from the motion mode.

In an embodiment of the above disclosed method, the product of the monitoring-session data comprises a motion mode, and a status of the patient is determined from the motion mode.

In an embodiment of the above disclosed method, the implant has been located within the patient for at least 10 weeks prior to the first monitoring session.

In an embodiment of the above disclosed method, the implant has changed alignment over a period of at least 2 weeks.

In an embodiment of the above disclosed method, the implant has loosened over a period of at least two weeks.

In an embodiment of the above disclosed method, the implant has deformed over a period of at least two weeks.

In an embodiment of the above disclosed method, the implant comprises a control circuit configured to cause the sensor to generate a sensor signal at a frequency that is related to a telemedicine code for the clinical or subclinical condition, and the sensor signal is generated at the frequency.

In an embodiment of the above disclosed method, the implant comprises a control circuit configured to cause the sensor to generate a sensor signal at a frequency that allows a doctor to qualify for payment under a telemedicine insurance code, and the sensor signal is generated at the frequency.

In an embodiment of the above disclosed method, the implant comprises a control circuit configured to cause the sensor to generate a sensor signal at a frequency that allows a doctor to qualify for full payment under a telemedicine insurance code, and the sensor signal is generated at the frequency.

An embodiment of the above disclosed method further comprising generating a sensor signal that is related to the implant at a frequency that allows (i) a doctor to qualify for full payment available under a telemedicine insurance code, or (ii) a doctor to qualify for payment available under a telemedicine insurance code.

Disclosed herein is a method comprising:

a. providing an intelligent prosthesis implanted in a bone adjacent to a joint of a patient, where an accelerometer is contained within the intelligent prosthesis, and where the accelerometer is positioned within the bone;

b. moving the implanted intelligent prosthesis relative to an external environment wherein the patient is located, where the implanted intelligent prosthesis is moved during a first monitoring session;

c. making first measurements with the accelerometer during the first monitoring session, where the first measurements provide first monitoring-session-data or a product thereof which identifies a status of the implanted intelligent prosthesis at a time of the first measurements.

In an embodiment of the above disclosed, the accelerometer is a plurality of accelerometers.

In an embodiment of the above disclosed method, the accelerometer is selected from a 1-axis accelerometer, a 2-axis accelerometer and a 3-axis accelerometer.

In an embodiment of the above disclosed method, the accelerometer operates in a broadband mode.

In an embodiment of the above disclosed method, the bone is a tibia.

In an embodiment of the above disclosed method, the accelerometer is located in a tibial extension of the intelligent prosthesis.

In an embodiment of the above disclosed method, the implanted intelligent prosthesis is moved relative to the external environment without an impact force being applied to the patient or the intelligent prosthesis during the first monitoring session.

In an embodiment of the above disclosed method, the external environment comprises a residence of the patient.

In an embodiment of the above disclosed method, the external environment comprises an operating room wherein the intelligent prosthesis has been implanted into the patient.

In an embodiment of the above disclosed method, the status of the implanted intelligent prosthesis is a characterization of the looseness of the implanted intelligent prosthesis within the bone.

In an embodiment of the above disclosed method, the status of the implanted intelligent prosthesis is a characterization of the alignment of the implanted intelligent prosthesis within the bone.

In an embodiment of the above disclosed method, the status of the implanted intelligent prosthesis is a characterization of the wear of the implanted intelligent prosthesis.

In an embodiment of the above disclosed method, the status of the implanted intelligent prosthesis is a characterization of bacterial infection of a region within the bone adjacent to the implanted intelligent prosthesis.

In an embodiment of the above disclosed method, the status of the implanted intelligent prosthesis indicates a subclinical condition.

In an embodiment of the above disclosed method, step b) is repeated after a waiting period, where the repeat of step b) comprises moving the implanted intelligent prosthesis relative to an external environment wherein the patient is located, where the implanted intelligent prosthesis is moved during a second monitoring session, and wherein second measurements are made with the accelerometer during the second monitoring session, where the second measurements provide second monitoring-session-data or a product thereof which identifies a status of the implanted of the implanted intelligent prosthesis at the time of the second measurements.

In an embodiment of the above disclosed method, step b) is repeated a plurality of times, the plurality of times separated from one another by identical or non-identical waiting periods, where the repeating of step b) comprises moving the implanted intelligent prosthesis relative to an

external environment wherein the patient is located, where the implanted intelligent prosthesis is moved during a plurality of monitoring sessions, and wherein measurements are made with the accelerometer during each of the plurality of monitoring sessions, where the measurements provide a plurality of monitoring-session-data or products thereof, each of which identifies a status of the implanted of the implanted intelligent prosthesis at the time of the measurements.

In an embodiment of the above disclosed method, step b) is repeated a plurality of times, the plurality of times separated from one another by identical or non-identical waiting periods, where the repeating of step b) comprises moving the implanted intelligent prosthesis relative to an external environment wherein the patient is located, where the implanted intelligent prosthesis is moved during a plurality of monitoring sessions, and wherein measurements are made with the accelerometer during each of the plurality of monitoring sessions, where the measurements provide a plurality of monitoring-session-data or products thereof, each of which identifies a status of the implanted of the implanted intelligent prosthesis at the time of the measurements; wherein the plurality is optionally selected from 2 to 20 monitoring sessions, and where the plurality of monitoring-session data taken together indicate a change in the status of the implanted intelligent prosthesis during the time when the plurality of monitoring sessions occurred.

In an embodiment of the above disclosed method, the change in the status is indicative of a healing of the tissue surrounding the implanted intelligent prosthesis.

In an embodiment of the above disclosed method, the change in the status is indicative of an infection of the tissue surrounding the implanted prosthesis.

In an embodiment of the above disclosed method, the change in the status is indicative of a loosening of the implanted intelligent prothesis within the bone.

In an embodiment of the above disclosed method, the change in status is indicative of wear of the implanted intelligent prosthesis.

In an embodiment of the above disclosed method, the change in status is indicative of malalignment of the implanted intelligent prosthesis.

In an embodiment of the above disclosed method, the change in status is indicative of a change in alignment of the implanted intelligent prosthesis.

[0021] The details of one or more embodiments are set forth in the description below. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Thus, any of the various embodiments described herein can be combined to provide further embodiments. Aspects of the embodiments can be modified, if necessary to employ concepts of the various patents, applications and publications as identified

herein to provide yet further embodiments. Other features, objects and advantages will be apparent from the description, the drawings, and the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] Exemplary features of the present disclosure, its nature and various advantages will be apparent from the accompanying drawings and the following detailed description of various embodiments. Non-limiting and non-exhaustive embodiments are described with reference to the accompanying drawings, wherein like labels or reference numbers refer to like parts throughout the various views unless otherwise specified. The sizes and relative positions of elements in the drawings are not necessarily drawn to scale. For example, the shapes of various elements are selected, enlarged, and positioned to improve drawing legibility. The particular shapes of the elements as drawn have been selected for ease of recognition in the drawings. One or more embodiments are described hereinafter with reference to the accompanying drawings in which:

[0023] FIG. 1 illustrates an exemplary intelligent implant.

[0024] FIG. 2 illustrates including the implant of FIG. 1 as part of a joint prosthesis, and locating that prosthesis in a tibia.

[0025] FIG. 3 is a context diagram of a kinematic implantable device environment in a patient's home, according to an embodiment.

[0026] FIG. 4 is a block diagram of an implantable circuit for an implantable prosthesis, such as an implantable knee prosthesis, where the circuit includes an implantable reporting processor (IRP), according to an embodiment.

[0027] FIG. 5 is a block diagram of a base-station circuit for a base station configured to communicate with the implantable circuit of FIG. 101, and to forward data from the implantable circuit to a remote processing server such as a cloud-based server.

[0028] FIG. 6 is a perspective view of an inertial measurement unit (IMU) of the implantable circuit of FIG. 4 and of a set of coordinate axes within the frame of reference of the IMU, according