ENCAPSULATED FORCE SENSOR FOR MEASURING A PARAMETER OF THE MUSCULAR-SKELETAL SYSTEM

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ABSTRACT

A sensing insert device (100) is disclosed for measuring a parameter of the muscular-skeletal system. The sensing insert device (100) can be temporary or permanent. Used intraoperatively, the sensing insert device (100) comprises an insert dock (202) and a sensing module (200). The sensing module (200) is a self-contained encapsulated measurement device having at least one contacting surface that couples to the muscular-skeletal system. The insert dock (202) is a passive component made for different prosthetic component manufacturers as well as for different size prosthetic components. The sensing module (200) fits in an opening or cavity of the insert dock (202). The intra-operative insert device is substantially equal in dimension to an implanted final insert. The sensing insert device (100) is also a permanent prosthetic component. The sensing module (200) residing within the sensing insert device and coupling to a bearing surface of the insert.
Fig. 3
LOAD SENSING PLATFORM

COMPACT LOW-POWER ENERGY SOURCE

SHORT RANGE TELEMETRY

HIGH PRECISION SENSING

INTEGRATED POSITION AND LOAD SENSING

Fig. 7

Fig. 8
ENCAPSULATED FORCE SENSOR FOR MEASURING A PARAMETER OF THE MUSCULAR-SKELETAL SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the priority benefit of U.S. provisional patent application Nos. 61/221,761, 61/221,767, 61/221,779, 61/221,788, 61/221,793, 61/221,801, 61/221,808, 61/221,817, 61/221,867, 61/221,874, 61/221,879, 61/221,881, 61/221,886, 61/221,889, 61/221,894, 61/221,901, 61/221,909, 61/221,916, 61/221,923, and 61/221,929 all filed 30 Jun. 2009; the disclosures of which are hereby incorporated herein by reference in their entirety.

FIELD

The present invention pertains generally to measurement of physical parameters, and particularly to, but not exclusively to, a hermetically encapsulated sensing module for communicating sensor data and measurements in real-time.

BACKGROUND

The skeletal system of a mammal is subject to variations among species. Further changes can occur due to environmental factors, degradation through use, and aging. An orthopedic joint of the skeletal system typically comprises two or more bones that move in relation to one another. Movement is enabled by muscle tissue and tendons attached to the skeletal system of the joint. Ligaments hold and stabilize the one or more joint bones positionally. Cartilage is a wear surface that prevents bone-to-bone contact, distributes load, and lowers friction.

There has been substantial growth in the repair of the human skeletal system. In general, orthopedic joints have evolved using information from simulations, mechanical prototypes, and patient data that is collected and used to initiate improved designs. Similarly, the tools being used for orthopedic surgery have been refined over the years but have not changed substantially. Thus, the basic procedure for replacement of an orthopedic joint has been standardized to meet the general needs of a wide distribution of the population. Although the tools, procedure, and algorithm joint a general need, each replacement procedure is subject to significant variation from patient to patient. The correction of these individual variations relies on the skill of the surgeon to adapt and fit the replacement joint using the available tools to the specific circumstance.

BRIEF DESCRIPTION OF THE DRAWINGS

Various features of the system are set forth with particularity in the appended claims. The embodiments herein, can be understood by reference to the following description, taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a perspective view of a medical sensing platform comprising an encapsulating enclosure in accordance with one embodiment;

FIG. 2 is a perspective view of a medical sensing device suitable for use as a bi-compartmental implant and comprising an encapsulating enclosure in accordance with one embodiment;

FIG. 3 is an illustration of an application of sensing insert device in accordance with an exemplary embodiment;

FIG. 4 is an illustration of a sensing insert device placed in a joint of the muscular-skeletal system for measuring a parameter in accordance with an exemplary embodiment;

FIG. 5 is an exemplary block diagram of the components of a sensing module in accordance with an exemplary embodiment;

FIG. 6 is a cross-sectional view of the sensing insert device in further detail according to one embodiment as an encapsulating enclosure;

FIG. 7 depicts high-level processing blocks of an encapsulated force sensor in accordance with one embodiment;

FIG. 8 is a cross-sectional view of a layout architecture of the sensing module in accordance with an exemplary embodiment;

FIG. 9 is a block diagram of a propagation tuned oscillator (PTO) to maintain positive closed-loop feedback in accordance with an exemplary embodiment;

FIG. 10 is a final insert device in accordance with an exemplary embodiment;

FIG. 11 is a perspective view of the sensing modules in the final insert in accordance with an exemplary embodiment; and

FIG. 12 is an illustration of the final insert installed in a knee in accordance with an exemplary embodiment.

DETAILED DESCRIPTION

Embodiments of the invention are broadly directed to measurement of physical parameters, and more particularly, to real-time measurement and communication of load, force, pressure, displacement, density, viscosity, or localized temperature by sensing structures or assemblies encapsulated within hermetic or non-hermetic modules or devices. Many parameters of interest within physical systems or bodies can be measured by evaluating changes in the transit time of energy waves or pulses having the property that their propagation velocity is affected by physical changes in a medium of propagation. Alternatively, piezo-resistive sensing, MEMS sensing, strain gauge sensing can also be incorporated into the sensing assembly. The physical parameter or parameters of interest include, but are not limited to, measurement of load, force, pressure, displacement, density, viscosity, localized temperature. The sensing platform that include the sensing assemblies can be placed on or within a body, instrument, appliance, vehicle, equipment, or other physical system.

In all of the examples illustrated and discussed herein, any specific materials, temperatures, times, energies, etc. for process steps or specific structure implementations should be interpreted to illustrative only and non-limiting. Processes, techniques, apparatus, and materials as known by one of ordinary skill in the art may not be discussed in detail but are intended to be part of an enabling description where appropriate.

Note that similar reference numerals and letters refer to similar items in the following figures. In some cases, numbers from prior illustrations will not be placed on subsequent figures for purposes of clarity. In general, it should be assumed that structures not identified in a figure are the same as previous prior figures.

One embodiment is a sensing platform that employs a combination of two or more load bearing surfaces incorpo-
rating features for contacting external objects. The sensing assembly comprises one or more transducers, a compressible energy propagating structure and media, and spring or springs or other means of elastic support, to measure force or pressure external to the sensing platform or displacement produced by contact with an external object. In a non-limiting example, the sensing platform measures load. A position of the center or focal point (or locus or centroid) of the applied load, force, pressure, or external contact on the load bearing or contacting surface or surfaces of the sensing platform can also be determined. The centroid or barycenter is considered the average of all points, weighted by the local density. In fluid mechanics, the force density has the physical dimensions of force per unit volume.

[0022] Force, pressure, displacement, density, or viscosity is measured by controlled compression or displacement of the compressible energy propagating structure or structures or media. The compression or displacement of the compressible energy propagating structure or structures or media is accurately controlled by the action of the spring or springs or other means of elastic support positioned in conjunction with the compressible energy propagating structure or structures or media between the contacting surfaces. Changes in compression or displacement of the compressible energy propagating structure or structures or media alter their physical length and may be detected by changes in transit time of energy pulses or waves propagating therein. The center or focal point (or locus or centroid) of the applied force, pressure, displacement, density, or viscosity on the load bearing or contacting surfaces may be determined by combining measurements taken with a combination of assemblages of energy transducers and compressible energy propagating structure or structures or media. For clarity, the remainder of the description focuses on a specific form of energy and medium of propagation. Ultrasound energy pulses or waves, the emission of ultrasound pulses or waves by ultrasound resonators or transducers, transmitted through ultrasound waveguides, and detected by ultrasound resonators or transducers will be used in the following discussion and examples of embodiments of the present invention as examples of energy pulses, waves, and propagation structures and media.

[0023] FIG. 1 is a perspective view of a medical sensing platform comprising an encapsulating enclosure in accordance with one embodiment. In general, parameters of the muscular-skeletal system can be measured with a sensing module 200 that in one embodiment is an integral part of a complete sensing insert device 100. The sensing module 200 is a self-contained sensor within an encapsulating enclosure that integrates sensing assemblages, an electronic assemblage that couples to the sensing assemblages, a power source, signal processing, and wireless communication. All components required for the measurement are contained in the sensing module 200. The sensing module 200 has at least one contacting surface for coupling to the muscular-skeletal system. A parameter of the muscular-skeletal system is applied to the contact surfaces to be measured by the one or more sensing assemblages therein. As will be disclosed in further detail herein, the sensing module 200 is part of a system that allows intra-operative and post-operative sensing of a joint of the muscular-skeletal system. More specifically, sensing module 200 is placed within a temporary or permanent prosthetic component that has a similar form factor as the passive prosthetic component currently being used. This has a benefit of rapid adoption because the sensing platform is inserted identically to the commonly used passive component but can provide much needed quantitative measurements with little or no procedural changes.

[0024] As shown, the sensing insert device 100 comprises an insert door 202 and the sensing module 200. Sensing insert device 100 is a non-permanent or temporary measurement device that is used intra-operatively to provide quantitative data related to the installation of prosthetic components such as in joint replacement surgery. The combination of the insert door 202 and sensing module 202 has a form factor substantially equal to a final insert device. The final insert device can be a passive component or sensored incorporating sensing module 200. The substantially equal form factor of sensing insert device 100 means that there are no extraneous structures in the surgical field that can interfere with the procedure. For example, a final insert device is designed to mimic the function of the natural component it is replacing. The final insert device allows natural movement of the muscular-skeletal system and does not interfere with ligaments, tendons, tissue, muscles, and other components of the muscular-skeletal system. Similarly, sensing insert device 100 allows exposure of the surgical field around the joint by having the similar form factor as the final insert thereby allowing the surgeon to make adjustments during the installation in a natural setting with quantitative measurements to support the modifications.

[0025] In one embodiment, insert door 202 is an adaptor. Insert door 202 is made in different sizes. In general, prosthetic components are manufactured in different sizes to accommodate variation in the muscular-skeletal system from person to person. In the example, the size of insert door 202 is chosen to mate with the selected prosthetic implant components. In particular, a feature 204 aligns with and retains insert door 202 in a fixed position to a prosthetic or natural component of the muscular-skeletal system. The insert door 202 is a passive component having an opening for receiving sensing module 200. The opening is positioned to place the contacting surfaces in a proper orientation to measure the parameter when used in conjunction with other prosthetic components. The insert door 202 as an adaptor can be manufactured at low cost. Moreover, insert door 202 can be formed for adapting to different prosthetic manufacturers thereby increasing system flexibility. This allows a standard sensing module 200 to be provided but customized for appropriate size and dimensions through door 202 for the specific application and manufacturer component.

[0026] The one or more sensing assemblages within sensing module 200 couple to the contacting surfaces of sensing module 200 for receiving the applied parameter of the muscular-skeletal system. In one embodiment, a sensing assemblage comprises one or more energy transducers coupled to an elastic structure. The elastic structure allows the propagation of energy waves. The forms of energy propagated through the elastic energy propagating structures may include, but is not limited to, sound, ultrasound, or electromagnetic radiation including radio frequency, infrared, or light. A change in the parameter applied to the contacting surfaces results in a change in the dimension of the elastic structure. The dimension of the elastic structure can be measured precisely using continuous wave, pulsed, or pulsed echo measurement. The dimension and material properties of the elastic structure have a known relationship to the parameter being measured. Thus, the dimension is precisely measured and converted to the parameter. Other factors such as movement or acceleration can be taken into account in the calculation.
As an example, a force, pressure, or load applied to the one or more contacting surfaces of sensing module 200 is used to illustrate a parameter measurement herein below. It should be noted that this is for illustration purposes and that the sensing module 200 can be used to measure other parameters.

[0027] As will be shown ahead, the encapsulating enclosure can serve in a first embodiment as a trial implant for orthopedic surgical procedures, namely, for determining load forces on prosthetic components and the musculoskeletal system. In a second embodiment, the encapsulating enclosure can be placed within a permanent prosthetic component for long term monitoring. The encapsulating enclosure supports and protects internal mechanical and electronic components from external physical, mechanical, chemical, and electrical, and electromagnetic intrusion that might compromise sensing or communication operations of the module or device. The integration of the internal components is designed to minimize adverse physical, mechanical, electrical, and ultrasonic interactions that might compromise sensing or communication operations of the module or device.

[0028] FIG. 2 is a perspective view of a medical sensing device suitable for use as a bi-compartmental implant and comprising an encapsulating enclosure in accordance with one embodiment. As shown, the load sensing insert device 100 comprises two sensing modules 200. Each sensing module 200 is a self-contained encapsulated enclosure that can make individual or coordinated parameter measurements. For example, the sensing insert device 100 can be used to assess load forces on a bi-compartmental knee joint implant. In particular, both sensing modules 200 can individually, or in combination, report applied loading forces. Bi-compartmental sensing provides the benefit of providing quantitative measurement to balance each compartment in relation to one another.

[0029] Similar to that described above, insert dock 202 is an adaptor having two openings instead of one. Insert dock 202 can be made in different sizes to accommodate different sized prosthetic components and different manufacturers. The insert dock 202 with two openings is a passive component for receiving two separate sensing modules 200. The opening is positioned to place the contacting surfaces in a proper orientation to measure the parameter when used in conjunction with other prosthetic components. In general, encapsulated enclosures can be positioned on or within, or engaged with, or attached or affixed to or within, a wide range of physical systems including, but not limited to, instruments, appliances, vehicles, equipment, or other physical systems as well as animal and human bodies, for sensing and communicating the parameter or parameters of interest in real time. Similar to that described above, insert dock 202 as an adaptor can be manufactured at low cost providing design flexibility and allowing rapid adoption of quantitative measurement.

[0030] FIG. 3 is an illustration of an application of sensing insert device 100 in accordance with an exemplary embodiment. The illustration shows the device 100 measuring a force, pressure, or load applied by the musculoskeletal system. In the illustration, device 100 can collect load data for real-time viewing of the load forces over various applied loads and angles of flexion. The sensing insert device 100 can measure the level and distribution of load at various points on the prosthetic component and transmits the measured load data by way data communication to a receiver station 110 for permitting visualization. This can aid the surgeon in making any adjustments needed to achieve optimal joint balancing.

[0031] In general, device 100 has at least one contacting surface that couples to the musculoskeletal system. As shown, a first and a second contacting surface respectively couple to a femoral prosthetic component 104 and a tibial prosthetic component 106. Device 100 is designed to be used in the normal flow of an orthopedic surgical procedure without special procedures, equipment, or components. Typically, one or more natural components of the musculoskeletal system are replaced when joint functionality substantially reduces a patient quality of life. A joint replacement is a common procedure in later life because it is prone to wear over time, can be damaged during physical activity, or by accident.

[0032] A joint of the musculoskeletal system provides movement of bones in relation to one another that can comprise angular and rotational motion. The joint can be subjected to loading and torque throughout the range of motion. The joint typically comprises two bones that move in relation to one another with a low friction flexible connective tissue such as cartilage between the bones. Natural lubricant in the joint in conjunction with the cartilage aid in joint movement. Sensing insert device 100 mimics the natural structure between the bones of the joint. Insert device 100 has a contacting surface on which a bone or a prosthetic component can moveably couple. A knee joint is disclosed for illustrative purposes but sensing insert device 100 is applicable to other joints of the musculoskeletal system. For example, the hip, spine, and shoulder have similar structures comprising two or more bones that move in relation to one another. In general, insert device 100 can be used between two or more bones allowing movement of the bones during measurement or maintaining the bones in a fixed position.

[0033] The load sensor insert device 100 and the receiver station 110 forms a communication system for conveying data via secure wireless transmission within a broadcasting range over short distances on the order of a few meters to protect against any form of unauthorized or accidental query. A combination of cyclic redundancy checks and a high repetition rate of transmission during data capture permits discarding of corrupted data without materially affecting display of data.

[0034] In the illustration, a surgical procedure is performed to place a femoral prosthetic component 104 onto a prepared distal end of the femur 102. Similarly, a tibial prosthetic component 106 is placed to a prepared proximal end of the tibia 108. The tibial prosthetic component 106 can be a tray or plate affixed to a planarized proximal end of the tibia 108. The sensing insert device 100 is a third prosthetic component that is placed between the plate of the tibial prosthetic component 106 and the femoral prosthetic component 104. The three prosthetic components enable the prostheses to emulate the functioning of a natural knee joint. In one embodiment, sensing insert device 100 is used during surgery and replaced with a final insert after quantitative measurements are taken to ensure optimal fit, balance, and loading of the prosthesis.

[0035] In one embodiment, sensing insert device 100 is a mechanical replica of a final insert. In other words, sensing insert device 100 has substantially equal dimensions to the final insert. The substantially equal dimensions ensure that the final insert when placed in the reconstructed joint will have similar loading and balance as that measured by sensing insert device 100 during the trial phase of the surgery. Moreover, passive trial inserts are commonly used during surgery to determine the appropriate final insert. Thus, the procedure
remains the same. It can measure loads at various points (or locations) on the femoral prosthetic component 104 and transmit the measured data to a receiving station 110 by way of an integrated loop antenna. The receiving station 110 can include data processing, storage, or display, or combination thereof and provide real-time graphical representation of the level and distribution of the load.

As one example, the sensing insert device 100 can measure forces (Fx, Fy, and Fz) with corresponding locations and torques (e.g. Tx, Ty, and Tz) on the femoral prosthetic component 104 and the tibial prosthetic component 106. It can then transmit this data to the receiving station 110 to provide real-time visualization for assisting the surgeon in identifying any adjustments needed to achieve optimal joint balancing.

FIG. 4 is an illustration of a sensing insert device 100 placed in a joint of the muscular-skeletal system for measuring a parameter in accordance with an exemplary embodiment. In particular, sensing insert device 100 is placed in contact between a femur 102 and a tibia 108 for measuring a parameter. In the example, a force, pressure, or load is being measured. The device 100 in this example can intra-operatively assess a load on prosthetic components during the surgical procedure. As mentioned previously, sensing insert device 100 collects data for real-time viewing of the load forces over various applied loads and angles of flexion. It can measure the level and distribution of load at various points on the prosthetic component and transmit the measured load data by way data communication to a receiver station 110 for permitting visualization. This can aid the surgeon in making any adjustments needed to achieve optimal joint balancing.

A proximal end of tibia 108 is prepared to receive tibial prosthetic component 106. Tibial prosthetic component 106 is a support structure that is fastened to the proximal end of the tibia and is usually made of a metal or metal alloy. The tibial prosthetic component 106 also retains the insert in a fixed position with respect to tibia 108. Similarly, a distal end of femur 102 is prepared to receive femoral prosthetic component 104. The femoral prosthetic component 104 is generally shaped to have an outer condylar articulating surface. The preparation of femur 102 and tibia 108 is aligned to the mechanical axis of the leg. The sensing insert device 100 provides a concave or flat surface against which the outer condylar articulating surface of the femoral prosthetic component 104 rides relative to the tibia prosthetic component 106. In particular, the top surface of the sensing module 200 faces the condylar articulating surface of the femoral prosthetic component 104, and the bottom surface of the insert dock 202 faces the top surface of the tibial prosthetic component 106.

A final insert is subsequently fitted between femoral prosthetic component 104 and tibial prosthetic component 106 that has a bearing surface that couples to femoral component 104 allowing the leg a natural range of motion. The final insert is has a wear surface that is typically made of a low friction polymer material. Ideally, the prosthesis has an appropriate loading, alignment, and balance that mimics the natural leg and maximizes the life of the artificial components.

The sensing insert device 100 is used to measure, adjust, and test the reconstructed joint prior to installing the final insert. As mentioned previously, the sensing insert device 100 is placed between the femur 102 and tibia 108. The condyle surface of femoral component 104 contacts a major surface of device 100. The major surface of device 100 approximates a surface of a final insert. Tibial prosthetic component 106 can include a cavity or tray on the major surface that receives and retains an insert dock 202 and a sensing module 200 during a measurement process. It should be noted that sensing insert device 100 is used to provide measurement data in conjunction with permanent prosthetic components. In other words, the permanent prosthetic components are the installed components of the patient.

Insert dock 202 is provided in different sizes and shapes. Insert dock 202 can be disposable or be cleaned and sterilized for reuse. In a fourth embodiment, device 100 is designed for different prosthetic sizes within the same manufacturer. In at least one embodiment, multiple docks of different dimensions are provided for a surgery. For example, the thickness of the final insert is determined by the surgical cuts to the muscular-skeletal system and measurements provided by sensing module 200. The surgeon may try two insert docks 202 of different thicknesses before making a final decision. In one embodiment, sensing insert device 100 selected by the surgeon has substantially equal dimensions to the final insert used. In general, insert dock 202 allows standardization on a single sensing module 200 for different prosthetic platforms. Thus, the sensing module 200 is common to the different insert docks 202 allowing improved quality, reliability, and performance.

In one embodiment, one or more insert docks 202 are used to determine an appropriate thickness that yields an optimal loading. In general, the absolute loading over the range of motion is kept within a predetermined range. Soft tissue tensioning can be used to adjust the absolute loading. The knee balance can also be adjusted within a predetermined range if a total knee reconstruction is being performed and a sensing module 202 is used in each compartment. Tibial prosthetic component 106 and device 100 have a combined thickness that represents a combined thickness of tibial prosthetic component 106 and a final (or chronic) insert of the knee joint. Thus, the final insert thickness or depth is chosen based on the trial performed using device 100. Typically, the final insert thickness is identical to the device 100 to maintain the measured loading and balance. In one embodiment, sensing module 200 and insert docks 202 are disposed of after surgery. Alternatively, the sensing module 200 and insert docks 202 can be cleaned, sterilized, and packaged for reuse.

The prosthesis incorporating device 100 emulates the function of a natural knee joint. Device 100 can measure loads or other parameters at various points throughout the range of motion. Data from device 100 is transmitted to a receiving station 110 via wired or wireless communications. In a first embodiment, device 100 is a disposable system. Device 100 can be disposed of after using the sensing insert device 100 to optimally fit the joint implant. Device 100 is a low cost disposable system that reduces capital costs, operating costs, facilitates rapid adoption of quantitative measurement, and initiates evidentiary based orthopedic medicine. In a second embodiment, a methodology can be put in place to clean and sterilize device 100 for reuse. In a third embodiment, device 100 can be incorporated in a tool instead of being a component of the replacement joint. The tool can be disposable or be cleaned and sterilized for reuse. In a fourth embodiment, device 100 can be a permanent component of
the replacement joint. Device 100 can be used to provide both short term and long term post-operative data on the implanted joint. In a fifth embodiment, device 100 can be coupled to the muscular-skeletal system. In all of the embodiments, receiving station 110 can include data processing, storage, or display, or combination thereof and provide real time graphical representation of the level and distribution of the load. Receiving station 110 can record and provide accounting information of device 100 to an appropriate authority.

[0044] The sensing insert device 100, in one embodiment, comprises a load sensing platform 121, an accelerometer 122, and sensing assemblies 123. This permits the sensing device 100 to assess a total load on the prosthetic components when it is being moved. The system accounts for forces due to gravity and motion. In one embodiment, load sensing platform 121 includes two or more load bearing surfaces, at least one energy transducer, at least one compressible energy propagating structure, and at least one member for elastic support. The accelerometer 122 can measure acceleration. Acceleration can occur when the load sensing device 100 is moved or put in motion. Accelerometer 122 can sense orientation, vibration, and impact. In another embodiment, the femoral component 104 can similarly include an accelerometer 127, which by way of a communication interface to the sensing insert device 100, can provide reference position and acceleration data to determine an exact angular relationship between the femur and tibia. The sensing assemblies 123 can reveal changes in length or compression of the energy propagating structure or structures by way of the energy transducer or transducers. Together the load sensing platform 121, accelerometer 122 (and in certain cases accelerometer 127), and sensing assemblies 123 measure force or pressure external to the load sensing platform or displacement produced by contact with the prosthetic components.

[0045] In at least one exemplary embodiment, an energy pulse is directed within one or more waveguides in device 100 by way of pulse mode operations and pulse shaping. The waveguide is a conduit that directs the energy pulse in a predetermined direction. The energy pulse is typically confined within the waveguide. In one embodiment, the waveguide comprises a polymer material. For example, urethane or polyethylene are polymers suitable for forming a waveguide. The polymer waveguide can be compressed and has little or no hysteresis in the system. Alternatively, the energy pulse can be directed through the muscular-skeletal system. In one embodiment, the energy pulse is directed through bone of the muscular-skeletal system to measure bone density. A transit time of an energy pulse is related to the material properties of a medium through which it traverses. This relationship is used to generate accurate measurements of parameters such as distance, weight, strain, pressure, wear, vibration, viscosity, and density to name a few.

[0046] Incorporating data from the accelerometer 122 with data from the other sensing components 121 and 123 assures accurate measurement of the applied load, force, pressure, or displacement by enabling computation of adjustments to offset this external motion. This capability can be required in situations wherein the body, instrument, appliance, vehicle, equipment, or other physical system, is itself operating or moving during sensing of load, pressure, or displacement. This capability can also be required in situations wherein the body, instrument, appliance, vehicle, equipment, or other physical system, is causing the portion of the body, instrument, appliance, vehicle, equipment, or other physical system being measured to be in motion during sensing of load, pressure, or displacement.

[0047] The accelerometer 122 can operate singly, as an integrated unit with the load sensing platform 121, and/or as an integrated unit with the sensing assemblies 123. Integrating one or more accelerometers 122 within the sensing assemblies 123 to determine position, attitude, movement, or acceleration of sensing assemblies 123 enables augmentation of presentation of data to accurately identify, but not limited to, orientation or spatial distribution of load, force, pressure, displacement, density, or viscosity, or localized temperature by controlling the load and position sensing assemblies to measure the parameter or parameters of interest relative to specific orientation, alignment, direction, or position as well as movement, rotation, or acceleration along any axis or combination of axes. Measurement of the parameter or parameters of interest may also be made relative to the earth's surface and thus enable computation and presentation of spatial distributions of the measured parameter or parameters relative to this frame of reference.

[0048] In one embodiment, the accelerometer 122 includes direct current (DC) sensitivity to measure static gravitational pull with load and position sensing assemblies to enable capture of, but not limited to, distributions of load, force, pressure, displacement, movement, rotation, or acceleration by controlling the sensing assemblies to measure the parameter or parameters of interest relative to orientations with respect to the earth's surface or center and thus enable computation and presentation of spatial distributions of the measured parameter or parameters relative to this frame of reference.

[0049] Embodiments of device 100 are broadly directed to measurement of physical parameters, and more particularly, to evaluating changes in the transit time of a pulsed energy wave propagating through a medium. In-situ measurements during orthopedic joint implant surgery would be of substantial benefit to verify an implant is in balance and under appropriate loading or tension. In one embodiment, the instrument is similar to and operates familiarly with other instruments currently used by surgeons. This will increase acceptance and reduce the adoption cycle for a new technology. The measurements will allow the surgeon to ensure that the implanted components are installed within predetermined ranges that maximize the working life of the joint prosthesis and reduce costly revisions. Providing quantitative measurement and assessment of the procedure using real-time data will produce results that are more consistent. A further issue is that there is little or no implant data generated from the implant surgery, post-operatively, and long term. Device 100 can provide joint status data to the orthopedic manufacturers and surgeons. Moreover, data generated by direct measurement of the implanted joint itself would greatly improve the knowledge of implanted joint operation and joint wear thereby leading to improved design and materials.

[0050] As mentioned previously, device 100 can be used for other joint surgeries; it is not limited to knee replacement implant or implants. Moreover, device 100 is not limited to trial measurements. Device 100 can be incorporated into the final joint system to provide data post-operatively to determine if the implanted joint is functioning correctly. Early determination of a problem using device 100 can reduce catastrophic failure of the joint by bringing awareness to a problem that the patient cannot detect. The problem can often
be rectified with a minimal invasive procedure at lower cost and stress to the patient. Similarly, longer term monitoring of the joint can determine wear or misalignment that if detected early can be adjusted for optimal life or replacement of a wear surface with minimal surgery thereby extending the life of the implant. In general, device 100 can be shaped such that it can be placed or engaged or affixed to or within load bearing surfaces used in many orthopedic applications (or used in any orthopedic application) related to the musculoskeletal system, joints, and tools associated therewith. Device 100 can provide information on a combination of one or more performance parameters of interest such as wear, stress, kinematics, kinetics, fixation strength, ligament balance, anatomical fit and balance.

[0051] FIG. 5 is an exemplary block diagram of the components of a sensing module 200 in accordance with an exemplary embodiment. It should be noted that the sensing module could comprise more or less than the number of components shown. As illustrated, the sensing module includes one or more sensing assemblages 303, a transceiver 320, an energy storage 330, electronic circuitry 307, one or more mechanical supports 315 (e.g., springs), and an accelerometer 302. In the non-limiting example, an applied compressive force can be measured by the sensing module.

[0052] The sensing assemblage 303 can be positioned, engaged, attached, or affixed to the contact surfaces 306. Mechanical supports 315 serve to provide proper balancing of contact surfaces 306. In at least one exemplary embodiment, contact surfaces 306 are load-bearing surfaces. In general, the propagation structure 305 is subject to the parameter being measured. Surfaces 306 can move and tilt with changes in applied load; actions which can be transferred to the sensing assemblages 303 and measured by the electronic circuitry 307. The electronic circuitry 307 measures physical changes in the sensing assemblage 303 to determine parameters of interest, for example a level, distribution and direction of forces acting on the contact surfaces 306. In general, the sensing module is powered by the energy storage 330.

[0053] As one example, the sensing assemblage 303 can comprise an elastic or compressible propagation structure 305 between a transducer 304 and a transducer 314. In the current example, transducer 304 can be an ultrasound (or ultrasonic) resonator, and the elastic or compressible propagation structure 305 can be an ultrasound (or ultrasonic) waveguide (or waveguides). The electronic circuitry 307 is electrically coupled to the sensing assemblages 303 and translates changes in the length (or compression or extension) of the sensing assemblages 303 to parameters of interest, such as force. It measures a change in the length of the propagation structure 305 (e.g., waveguide) responsive to an applied force and converts this change into electrical signals which can be transmitted via the transceiver 320 to convey a level and a direction of the applied force. In other arrangements herein contemplated, the sensing assemblage 303 may require only a single transducer. In yet other arrangements, the sensing assemblage 303 can include piezoelectric, capacitive, optical or temperature sensors or transducers to measure the compression or displacement. It is not limited to ultrasonic transducers and waveguides.

[0054] The accelerometer 302 can measure acceleration and static gravitational pull. Accelerometer 302 can be single-axis and multi-axis accelerometer structures that detect magnitude and direction of the acceleration as a vector quantity. Accelerometer 302 can also be used to sense orientation, vibration, impact and shock. The electronic circuitry 307 in conjunction with the accelerometer 302 and sensing assemblages 303 can measure parameters of interest (e.g., distributions of load, force, pressure, displacement, movement, rotation, torque and acceleration) relative to orientations of the sensing module with respect to a reference point. In such an arrangement, spatial distributions of the measured parameters relative to a chosen frame of reference can be computed and presented for real-time display.

[0055] The transceiver 320 comprises a transmitter 309 and an antenna 310 to permit wireless operation and telemetry functions. In various embodiments, the antenna 310 can be configured by design as an integrated loop antenna. As will be explained ahead, the integrated loop antenna is configured at various layers and locations on the electronic substrate with electrical components and by way of electronic control circuitry to conduct efficiently at low power levels. Once initiated the transceiver 320 can broadcast the parameters of interest in real-time. The telemetry data can be received and decoded with various receivers, or with a custom receiver. The wireless operation can eliminate distortion of, or limitations on, measurements caused by the potential for physical interference by, or limitations imposed by, wiring and cables connecting the sensing module with a power source or with associated data collection, storage, display equipment, and data processing equipment.

[0056] The transceiver 320 receives power from the energy storage 330 and can operate at low power over various radio frequencies by way of efficient power management schemes, for example, incorporated within the electronic circuitry 307. As one example, the transceiver 320 can transmit data at selected frequencies in a chosen mode of emission by way of the antenna 310. The selected frequencies can include, but are not limited to, ISM bands recognized in International Telecommunication Union regions 1, 2 and 3. A chosen mode of emission can be, but is not limited to, Gaussian Frequency Shift Keying (GFSK), Amplitude Shift Keying (ASK), Phase Shift Keying (PSK), Minimum Shift Keying (MSK), Frequency Modulation (FM), Amplitude Modulation (AM), or other versions of frequency or amplitude modulation (e.g., binary, coherent, quadrature, etc.).

[0057] The antenna 310 can be integrated with components of the sensing module to provide the radio frequency transmission. The substrate for the antenna 310 and electrical connections with the electronic circuitry 307 can further include a matching network. This level of integration of the antenna and electronics enables reductions in the size and cost of wireless equipment. Potential applications may include, but are not limited to any type of short-range handheld, wearable, or other portable communication equipment where compact antennas are commonly used. This includes disposable modules or devices as well as reusable modules or devices and modules or devices for long-term use.

[0058] The energy storage 330 provides power to electronic components of the sensing module. It can be charged by wired energy transfer, short-distance wireless energy transfer or a combination thereof. External power sources can include, but are not limited to, a battery or batteries, an alternating current power supply, a radio frequency receiver, an electromagnetic induction coil, a photoelectric cell or cells, a thermocouple or thermocouples, or an ultrasound transducer or transducers. By way of the energy storage 330, the sensing module can be operated with a single charge until the internal energy is drained. It can be recharged periodically to enable continuous
operation. The energy storage 330 can utilize common power management technologies such as replaceable batteries, supply regulation technologies, and charging system technologies for supplying energy to the components of the sensing module to facilitate wireless applications.

[0059] The energy storage 330 minimizes additional sources of energy radiation required to power the sensing module during measurement operations. In one embodiment, as illustrated, the energy storage 330 can include a capacitive energy storage device 308 and an induction coil 311. External source of charging power can be coupled wirelessly to the capacitive energy storage device 308 through the electromagnetic induction coil or coils 311 by way of inductive charging. The charging operation can be controlled by power management systems designed into, or with, the electronic circuitry 307. As one example, during operation of electronic circuitry 307, power can be transferred from capacitive energy storage device 308 by way of efficient step-up and step-down voltage conversion circuitry. This conserves operating power of circuit blocks at a minimum voltage level to support the required level of performance.

[0060] In one configuration, the energy storage 330 can further serve to communicate downlink data to the transceiver 320 during a recharging operation. For instance, downlink control data can be modulated onto the energy source signal and thereafter demodulated from the induction coil 311 by way of electronic control circuitry 307. This can serve as a more efficient way for receiving downlink data instead of configuring the transceiver 320 for both uplink and downlink operation. As one example, downlink data can include updated control parameters that the sensing module uses when making a measurement, such as external positional information, or for recalibration purposes, such as spring biasing. It can also be used to download a serial number or other identification data.

[0061] The electronic circuitry 307 manages and controls various operations of the components of the sensing module, such as sensing, power management, telemetry, and acceleration sensing. It can include analog circuits, digital circuits, integrated circuits, discrete components, or any combination thereof. In one arrangement, it can be partitioned among integrated circuits and discrete components to minimize power consumption without sacrificing functionality or performance. Partitioning functions between digital and analog circuit enhances design flexibility and facilitates minimizing power consumption without sacrificing functionality or performance. Accordingly, the electronic circuitry 307 can comprise one or more Application Specific Integrated Circuit (ASIC) chips, for example, specific to a core signal processing algorithm.

[0062] In another arrangement, the electronic circuitry can comprise a controller such as a programmable processor, a Digital Signal Processor (DSP), a microcontroller, or a microprocessor, with associated storage memory and logic. The controller can utilize computing technologies with associated storage memory such as a Flash, ROM, RAM, SRAM, DRAM or other like technologies for controlling operations of the aforementioned components of the sensing module. In one arrangement, the storage memory may store one or more sets of instructions (e.g., software) embodying any one or more of the methodologies or functions described herein. The instructions may also reside, completely or at least partially, within other memory, and/or a processor during execution thereof by another processor or computer system.

[0063] FIG. 6 is a cross sectional view of the sensing insert device 100 in further detail according to one embodiment as an encapsulating enclosure. As shown, the sensing insert device 100 comprises the sensing module 200 and the insert dock 202. The insert dock 202 in this embodiment provides a concave surface. In a first configuration, the insert dock 202 can further include an insert cover 704 to seal in the sensing module 200. The insert cover 704 couples to a contacting surface of sensing module 200. In a second configuration, the insert cover 704 may be absent, and the sensing module 200 alone is sealed.

[0064] In either configuration, the sensing module 200 can be hermetically sealed to form the encapsulating enclosure. The sensing module 200 and insert dock 202 are sterilized in sealed packages that are opened within the surgical field prior to use. The sensing module 200 is placed through an opening into a cavity of insert dock 202. The insert cover 704 can overlie sensing module 200. In one embodiment, the sensing insert device 100 is used intra-operatively to measure parameters related to prosthetic implantation during surgery. The sensing insert device 100 comprising insert dock 202 and sensing module 200 adds flexibility by simplifying customization for different manufacturers. Alternatively, the sensing insert device 100 can be formed as a single measurement device where the sensing module 200 is incorporated in an encapsulating enclosure and cannot be removed. The sensing module 200 fits within or at a boundary of dock 202. No components extend out in the surgical area because all measurement circuitry is contained and resides within sensing module 200. This enclosure permits the sensing module 200 to measure parameters of interest within a wide range of applications including, but not limited to, applications within adverse and harsh environments, long-term applications, or medical applications. It can also be constructed in a wide range of sizes from very compact to large as required to fit the application. The hermetic sealing facilitates real time measurement and communication of physiological parameters within animal or human bodies including, but not limited to, loading within individual joints, bone density, movement, fluid motion, various parameters of interstitial fluids including, but not limited to, viscosity, pressure, and localized temperature with applications throughout the vascular, lymph, respiratory, and digestive systems, as well as within or affecting muscles, bones, joints, and soft tissue areas.

[0065] In the first configuration, the encapsulating enclosure comprises a unitary main body 242 and load bearing or contact surfaces 243 that can be, but are not limited to, dissimilar materials combined to form a hermetic or non-hermetic module or device. The components of the encapsulating structure can also consist of, but are not limited to, biocompatible materials. In the second configuration, the encapsulating enclosure comprises the insert dock 202, the sensing module 200, and the insert cover 704. For medical applications, the encapsulating enclosure is hermetic. The encapsulating enclosure can comprise biocompatible materials, for example, but not limited to, polycarbonate, steel, silicon, neoprene, and similar materials.

[0066] Polycarbonate is an example material that fulfills the molding and hermetic requirements for the unitary main body. Polycarbonate and steel are examples of materials that fulfill the interface and hermetic requirements for the load bearing or contacting surfaces. In the example of combining separate components of polycarbonate and steel to construct an encapsulating enclosure, silicon, silicon adhesive, and
neoprene are examples of materials that fulfill the sealing and flexibility requirements for interfacing the polycarbonate and steel components.

[0067] The sensing module 200 can also be incorporated into, but not limited to, handheld instruments, such as one that might be commonly used for evaluation of the flexion-extension gap; or a final, chronically implanted prosthetic implants, such as a tibial bearing or insert; as well as many other in vivo or external applications enabled by the flexibility to encapsulate the wireless load sensing module within a wide range of shapes and sizes. This wireless load sensing module or device may also have a wide range of non-medical and applications as well as medical applications.

[0068] The sensing module 200 can also be used in non-medical applications that require measurement of, but not limited to, load, force, pressure, or movement of portions of physical systems, or load, force, pressure placed upon, or movement of, physical systems or bodies themselves, or load, force, pressure, or movement caused by external objects in the environment of the physical systems or bodies, or combinations of these parameters. The sensing module 200 can be ported to applications where the following attributes are preferred: measurement of parameters of interest in real time, communication of measured values in real time, exemplary accuracy and precision of measurements, or a wide range of sizes of the sensing and communication module or device to fit requirements of applications or harsh environments within which the measurement data is captured, or any combination of these attributes.

[0069] FIG. 7 depicts high-level processing blocks of an encapsulated force sensor 600 in accordance with one embodiment. The blocks are operatively coupled together within the encapsulated enclosure of the sensing module 200 and together form an encapsulated force sensor 600. An ASIC or application specific integrated circuit is used to minimize the form factor by incorporating most of the circuitry on a single die. The encapsulated force sensor 600 comprises the hermetic seal 623 and may include more or less than the number of high-level processing blocks shown. In one embodiment, a temporary test interconnect or test tab 625 can be used during set-up, calibration or testing that can be removed after all testing, calibration, and programming is complete.

[0070] Load sensing platform block A is responsible for detecting and supporting load requirements. Compact low-power energy source block B is responsible for powering components of the sensing module 200. In one embodiment, a low-power energy source block B includes a super-capacitor that can be charged in a short period of time prior to surgery. The super-capacitor can be charged by inductive coupling. The stored charge on the super-capacitor is sufficient to power encapsulated force sensor 600 for the duration of the surgery. The output voltage of the super-capacitor can be regulated. Integrated position and load sensing block C is responsible for interpreting load and position measurements. High-Precision sensing block D is responsible for sensing precise load measurements such as level and distribution of force. It permits reliable measurement of the load across the entire range of flexion of the knee joint. Short-range telemetry block E is responsible for transmitting load and position measurements to a receiving system.

[0071] Notably, the encapsulating force sensor 600 supports and protects the specialized mechanical and electronic components from external physical, mechanical, chemical, and electrical, and electromagnetic intrusion that might compromise sensing or communication operations of the module or device. The encapsulating force sensor 600 also supports internal mechanical and electronic components and minimizes adverse physical, mechanical, electrical, and ultrasonic interactions that might compromise sensing or communication operations of the module or device.

[0072] The housing electrically insulates the internal electronic, sensing, and communication components. The encapsulating force sensor 600 eliminates parasitic paths that might conduct ultrasonic energy and compromise excitation and detection of ultrasound waves within the sensing assemblages during sensing operations. A temporary bi-directional electrical interconnect assures a high level of electrical observation and controllability of the electronic assembly within the encapsulating force sensor 600. The temporary interconnect also provides a high level of electrical observation of the sensing subsystem, including the transducers, waveguides, and mechanical spring or elastic assembly.

[0073] The encapsulating force sensor 600 has a compact size permitting it to fit for example within a trial insert to measure the level and incidence of the load on subsequent implanted prosthetic devices. It can be constructed using standard components and manufacturing processes. Manufacturing carriers or fixtures can be designed to emulate the final encapsulating enclosure of the sensing module 200. Calibration data can be obtained during the manufacturing process thus enabling capture of accurate calibration data. These calibration parameters can be stored within the memory circuits integrated into the electronics assemblage of the sensing module 200. Testability and calibration further assures the quality and reliability of the encapsulated enclosure.

[0074] Examples of a wide range of potential medical applications can include, but are not limited to, implantable devices, modules within implantable devices, intra-operative implants or modules within intra-operative implants or trial inserts, modules within inserted or ingested devices, modules within wearable devices, modules within handheld devices, modules within instruments, appliances, equipment, or accessories of all of these, or disposables within implants, trial inserts, inserted or ingested devices, wearable devices, handheld devices, instruments, appliances, equipment, or accessories to these devices, instruments, appliances, or equipment.

[0075] FIG. 8 is a cross-sectional view of a layout architecture of the sensing module 200 in accordance with an exemplary embodiment. The blocks are operatively coupled together within the encapsulated enclosure of the sensing module 200 and together form an encapsulated force sensor 900. The encapsulated force sensor 900 illustrates an exemplary load sensing platform block A of the encapsulating force sensor 600 according to one embodiment. In general, the sensors overlie the electronics within the assembly to achieve the form factor required for implanting. It comprises a top steel plate 904 coupled to a lower printed circuit board (PCB) 918 by way of spring retainer 906, discrete spring 908, and spring post 914. The load sensing platform block A is biased with springs or other means of elastic support to accurately maintain a required distance between the load bearing or contact surfaces such as top cover 902 and to minimize hysteresis due to material properties of waveguide 910.

[0076] Ultrasound waveguide 910 is coupled to the top cover 902. A force applied to the top cover 902 compresses
waveguide 910. Lower piezo 924 and upper piezo 912 are piezoelectric transducers respectively coupled to waveguide 910 at a first and second location. In one embodiment, the transducers are ultrasonic transducers. Waveguide 910 is a compressible propagating medium for ultrasonic energy waves. The transducers emit energy waves and detect propagated energy waves in waveguide 910. Electronic circuitry is coupled to lower piezo 924 and upper piezo 912 to measure transit time, frequency, or phase of the propagated energy waves. The transit time, frequency, or phase of energy waves propagating between the first and second locations of waveguide 910 can be precisely measured and therefore the length of the ultrasonic waveguide 910. The length of waveguide 910 is calculated by a known function relating material properties of the waveguide 910 to the parameter being measured. In the example, a force, pressure, or load is calculated from the measured length of waveguide 910. More than one waveguide 910 can be coupled to top cover 902 to measure the parameter value and the position where the parameter is applied to cover 902. For example, the magnitude and position of the loading on the contacting surface of sensing module 200 applied by femur 102 and tibia 108 to sensing module 200 can be measured and displayed. Multiple springs or other means of elastic support coupled with multiple sensing assemblages attached between the load bearing surfaces enable accurate translation of the extent and location of the center or focal point (or locus or centroid) of the load.

[0077] The encapsulated force sensor 900 can accurately and repeatedly measure one pound changes in load with changes in length of a waveguide comprising 2.5 microns. The maximum change in the present implementation is specified at less than 5.0 microns. This assures that the size of the sensing module 200 throughout all measurements remains within the required dimension (e.g., distance) of the insert between the load bearing surfaces of the prosthetic components.

[0078] An exemplary level of control of the compression or displacement of the waveguides 910 with changes in load, force, pressure, or displacement is achieved by positioning the spring or springs 908 or other means of elastic support, including the waveguides 910 themselves, between the load bearing contact surfaces to minimize any tendency of the load bearing contact surfaces to cantilever. Cantilevering can compromise the accuracy of the inclination of the load bearing contact surface whenever load, force, pressure, or displacement is applied to any point near a periphery of the load bearing contact surfaces. In one embodiment, springs 908 are disc springs. The spring 908 is held in a predetermined location by spring post 914 and spring retainer 904.

[0079] The walls of the unitary main body 957 include a small gap to enable the steel plate 904 to move. The hermetic seal is also flexible to allow the steel plate 904 of the force sensor 904 to slide up and down, like a piston, for distances on the order of a hundred microns without compromising integrity of the seal. The hermetic seal completes manufacturing, sterilization, and packaging processes without compromising ability to meet regulatory requirements for hermeticity. The level of hermeticity is sufficient to assure functionality and biocompatibility over the lifetime of the device. Implant devices with total implant time less than 24 hours may have less stringent regulatory requirements for hermeticity. Unbiased electrical circuitry is less susceptible to damage from moisture. The electronics in one embodiment are only powered during actual usage. In another embodiment, the encapsulated force sensor 900 employs low duty cycles to serve as a measurement-on-demand device to efficiently perform at low total operating time when the electronics are powered on.

[0080] FIG. 9 is a block diagram 1000 of a propagation tuned oscillator (PTO) 4 to maintain positive closed-loop feedback in accordance with an exemplary embodiment. The measurement system includes a sensing assemblage 1 and propagation tuned oscillator (PTO) 4 that detects energy waves 2 in one or more waveguides 3 of the sensing assemblage 1. In one embodiment, energy waves 2 are ultrasonic waves. A pulse 11 is generated in response to the detection of energy waves 2 to initiate a propagation of a new energy wave in waveguide 3. It should be noted that ultrasonic energy pulses or waves, the emission of ultrasonic pulses or waves by ultrasonic resonators or transducers, transmitted through ultrasonic waveguides, and detected by ultrasonic resonators or transducers are used merely as examples of energy pulses, waves, and propagation structures and media. Other embodiments herein contemplated can utilize other wave forms, such as, light.

[0081] The sensing assemblage 1 comprises transducer 5, transducer 6, and a waveguide 3 (or energy propagating structure). In a non-limiting example, sensing assemblage 1 is affixed to load bearing or contacting surfaces 8. External forces applied to the contacting surfaces 8 compress the waveguide 3 and change the length of the waveguide 3. Under compression, transducers 5 and 6 will also be moved closer together. The change in distance affects the transit time 7 of energy waves 2 transmitted and received between transducers 5 and 6. The propagation tuned oscillator 4 in response to these physical changes will detect each energy wave sooner (e.g., shorter transit time) and initiate the propagation of new energy waves associated with the shorter transit time. As will be explained below, this is accomplished by way of PTO 4 in conjunction with the pulse generator 10, the mode control 12, and the phase detector 14.

[0082] Notably, changes in the waveguide 3 (energy propagating structure or structures) alter the propagation properties of the medium of propagation (e.g., transit time 7). The energy wave can be a continuous wave or a pulsed energy wave. A pulsed energy wave approach reduces power dissipation allowing for a temporary power source such as a battery or capacitor to power the system during the course of operation. In at least one exemplary embodiment, a continuous wave energy wave or a pulsed energy wave is provided by transducer 5 to a first surface of waveguide 3. Transducer 5 generates energy waves 2 that are coupled into waveguide 3. In a non-limiting example, transducer 5 is a piezoelectric device capable of transmitting and receiving acoustic signals in the ultrasonic frequency range.

[0083] Transducer 6 is coupled to a second surface of waveguide 3 to receive the propagated pulsed signal and generates a corresponding electrical signal. The electrical signal output by transducer 6 is coupled to phase detector 14. In general, phase detector 14 compares the timing of a selected point on the waveform of the detected energy wave with respect to the timing of the same point on the waveform of other propagated energy waves. In a first embodiment, phase detector 14 can be a zero-crossing receiver. In a second embodiment, phase detector 14 can be an edge-detect receiver. In the example where sensing assemblage 1 is compressed, the detection of the propagated energy waves 2 occurs earlier (due to the length/distance reduction of waveguide 3) than a signal prior to external forces being
applied to contacting surfaces. Pulse generator 10 generates a new pulse in response to detection of the propagated energy waves 2 by phase detector 14. The new pulse is provided to transducer 5 to initiate a new energy wave sequence. Thus, each energy wave sequence is an individual event of energy wave propagation, energy wave detection, and energy wave emission that maintains energy waves 2 propagating in waveguide 3.

[0084] The transit time 7 of a propagated energy wave is the time it takes an energy wave to propagate from the first surface of waveguide 3 to the second surface. There is delay associated with each circuit described above. Typically, the total delay of the circuitry is significantly less than the propagation time of an energy wave through waveguide 3. In addition, under equilibrium conditions variations in circuit delay are minimal. Multiple pulse to pulse timings can be used to generate an average time period when change in external forces occur relatively slowly in relation to the pulsed signal propagation time such as in a physiologic or mechanical system. The digital counter 20 in conjunction with electronic components counts the number of propagated energy waves to determine a corresponding change in the length of the waveguide 3. These changes in length change in direct proportion to the external force thus enabling the conversion of changes in parameters or parameters of interest into electrical signals.

[0085] The block diagram 1000 further includes counting and timing circuitry. More specifically, the timing, counting, and clock circuitry comprises a digital timer 20, a digital timer 22, a digital clock 24, and a data register 26. The digital clock 24 provides a clock signal to digital counter 20 and digital timer 22 during a measurement sequence. The digital counter 20 is coupled to the propagation tuned oscillator 4. Digital timer 22 is coupled to data register 26. Digital timer 20, digital timer 22, digital clock 24 and data register 26 capture transit time 7 of energy waves 2 emitted by ultrasound resonator or transducer 5, propagated through waveguide 3, and detected by or ultrasound resonator or transducer 5 or 6 depending on the mode of the measurement of the physical parameters of interest applied to surfaces 8. The operation of the timing and counting circuitry is disclosed in more detail hereinbelow.

[0086] The measurement data can be analyzed to achieve accurate, repevable, high precision and high resolution measurements. This method enables the setting of the level of precision or resolution of captured data to optimize trade-offs between measurement resolution versus frequency, including the bandwidth of the sensing and data processing operations, thus enabling a sensing module or device to operate at its optimal operating point without compromising resolution of the measurements. This is achieved by the accumulation of multiple cycles of excitation and transit time instead of averaging transit time of multiple individual excitation and transit cycles. The result is accurate, repeatable, high precision and high resolution measurements of parameters of interest in physical systems.

[0087] In at least one exemplary embodiment, propagation tuned oscillator 4 in conjunction with one or more sensing assemblage 1 are used to take measurements on a muscular-skeletal system. In a non-limiting example, sensing assemblage 1 is placed between a femoral prosthetic component and tibial prosthetic component to provide measured load information that aids in the installation of an artificial knee joint. Sensing assemblage 1 can also be a permanent component or a muscular-skeletal joint or artificial muscular-skeletal joint to monitor joint function. The measurements can be made in extension and in flexion. In the example, assemblage 1 is used to measure the condyle loading to determine if it falls within a predetermined range and location. Based on the measurement, the surgeon can select a thickness of the insert such that the measured loading and incidence with the final insert in place will fall within the predetermined range. Soft tissue tensioning can be used by a surgeon to further optimize the force or pressure. Similarly, two assemblages 1 can be used to measure both condyles simultaneously or multiplexed. The difference in loading (e.g., balance) between condyles can be measured. Soft tissue tensioning can be used to reduce the force on the condyle having the higher measured loading to reduce the measured pressure difference between condyles.

[0088] One method of operation holds the number of energy waves propagating through waveguide 3 as a constant integer number. A time period of an energy wave corresponds to energy wave periodicity. A stable time period is one in which the time period changes very little over a number of energy waves. This occurs when conditions that affect sensing assemblage 1 stay consistent or constant. Holding the number of energy waves propagating through waveguide 3 to an integer number is a constraint that forces a change in the time between pulses when the length of waveguide 3 changes. The resulting change in time period of each energy wave corresponds to a change in aggregate energy wave time period that is captured using digital counter 20 as a measurement of changes in external forces or conditions applied to contacting surfaces 8.

[0089] A further method of operation according to one embodiment is described hereinbelow for energy waves 2 propagating from transducer 5 and received by transducer 6. In at least one exemplary embodiment, energy waves 2 is an ultrasonic energy wave. Transducers 5 and 6 are piezo-electric resonator transducers. Although not described, wave propagation can occur in the opposite direction being initiated by transducer 6 and received by transducer 5. Furthermore, detecting ultrasound resonator transducer 6 can be a separate ultrasound resonator as shown or transducer 5 can be used solely depending on the selected mode of propagation (e.g., reflective sensing). Changes in external forces or conditions applied to contacting surfaces 8 affect the propagation characteristics of waveguide 3 and alter transit time 7. As mentioned previously, propagation tuned oscillator 4 holds constant an integer number of energy waves 2 propagating through waveguide 3 (e.g., an integer number of pulsed energy wave time periods) thereby controlling the repetition rate. As noted above, once PTO 4 stabilizes, the digital counter 20 digitizes the repetition rate of pulsed energy waves, for example, by way of edge-detection, as will be explained hereinbelow in more detail.

[0090] In an alternate embodiment, the repetition rate of pulsed energy waves 2 emitted by transducer 5 can be controlled by pulse generator 10. The operation remains similar where the parameter to be measured corresponds to the measurement of the transit time 7 of pulsed energy waves 2 within waveguide 3. It should be noted that an individual ultrasonic pulse can comprise one or more energy waves with a damping wave shape. The energy wave shape is determined by the electrical and mechanical parameters of pulse generator 10, interface material or materials, where required, and ultrasound resonator or transducer 5. The frequency of the energy...
waves within individual pulses is determined by the response of the emitting ultrasound resonator 4 to excitation by an electrical pulse 11. The mode of the propagation of the pulsed energy waves 2 through waveguide 3 is controlled by mode control circuitry 12 (e.g., reflectance or uni-directional). The detecting ultrasound resonator or transducer may either be a separate ultrasound resonator or transducer 6 or the emitting resonator or transducer 5 depending on the selected mode of propagation (reflectance or unidirectional).

[0091] In general, accurate measurement of physical parameters is achieved at an equilibrium point having the property that an integer number of pulses are propagating through the energy propagating structure at any point in time. Measurement of changes in the “time-of-flight” or transit time of ultrasound energy waves within a waveguide of known length can be achieved by modulating the repetition rate of the ultrasound energy waves as a function of changes in distance or velocity through the medium of propagation, or a combination of changes in distance and velocity, caused by changes in the parameter or parameters of interest.

[0092] It should be noted that ultrasound energy pulses or waves, the emission of ultrasound pulses or waves by ultrasound resonators or transducers, transmitted through ultrasound waveguides, and detected by ultrasound resonators or transducers are used merely as examples of energy pulses, waves, and propagation structures and media. Other embodiments herein contemplated can utilize other wave forms, such as, light. Furthermore, the velocity of ultrasound waves within a medium may be higher than in air. With the present dimensions of the initial embodiment of a propagation tuned oscillator the waveguide is approximately three wavelengths long at the frequency of operation.

[0093] Measurement by propagation tuned oscillator 4 and sensing assembly 1 enables high sensitivity and high signal-to-noise ratio. The time-based measurements are largely insensitive to most sources of error that may influence voltage or current driven sensing methods and devices. The resulting changes in the transit time of operation correspond to frequency, which can be measured rapidly, and with high resolution. This achieves the required measurement accuracy and precision thus capturing changes in the physical parameters of interest and enabling analysis of their dynamic and static behavior.

[0094] These measurements may be implemented with an integrated wireless sensing module or device having an encapsulating structure that supports sensors and load bearing or contacting surfaces and an electronic assembly that integrates a power supply, sensing elements, energy transducer or transducers and elastic energy propagating structure or structures, biasing spring or springs or other form of elastic members, an accelerometer, antennas and electronic circuitry that processes measurement data as well as controls all operations of ultrasound generation, propagation, and detection and wireless communications. The electronics assembly also supports testability and calibration features that assure the quality, accuracy, and reliability of the completed wireless sensing module or device.

[0095] The level of accuracy and resolution achieved by the integration of energy transducers and an energy propagating structure or structures coupled with the electronic components of the propagation tuned oscillator enables the construction of, but is not limited to, compact ultra low power modules or devices for monitoring or measuring the parameters of interest. The flexibility to construct sensing modules or devices over a wide range of sizes enables sensing modules to be tailored to fit a wide range of applications such that the sensing module or device may be engaged with, or placed, attached, or affixed to, on, or within a body, instrument, appliance, vehicle, equipment, or other physical system and monitor or collect data on physical parameters of interest without disturbing the operation of the body, instrument, appliance, vehicle, equipment, or physical system.

[0096] FIG. 10 is a final insert 1102 in accordance with an exemplary embodiment. In the example, the final insert 1102 is a prosthetic component for a total knee reconstruction. Insert 1102 comprises two bearing surfaces that couple to the condyles of a femur or femoral prosthetic component. A bottom surface of insert 1102 couples to a tibial implant. The final insert 1102 is an active device for measuring a parameter of the muscular-skeletal system. A sensing module 1104 as disclosed hereinabove underlies each bearing surface of insert 1102. In one embodiment, a contacting surface of insert 1102 couples to the bearing surface. The final insert 1102 is a permanent or quasi-permanent member of the joint prosthesis that provides long term post-operative sensing of the joint. Quasi-permanent refers to the fact that insert 1102 has a wear surface that has a finite life time that could need replacing depending on a number of factors such as life style, physical shape, and length of use. Final insert 1102 replaces a passive insert that has no sensing capability. In one embodiment, an external device proximally located to the knee prosthesis can inductively charge the sensing module 1104. A super capacitor is charged in sensing module 1104 that powers the sensor and circuitry to perform the one or more measurements.

[0097] FIG. 11 is a perspective view of sensing modules 1104 in final insert 1102 in accordance with an exemplary embodiment. Final insert 1102 is shown being separated in two halves via a horizontal cut to show sensing modules 1104. Final insert 1102 is used in a total knee reconstruction where both knee compartments are replaced. A single sensing module 1104 could be useful for a partial reconstruction. Bearing surfaces 1204 couple to a femoral prosthetic component (not shown) such that the articulating surfaces allow movement of the muscular-skeletal system. In the example, a bottom surface 1206 of the final insert 1102 aligns and couples to a tibial prosthetic component. In the example, the bottom surface 1206 is a support surface that retains insert 1102 in a fixed position relative to a mechanical axis of the leg. Furthermore, the bottom surface 1206 and a surface of the tibial prosthetic component are non-articulating.

[0098] Sensing modules 1104 underlie bearing surfaces 1204. A parameter of the muscular-skeletal system is applied to the bearing surface 1204 and couples through the material of final insert 1102 to contacting surfaces 1202 of sensing modules 1104. The bearing surfaces 1204 are typically a high strength polymer such as ultra high molecular weight polyethylene. In a non-limiting example, a force, pressure, or load is the parameter measured by sensing module 1104. Sensing module 1104 can measure parameter magnitude and the location where the parameter is applied. Sensing module 1104 can have a surface that mirrors or replicates the surface of bearing surfaces 1204.

[0099] In one embodiment, the final insert 1102 can be precision molded in two or more pieces that allow the positioning and insertion of sensing module 1104. As shown, the final insert is formed in two halves. The upper half includes the bearing surfaces 1204. The insert can be formed of a composite material. The composite material will at least
include the bearing surface material and a second material that is attached or bonded together. A cavity is formed in predetermined locations that receive sensing modules 1104. The cavities correspond to bearing surfaces 1104 for each compartment of the knee. The sensing modules 1104 are placed in each cavity. The halves of final insert 1102 are then fastened together whereby the contacting surface 1202 operatively couples to a corresponding bearing surface 1204. The contact surfaces 1202 have a positional relationship to bearing surfaces 1104 allowing position detection where the parameter is applied. The halves of final insert 1102 can be mechanically fastened, attached by adhesive, thermally bonded or connected by other method such that halves will not separate under all operating conditions. The fastening process can also form a seal that isolates sensing modules 1104 from the external environment.

[0100] FIG. 12 is an illustration of the final insert 1102 installed in a knee in accordance with an exemplary embodiment. In the example, a femoral prosthetic component 1210 is coupled to a prepared 1214 femur. Similarly, a tibial prosthetic component 1212 is coupled to a prepared tibia 1216. The preparation includes alignment of the prosthetic components to a mechanical axis. The insert is placed between the tibial prosthetic component 1212 and femoral prosthetic component 1210. The artificial condyles of femoral prosthetic component 1210 articulate with a bearing surface of final insert 1102 that allows movement of the leg.

[0101] As disclosed above, final insert 1102 includes a sensing module that can transmit data to a processor 1208. The processor can be in a tool, equipment, computer, display, or other device. As shown, the processor is in a notebook computer. Receiver circuitry is coupled to processor 1208 that can communicate with the sensing module. Typically, the receiver circuitry is placed in close proximity to final insert 1102 to receive the short-range transmission. In one embodiment, the sensing module can only transmit data. In a second embodiment, the sensing module can have two-way communication between the sensing module and processor 1208.

[0102] The loading, balance, and position can be adjusted during surgery within predetermined quantitatively measured ranges through surgical techniques and adjustments using data from a trial insert and final insert 1102. Both the trial and final inserts include the sensing module to provide measured data to processor 1208 for display. The final insert 1102 is also used to monitor the reconstructed joint long term. The data can be used by the patient and health care providers to ensure that the joint is functioning properly during rehabilitation and as the patient returns to an active normal lifestyle. Conversely, the patient or health care provider is notified when the measured parameters are out of specification. This provides early detection of a problem that can be resolved with minimal stress to the patient. The data from final insert 1102 can be displayed on a screen in real time using data from the embedded sensing module. In one embodiment, a handheld device is used to receive data from final insert 1102. The handheld device can be held in proximity to the knee allowing a strong signal to be obtained for reception of the data.

[0103] In general, final insert 1102 is an example of a sensor system that can be integrated into prosthetic components. The form factor of the sensing assemblages, layout architecture, electronic circuitry, and housing allow it to fit in one or more prosthetic components. Moreover, it is a self-contained device that performs the measurement without extraneous devices. The sensing module can also be placed in femoral prosthetic component 1210 or tibial prosthetic component 1212 to measure a parameter of interest. Data generated by the device can be sent to a database for analysis.

[0104] Artificial components for other joint replacement surgeries have a similar operational form as the knee joint example. The joint typically comprises two or more bones with a cartilaginous surface as a bearing surface that allows joint movement. The cartilage also acts to absorb loading on the joint and prevents bone-to-bone contact. Reconstruction of the hip, spine, shoulder, and other joints have similar functioninginsert structures having at least one bearing surface.

Like the knee joint, these other insert structures typically comprise a polymer material. The polymer material is formed for a particular joint structure. For example, the hip insert is formed in a cup shape that is fitted into the pelvis. In general, the size and thickness of these other joint inserts allow the integration of the sensing module. It should be noted that the sensing module disclosed herein contemplates use in both trial inserts and permanent inserts for the other joints of the muscular-skeletal system thereby providing quantitative parameter measurements during and post surgery.

[0105] While the present invention has been described with reference to particular embodiments, those skilled in the art will recognize that many changes may be made thereto without departing from the spirit and scope of the present invention. Each of these embodiments and obvious variations thereof is contemplated as falling within the spirit and scope of the invention.

1. A sensing system for measurement of a parameter of the muscular-skeletal system comprising:
   a trial insert having dimensions substantially equal to the dimensions of a final insert;
   a sensing module in the trial insert to measure the parameter.

2. The sensing system of claim 1 where the sensing module is placed in a cavity of the trial insert.

3. The sensing system of claim 1 where the sensing module is encapsulated to be hermetically sealed.

4. The sensing system of claim 2 where the trial insert comprises a shell having a feature that operatively couples to a prosthetic component where the shell includes an opening to receive the sensing module.

5. The sensing system of claim 1 where the trial insert interfaces with permanent prosthetic components.

6. The sensing system of claim 1 where the trial insert includes a cover overlying a contacting surface of the sensing module.

7. The sensing system of claim 1 where the trial insert measures a force, pressure, or load that is substantially equal to the force, pressure, or load applied by the muscular-skeletal system to the final insert when installed.

8. The sensing system of claim 1 where the sensing platform comprises
   one or more sensing assemblages;
   electronic circuitry operatively coupled to the one or more sensing assemblages to measure the parameter;
   a power source coupled to the electronic circuitry;
   a transmitter coupled to the electronic circuitry;
   an antenna coupled to the transmitter; and
   an enclosure that encapsulates the electronic circuitry, the power source, antenna, transmitter, and the one or more sensing assemblages
   where a transit time, frequency, or phase is measured by the sensing platform.
8. (canceled)
9. The sensing system of claim 1 where the sensing module is disposed of after surgery.
10. A prosthetic component with sensing capability for in-situ measurement of the muscular-skeletal system comprising a final insert having a bearing surface where a sensing module resides within the final insert and where the sensing module includes a contacting surface that couples to the bearing surface to measure loading thereon.
11. The prosthetic component 10 where a capacitor in the sensing module is inductively charged and where the capacitor powers the sensing module to measure a parameter of the muscular-skeletal system.
12. The prosthetic component of claim 11 where a transit time, frequency, or phase is measured by the sensing module corresponding to the parameter applied to the bearing surface of the final insert.
13. The sensing system of claim 12 where the sensing platform comprises one or more sensing assemblages; electronic circuitry operatively coupled to the one or more sensing assemblages to measure the parameter; a power source coupled to the electronic circuitry; a transmitter coupled to the electronic circuitry; an antenna coupled to the transmitter; and an enclosure that encapsulates the electronic circuitry, the power source, and the one or more sensing assemblages.
14. The sensing system of claim 13 where the sensing assemblage comprises: a compressible waveguide; and at least one transducer to emit an energy wave into the compressible waveguide and detect a propagated energy wave.
15. The sensing system of claim 13 where the sensing assemblage comprises a MEMS structure, a strain gauge, or a piezo-resistive sensor.
16. The sensing system of claim 11 where the sensing module measures position where the parameter is applied to the bearing surface of the final insert.
17. A trial insert for knee reconstruction comprising: a dock having an opening; and at least one sensing module placed in the dock where the trial insert has dimensions substantially equal to a final insert.
18. The trial insert of claim 17 further including a feature on the dock for aligning and retaining the dock to a tibial prosthetic component.
19. The trial insert of claim 17 where the at least one sensing module couples to permanent femoral and tibial prosthetic components during a measurement.
20. The trial insert of claim 17 where the sensing module has no components extending into the surgical field.

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