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Orthopedic measurement system

Abstract

A measurement system comprising a measurement device and a computer. The measurement device is configured to measure a force, pressure, or load applied by the musculoskeletal system. The measurement device comprises an enclosure and a structure configured to fit within an opening in the enclosure. The enclosure is hermetically sealed housing electronic circuitry and at least one sensor. The structure is configured to couple to the musculoskeletal system. At least three sensors underlie and couple to the structure to measure a force, pressure, or load applied to a surface of the structure. The structure includes at least three anti-cantilevering structures. At least one of the three anti-cantilevering structures is configured to couple to the enclosure to limit canting of the structure when the musculoskeletal system couples to the surface of the structure outside a predetermined area.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS (1) This application claims the benefit of priority under 35 U.S.C. § 119 from U.S. Provisional Application No. 63/188,296, filed on May 13, 2021, which is incorporated by reference herein in its entirety.

FIELD
(1) The present disclosure relates generally to orthopedic medical devices, and more specifically to devices that generate quantitative measurement data in real-time.
BACKGROUND
(2) 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.
(3) There has been substantial growth in the repair of the human skeletal system. In general, prosthetic 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 artificial joint meet 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. It would be of great benefit if quantitative measurement data could be provided in real-time to support a subjective feel of a surgeon in an operating room environment for the installation of one or more prosthetic components.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
(1) FIG. **1** is an illustration of a measurement system configured to couple to a musculoskeletal system in accordance with an example embodiment;
(2) FIG. **2**A is an illustration of an upper housing illustrating an opening in accordance with an example embodiment;
(3) FIG. **2**B is a magnified view of an anti-cantilever structure over hanging a periphery of the upper housing in accordance with an example embodiment;
(4) FIG. **3** is an illustration of the interior of the upper housing with structures within openings in accordance with an example embodiment;
(5) FIG. **4** is an illustration of the surfaces of the structures in accordance with an example embodiment;
(6) FIG. **5** is top view of the measurement system with loading of the musculoskeletal system applied to the surface of the structure outside the triangle in accordance with an example embodiment;
(7) FIG. **6** is an illustration showing an interior view of the upper housing with the structures in accordance with an example embodiment;
(8) FIG. **7** is an illustration of a force being applied outside the boundary of the polygon in accordance with an example embodiment;
(9) FIG. **8** is an illustration of the structure canting due to a force, pressure, or load being applied to the surface outside the triangle of FIG. **5** in accordance with an example embodiment;
(10) FIG. **9** is an illustration of the bottom housing in accordance with an example embodiment; and
(11) FIG. **10** is a cross-sectional view of the upper housing illustrating the O-ring placed around the structure forming a hermetic seal between the structure and the upper housing in accordance with an example embodiment.
DETAILED DESCRIPTION
(12) The following description of exemplary embodiment(s) is merely illustrative in nature and is in no way intended to limit the invention, its application, or uses.
(13) 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 the enabling description where appropriate.

(14) While the specification concludes with claims defining the features of the invention that are regarded as novel, it is believed that the invention will be better understood from a consideration of the following description in conjunction with the drawing figures, in which like reference numerals are carried forward.

(15) The example embodiments shown herein below of the measurement apparatus are illustrative only and do not limit use for other parts of a body. In general, the measurement system disclosed herein can be used to measure parameters of the musculoskeletal system. The measurement system or the measurement device can also support installation of prosthetic components to the musculoskeletal system. The measurement system can be coupled to a bone, knee, hip, ankle, spine, shoulder, hand, wrist, foot, fingers, toes, and other areas of the musculoskeletal system to measure at least one parameter. In one embodiment, the measurement system is configured to measure parameters that support a calculation of a position of applied load by the musculoskeletal system and the load magnitude at the position of applied load. The measurement system supports measurement of parameters in real-time during surgery to provide information to a surgeon or surgical team. In general, the principles disclosed herein are meant to be adapted for use in orthopedic pre-operative planning, intra-operative assessment, post-operative assessment, rehabilitation, and long-term monitoring of the musculoskeletal system. In one embodiment, the measurement system is configured to be within a joint of the musculoskeletal system and support movement of the joint. In one embodiment, the measurement system can have a similar shape or form factor as a prosthetic component that is subsequently coupled to the musculoskeletal system.

(16) The following description of embodiment(s) is merely illustrative in nature and is in no way intended to limit the invention, its application, or uses. For simplicity and clarity of the illustration(s), elements in the figures are not necessarily to scale, are only schematic and are non-limiting, and the same reference numbers in different figures denote the same elements, unless stated otherwise. Additionally, descriptions and details of well-known steps and elements are omitted for simplicity of the description. Notice that once an item is defined in one figure, it may not be discussed or further defined in the following figures.

(17) The terms “first”, “second”, “third” and the like in the Claims or/and in the Detailed Description are used for distinguishing between similar elements and not necessarily for describing a sequence, either temporally, spatially, in ranking or in any other manner. It is to be understood that the terms so used are interchangeable under appropriate circumstances and that the embodiments described herein are capable of operation in other sequences than described or illustrated herein.

(18) 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.

(19) 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 the enabling description where appropriate. 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 be 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.

(20) The orientation of the x, y, and z-axes of rectangular Cartesian coordinates is assumed to be such that the x and y axes define a plane at a given location, and the z-axis is normal to the x-y plane. The axes of rotations about the Cartesian axes of the device are defined as yaw, pitch and roll. With the orientation of the Cartesian coordinates defined in this paragraph, the yaw axis of rotation is the z-axis through body of the device. Pitch changes the orientation of a longitudinal axis of the device. Roll is rotation about the longitudinal axis of the device. The orientation of the

X, Y, Z axes of rectangular Cartesian coordinates is selected to facilitate graphical display on computer screens having the orientation that the user will be able to relate to most easily. Therefore the image of the device moves upward on the computer display whenever the device itself moves upward for example away from the surface of the earth. The same applies to movements to the left or right.

(21) Although inertial sensors are provided as enabling examples in the description of embodiments, any tracking device (e.g., a GPS chip, acoustical ranging, IMU (inertial measurement unit), accelerometer, magnetometer, gyroscope, inclinometers, or MEMs devices) can be used within the scope of the embodiments described. The tracking devices can be used to determine position, trajectory, movement, or motion in real-time. The tracking devices can also support measurement of joint rotation and joint alignment.

(22) At least one embodiment is directed to a kinetic orthopedic measurement system to aid a surgeon in determining real time alignment, range of motion, loading, impingement, and contact point of orthopedic implants. Although the system is generic to any orthopedic surgery (e.g., spinal, shoulder, knee, hip, ankle, wrist, finger, toe, bone, musculoskeletal, etc.) the following example(s) deal with orthopedic surgery as a non-limiting example of an embodiment of the invention.

(23) The non-limiting embodiment described herein is related to quantitative measurement based orthopedic surgery and referred to herein as the kinetic system. The kinetic system includes a sensor system that provides quantitative measurement data and feedback that can be provided visually, audibly, or haptically to a surgeon or surgical team. The kinetic system provides the surgeon real-time dynamic data regarding force, pressure, or loading on the joint, contact and congruency through a full range of motion, and information regarding impingement.

(24) In general, kinetics is the study of the effect of forces upon the motion of a body or system of bodies. Disclosed herein is a system for kinetic assessment of the musculoskeletal system. The kinetic system can be for the installation of prosthetic components or for monitoring and assessment of permanently installed components to the musculoskeletal system. For example, installation of a prosthetic component can require one or more bone surfaces to be prepared to receive a device or component. The kinetic system is designed to take quantitative measurements of at least the load, position of load, or alignment with the forces being applied to the joint similar to that of a final joint installation. The sensored measurement components are designed to allow ligaments, tissue, and bone to be in place while the quantitative measurement data is taken. This is significant because the bone cuts take into account the kinetic forces where a kinematic assessment and subsequent bone cuts could be substantial changed from an alignment, load, and position of load once the joint is reassembled.

(25) A prosthetic joint installation can benefit from quantitative measurement data in conjunction with subjective feedback of the prosthetic joint to the surgeon. The quantitative measurements can be used to determine adjustments to bone, prosthetic components, or tissue prior to final installation. Permanent sensors can also be housed in final prosthetic components to provide periodic data related to the status of the implant. Data collected intra-operatively and long term can be used to determine parameter ranges for surgical installation and to improve future prosthetic components. The physical parameter or parameters of interest can include, but are not limited to, measurement of height, length, width, tilt/slope, position, orientation, load magnitude, force, pressure, contact point location, displacement, density, viscosity, pH, light, color, sound, optical, vascular flow, visual recognition, humidity, alignment, position, rotation, inertial sensing, turbidity, bone density, fluid viscosity, strain, angular deformity, vibration, torque, elasticity, motion, acceleration, infection, pain, or temperature. Often, several measured parameters are used to make a quantitative assessment. A graphical user interface can support assimilation of measurement data in real-time during surgery. Parameters can be evaluated relative to orientation, alignment, direction, displacement, or position as well as movement, rotation, or acceleration along an axis or combination of axes by wireless sensing modules or devices positioned on or within a body,

instrument, appliance, vehicle, equipment, or other physical system.

(26) At least one embodiment is directed to a system for adjusting or monitoring a contact position of a musculoskeletal joint for stability comprising: a tool, device, or prosthetic component configured to rotate after being coupled to a bone; a tool, device, or sensored prosthesis having an articular surface to support movement of the musculoskeletal system, where the tool, device, or sensored prosthesis has a plurality of sensors coupled to a surface and a position tracking system configured to measure position, slope, rotation, or trajectory in 3D space, and a computer system configured to wirelessly receive quantitative measurement data from the tool, device, or sensored prosthesis where the computer includes a display to provide the measurement data to a surgical team, a doctor, medical staff, or patient. In one embodiment, the computer system and display is within the operating room where the surgical procedure is performed.

(27) In the present invention parameters are measured with an integrated wireless sensing module or device comprising an encapsulating structure that supports sensors and contacting surfaces and an electronic assemblage that integrates a power supply, one or more sensors, one or more pressure sensors, transducers, one or more inertial sensors, antennas and electronic circuitry that processes measurement data as well as controlling operation of energy conversion, detection, measurement, and wireless communications. The wireless sensing module or device 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 parameters of interest in real time.

(28) 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.

(29) In one embodiment, a patient can receive quantitative measurement data from one or more sensors coupled to the musculoskeletal system, installed prosthetic component or coupled to bone. Thus, the patient can be monitored pre-operatively for assessment, intra-operatively to support installation of a prosthetic component or repair of the musculoskeletal system, and post-operatively after being released from surgery and during rehabilitation using the sensor technology. The measurement data can support optimization of therapy and indicate problems that may occur. The effects of the therapy program using the intelligent prosthetic components can be linked to proper joint function and the patient can be educated on the recovery relative to their specific plan and supported by clinical evidence from a prosthetic component data base. In one embodiment, when the prosthesis is activated, the data will be transmitted (RF/Bluetooth) to a patient recovery application. In one embodiment, the application can be on a computer or a device such as a smart phone. The quantitative measurement data from the sensors will be uploaded into a cloud based VPN (virtual private network) that is HIPPA Compliant. The quantitative measurement data can be assessed by one or more computer programs and updates, work flows, and the measurement data can be sent to the treating physician and health care team. The intelligent prosthesis can be used to support post-op exercises, treatment, or pharmaceuticals that can accelerate the healing phase. Furthermore, different reconstruction techniques can be compared with real-time data. Evaluations of the effects of reconstruction when combined with multi ligamentous injuries can also be analyzed. Healing phase monitoring related to graft adherence to the host tunnels (bone to bone, tendon to bone, composite to bone) can provide quantitative measurement data related thereto. Other important parameters can also be generated such as improving range of motion ROM and terminal extension, achieving improved muscle strength, improved proprioception, improved stability, and improved gait mechanics.

(30) FIG. **1** is an illustration of a measurement system **10** configured to couple to a musculoskeletal system in accordance with an example embodiment. Measurement system **10** comprises one or

more sensors configured to measure one or more parameters, a computer **22**, and a display **24**. Electronic circuitry couples to the one or more sensors to control a measurement process and transmit measurement data. In one embodiment, the electronic circuitry and the one or more sensors are hermetically sealed within measurement system **10**. Measurement system **10** can adapted for use pre-operatively, intra-operatively, or post-operatively to generate measurement data. Measurement data from measurement system **10** is configured to be transmitted to computer **22**. In one embodiment, computer **22** and display **24** include one or more computer programs to process the measurement data, a graphical user to provide the measurement data, provide one or more actions based on the measurement data, generate workflows, or convert the measurement data into a form that can be rapidly assimilated by users of measurement system **10**. In one embodiment, measurement system **10** is configured to be used intra-operatively during surgery to support installation of one or more prosthetic components. The quantitative measurement data from measurement system **10** is configured is used to optimize installation of one or more prosthetic components. Similarly, measurement system **10** can be part of one or more prosthetic components installed in the musculoskeletal system. The measurement data from measurement system **10** in a prosthetic component can provide information related to infection detection, pain mitigation, alignment, wear, range of motion, rotation, position, glue joint integrity, or other longer term maintenance issues that can affect reliability or performance of the joint or prosthetic component. Measurement system **10** provides measurement data in real-time that is processed by computer **22** and displayed on display **24**.

(31) In the example, measurement system **10** is used intra-operatively to support an installation of a prosthetic component. Measurement system **10** comprises an upper housing **18** and a lower housing **20** that couple together to form enclosure **16**. In one embodiment, enclosure **16** is hermetically sealed to seal electronic circuitry and sensors within enclosure **16** from an external environment. A structure **12** and a structure **14** couple respectively within a first opening and a second opening in upper housing **18**. Structure **12** and structure **14** are configured to move relative to the enclosure **16**. In the example, enclosure **16** couples within a joint of the musculoskeletal system. In one embodiment, measurement system **10** is configured to couple within a knee joint. Condyles of a femur respectively couple to structures **12** and **14**. A tibia is configured to couple to lower housing **20**. Measurement system **10** is configured to support movement of the knee joint while generating measurement data. In one embodiment, measurement system **10** measures loading at predetermined locations on a surface of structure **12** and at predetermined locations on a surface of structure **14**. In one embodiment, the predetermined locations on the surface of structure **12** are vertexes of a polygon. Similarly, the predetermined locations on the surface of structure **14** are vertexes of a polygon. In one embodiment, the polygon of structure **12** can be different in size or shape from the polygon of structure **14**. In one embodiment, a sensor underlies each predetermined location of structures **12** and **14**. A force, pressure, or load is applied to structure **12** and structure **14** by the musculoskeletal system. Structures **12** and **14** can move relative to enclosure **16** such that the force, pressure, or load is applied to the sensors underlying structure **12** or structure **14**.

(32) Computer **22** receives measurement data from measurement system **10**. In one embodiment, computer **12** calculates a position of applied load to structure **12** or structure **14**. The position of applied load can also be called a contact point where the condyles of the femur couple to structure **12** or structure **14**. Computer **22** calculates the position of applied load using the predetermined locations on the surface of structure **12** or structure **14** and the load magnitude at the predetermined locations on the surface of structure **12** or structure **14**. Computer **22** also calculates the load magnitude at the position of applied load on structure **12** or structure **14** from the measurement data. In one embodiment, the position of applied load and the load magnitude at the position of applied load is displayed on display **24** of computer **22** in real-time. In one embodiment, a change in loading on a sensor underlying structure **12** or structure **14** will result in a change in the position of applied load and the load magnitude at the position of applied load. The surface of structure **12**

is above a surface of enclosure **16** adjacent to the surface of structure **12**. Similarly, the surface of structure **14** is above a surface of enclosure **16** adjacent to the surface of structure **12**. In general, the position of applied load is designed to be applied only to structure **12** or structure **14**. In one embodiment, the position of applied load moving off structure **12** or structure **14** is considered an error that needs to be corrected and will be indicated on display **24** of computer **22**. In one embodiment, the surgical team is notified by computer **22** when the position of applied load moves to an adjacent area of enclosure **16** and leaves structure **12** or structure **14**. Note that the sensors underlying structure **12** or structure **14** will change from being loaded to unloaded if a condyle of the femur moves from being on structure **12** or structure **14** to the surface that is adjacent on enclosure **16**. Alternatively, the surface of structure **12** or the surface of structure **14** can be contoured such that the surface is not planar. The surface can have a contour that prevents or limits movement to decouple from the surface of structure **12** or structure **14** as the point of applied load moves toward the edge of structure **12** or structure **14**. In any case, display **24** will show movement of the point of applied load and the movement of the point of applied load over a range of motion of the joint. Further discussion herein below of the operation of measurement system **10** may describe a single side showing operation of structure **12** or structure **14**. It should be noted that operation of structure **12** and structure **14** on either side of double arrow **26** will operate similar so what is disclosed herein below will correspond to operation of structure **12** and structure **14** and the disclosed material applies to either structure of measurement system **10**.

(33) FIG. **2**A is an illustration of upper housing **18** illustrating an opening **30** in accordance with an example embodiment. An interior view of upper housing **18** has structure **12** of FIG. **1** removed with structure **14** coupled to upper housing **18**. A periphery **38** is a region of upper housing **18** that is adjacent to opening **30**. Similarly, a periphery **40** of upper housing **18** is adjacent to an opening of upper housing **18** in which structure **14** is placed within. In the example, three sensors will underlie structure **12** of FIG. **1** and three sensors will underlie structure **14**. In the example, a first sensor will underlie and couple to area **32** of structure **14**, a second sensor will underlie and couple to an area **34** of structure **14**, and a third sensor will underlie and couple to an area **36** of structure **14**. In one embodiment, area **32**, area **34**, and area **36** couple to vertexes of a polygon on the surface of structure **14**. The polygon in the example is a triangle. The vertexes of the polygon on the surface of structure **14** related to area **32**, **34**, and **36** are known by computer **22** of FIG. **1**. The musculoskeletal system will couple to the surface structure **14** at a position of applied load or contact point. The position of applied load is calculated by computer **22** of FIG. **1** using the measurement data from the first, second, and third sensors and the position of the vertexes on the surface of structure **14**. Computer **22** of FIG. **1** can further calculate the load magnitude at the position of applied load using the load magnitudes measured at the vertexes of the polygon. The position of applied load and the load magnitude applied to structure **12** and **14** are calculated in real-time and displayed on display **24**. The load magnitude and the position of applied load will move as the loading changes at the vertexes of the polygon. An anti-cantilever structure **42**, an anti-cantilever structure **44**, and an anti-cantilever structure **46** are formed on structure **14**. In one embodiment, anti-cantilever structures **42**, **44**, and **46** over hang periphery **40** of upper housing **18**. The anti-cantilever structures **42**, **44**, and **46** are configured to limit cantilevering or to prevent canting of structure **14** to support measurement of the position of applied load and load magnitude at the position of applied load when the position of applied load is outside the polygon. Structure **12** will also have similar anti-cantilever structures. In general, there will be at least three anti-cantilever structures on structure **12** or structure **14** to limit cantilevering of structure **12** or structure **14** when the position of applied load is outside the polygon. At least one of the three anti-cantilever structures will prevent canting of structure **12** or **14** as the position of applied load to the surface of structure **12** or **14** approaches the outermost regions outside the polygon.

(34) FIG. **2**B is a magnified view of anti-cantilever structure **46** over hanging periphery **40** of upper housing **18** in accordance with an example embodiment. The view is an interior view of upper

housing **18** showing structure **14** within the opening in upper housing **18**. Anti-cantilever structures **42** and **44** of FIG. **2** overhang periphery **40** of upper housing **18** similarly. In one embodiment, anti-cantilever structure **46** is spaced a predetermined distance between a surface of periphery **40** of upper housing **18** and anti-cantilever structure **46** when the surface of structure **14** is unloaded. Similarly, anti-cantilever structures **42** and **44** are spaced from periphery **40** of upper housing **18** by the same predetermined distance when the surface of structure **14** is unloaded. Anti-cantilever structure **46** limits cantilevering of structure **14** when the position of applied load is outside the polygon in an area that moves anti-cantilever structure **46** towards periphery **40** of upper housing. In general, the musculoskeletal system applying a force or load to an area on the surface of structure **14** on the opposite side from where anti-cantilever structure **46** is located will cause structure to cantilever. Further movement towards the edge of the surface of structure **14** will cause anti-cantilever structure **46** to couple to periphery **40**. Structure **14** is prevented from further cantilevering when anti-cantilever structure **46** couples to periphery **40** of upper housing **18**. Anti-cantilever structure **42** and **44** operates similarly to prevent cantilevering when the position of applied load is outside the polygon in areas that cause either anti-cantilever structure **42** or **44** to cantilever and couple to periphery **40** of upper housing **18**. Anti-cantilever structures **42**, **44**, and **46** of FIG. **2** limits unloading of one or more sensors when the position of applied load is outside the vertexes of the polygon. Moreover, anti-cantilever structures **42**, **44**, and **46** of FIG. **2** allow the position of applied load and the load magnitude at the position of applied load to the surface of structure **14** to be measured accurately as the position of applied load moves outside the polygon.

(35) FIG. **3** is an illustration of the interior of upper housing **18** with structure **12** and structure **14** within openings in accordance with an example embodiment. More specifically, structure **12** is coupled within opening **30** shown in FIG. **2**A. Upper housing **18** has periphery **38** adjacent to opening **30** of FIG. **2**. In one embodiment, area **52**, area **54**, and area **56** couple to vertexes of a polygon on the surface of structure **12**. The vertexes of the polygon on the surface of structure **14** related to area **52**, **54**, and **56** are known by computer **22** of FIG. **1**. Area **52**, area **54**, and area **56** each couple to a sensor configured to measure loading such as a capacitor, strain gauge, MEMs device, piezo device or other sensors configured to measure a parameter related to measuring a force, pressure, or load. In the example, the polygon of structure **12** is a triangle with three corresponding sensors configured for measuring the force, pressure, or load applied by the musculoskeletal system to the surface of structure **12**. Structure **12** also has anti-cantilevering structures to limit cantilevering or canting of structure **12** when the position of applied load to the surface of structure **12** is outside the polygon. In general, structure **12** and structure **14** has at least three anti-cantilevering structures to limit canting of structure **12** or structure **14**. Anti-cantilevering structures **62**, **64**, and **66** are shown underlying periphery **38** adjacent to the opening in which structure **12** fits in upper housing **18**. Anti-cantilevering structures **62**, **64**, and **66** support measurement of the loading when the position of applied load is outside the polygon. Anti-cantilevering structures **62**, **64**, and **66** are spaced a predetermined distance from periphery **38** of upper housing **18**. A load applied outside the polygon will cause structure **12** to cant. In one embodiment, canting occurs on an opposing side from which the load is applied. The cant of structure **12** will increase as the position of applied load moves away from the boundary of the polygon until one or more of anti-cantilevering structures **62**, **64**, or **66** couple to periphery **38** of upper housing **16**. Thus, structure **12** is allowed to cant the predetermined distance before being stopped from any further canting even if the position of applied load moves farther from the boundary of the polygon. Referring briefly to FIGS. **3** and **4**, anti-cantilevering structures **42**, **44**, and **46** operate similarly for structure **14** as discussed herein above for coupling to periphery **40** of upper housing **18** as structure **14** cants due to the position of applied load moving outside the boundary of triangle **110**

(36) FIG. **4** is an illustration of the surfaces of structure **12** and structure **14** in accordance with an example embodiment. A triangle **110** and a triangle **112** are respectively drawn on structure **12** and

structure **14**. Triangle **110** has vertexes **72**, **74**, and **76** that couple to sensors respectively underlying areas **52**, **54**, and **56**. Triangle **112** has vertexes **92**, **94**, and **96** that couple to sensors underlying areas **32**, **34**, and **36**. In one embodiment, triangles **110** and **112** can differ in area, size, and shape. In general, accurate measurement of the position of applied load and the load magnitude at the position of applied load on the surface of structures **12** and **14** can be calculated when the position of applied load is at the boundary or within triangles **110** and **112**. The loading is distributed to each sensor underlying each vertex when the position of applied load is in or at the boundary of triangle **110** or triangle **112**. Thus, each sensor is operating within a normal load range that is configured to provide accurate measurement of a portion of the total force, pressure, or load magnitude applied at the position of applied load. As previously, mentioned the measurement data is transmitted to computer **22** of FIG. **1** and the force, pressure, or load measurement data measured at the vertexes of triangle **110** or triangle **112** is used to calculate the position of applied load on within triangles **110** or **112** and the load magnitude at the position of applied load. Computer **22** of FIG. **1** also has the location of the vertexes of triangle **110** or **112** to support the calculation of the position of applied load and the load magnitude at the position of applied load.

(37) Measurement of the position of applied load and the load magnitude at the position of applied load is less accurate outside of the boundary of the polygon. In general, a force, pressure, or load applied to the surface of structure **12** or structure **14** outside triangle **110** or triangle **112** can produce canting of structure **12** or structure **14**. Canting occurs because the surface of structure **12** or structure **14** is loaded outside one or more vertexes. Note that structures **12** or **14** couple loading applied to the surface to a sensor underlying each vertex. Thus, the position of applied load being applied outside the triangle **112** or triangle **114** causes one or more sensors to become a pivot point as they are interior to the position of applied load thereby causing structure **12** or structure **14** to cant. In one embodiment, the error is minimized or corrected by computer **22** of FIG. **1** to produce the position of applied load and the load magnitude at the position of applied load with an error that is acceptable for the application. How this is done will be disclosed in more detail here in below. Also, one or more sensors at the vertexes of the polygon may become lightly loaded or unloaded as the position of applied load moves outside the boundary of the polygon. Measurement data from the lightly loaded or unloaded sensors may be outside a measurement range of a sensor for tracking the position of applied load or be less accurate. Conversely, all or most of the loading can be placed on a single sensor at the vertex of the polygon when the loading is outside the boundary of the polygon. Measurement data from the heavily loaded sensor may be outside the measurement range of a sensor for tracking the position of applied load or be less accurate. In one embodiment, a surgeon or surgical team have a need to track the position of applied load and the load magnitude at the position of applied load when the position of applied load moves outside the boundary of the polygon. Measurement system **10** is configured to support accurate measurement outside the polygon.

(38) In the example, the polygons of measurement system **10** are triangles **110** and **112**. A sensor couples to and underlies each vertex **72**, **74**, and **76** of triangle **110** on the surface of structure **12**. Similarly, a sensor couples to and underlies each vertex **92**, **94**, and **96** of triangle **112** on the surface of structure **14**. In one embodiment, vertexes **72**, **74**, and **76** of triangle **110** and vertexes **92**, **94**, and **96** of triangle **110** are placed at or near a periphery of structure **12** or structure **14**. In the example, a region **78**, a region **80**, and a region **82** are defined as regions outside of triangle **110**. Referring briefly to FIG. **3**, anti-cantilevering structures **42**, **44**, and **46** of structure **14** and anti-cantilevering structures **62**, **64**, and **66** of structure **12** are configured to respectively limit canting of structures **14** and **12** and support accurate measurement outside of triangle **110** and triangle **112**. The point of applied load coupling to the farthest distance from the boundary of triangle **12** or triangle **14** will have the worst error. In general, regions **78**, **80**, and **82** on the surface of structure **12** or regions **98**, **100**, and **102** on the surface of structure **14** have different shapes such that the farthest distance from the boundary will differ for each region. In the example, the locations

farthest from the boundary of triangle **110** on the surface of structure **12** is location **84** in region **78**, location **86** in region **80**, and location **88** in region **82**. The locations farthest from the boundary of triangle **112** on the surface of structure **14** are location **104**, location **106**, and location **108**. The maximum measurement error would occur at locations **84**, **86**, or **88** or locations **104**, **206**, and **108**.

(39) FIG. **5** is top view of measurement system **10** with loading of the musculoskeletal system applied to the surface of structure **12** outside triangle **110** in accordance with an example embodiment. Measurement system **10** supports load measurement when the load is applied within triangle **110** and as the position of applied load moves outside triangle **110**. In one embodiment, measurement system **10** is used in surgery to provide measurement data to support installation of a prosthetic component. In the example, measurement system **10** is used to support the installation of a knee joint. The condyles of a femur are configured to couple to structures **12** and **14**. The position of applied load on structure **12** and structure **14** is a contact point where a condyle of the femur couples to structure **12** or structure **14**. In one embodiment, the contact point of the medial or lateral condyle of the femur does not remain stationary on the surface of structure **12** or the surface of structure **14** as the leg is moved through a range of motion. In one embodiment, the position of applied load moving outside triangle **110** or triangle **112** is considered acceptable over the range of motion. In other words, the position of applied load and the load magnitude at the position of applied load on the surface of structure **12** or structure **14** is tracked and reported by computer **22** and displayed on display **24** for measurement system **10**.

(40) An example of loading outside triangle **110** is disclosed to illustrate what occurs in measurement system **10** to provide accurate position of applied load and the load magnitude at the position of applied load as the position of applied load transitions from within triangle **110** to moving outside triangle **110**. Although the example is directed toward structure **12** the operation of structure **14** will operate similarly. Also, the disclosed concept relates to the position of applied load moving outside triangle **110** or **112** respectively in regions **78**, **80**, and **82** or regions **98**, **100**, and **102**. In general, the process disclosed herein below can be used to measure the position of applied load and the load magnitude in regions outside the boundary of any polygon shape and is not limited to a triangle in the example. In the example, F.sub.applied **120** is applied in region **82** of the surface of structure **12** outside of triangle **110**. F.sub.applied **120** is in proximity to vertex **76** of triangle **110**. As mentioned previously, a sensor underlies vertex **76** for providing measurement data at vertex **76** to support calculation of the position of applied load. F.sub.applied **120** being applied outside triangle **110** in region **82** causes structure **12** to cant. In the example, an anti-cantilevering structure will limit canting of structure **12** and produce a F.sub.reaction **132** counteracting force outside region **78**. In general, canting movement of structure **12** is prevented by anti-cantilevering structures **62**, **64**, or **66** coupling to upper housing **18** of FIG. **6**. More than one of anti-cantilevering structures **62**, **64**, or **66** can couple to upper housing **18** as structure **12** to prevent canting.

(41) FIG. **6** is an illustration showing an interior view of upper housing **18** with structures **12** and **14** in accordance with an example embodiment. Areas **52**, **54**, and **56** on an interior surface of structure **12** respectively couple to vertexes **72**, **74**, and **76** on the surface of structure **12** of FIG. **5**. A first, second, and third sensor respectively underlies each area **52**, **54**, and **56**. A position of applied load on the surface of structure **12** distributes the force, pressure, or load to the first, second, and third sensors through areas **52**, **54**, and **56** on the interior surface of structure **12**. Similarly, areas **32**, **34**, and **36** on an interior surface of structure **14** respectively couple to vertexes **92**, **94**, and **96** on the surface structure **14**. A fourth, fifth, and sixth sensor respectively underlies each area **32**, **34**, and **36**. A position of applied load on the surface of structure **14** distributes the force, pressure, or load to the first, second, and third sensors through areas **32**, **34**, and **36**.

(42) Anti-cantilevering structures **62**, **64**, and **66** overlie a portion of periphery **38** of structure **12** adjacent to the opening in which structure **12** is fitted. Similarly, anti-cantilevering structures **42**, **44**, and **46** of structure **14** overlie a portion of periphery **40** adjacent to the opening in which structure **14** is fitted. In general, a position applied load in a region outside the boundary of the

polygon will cause the load bearing structure to cant upward on an opposing side to the position of applied load. One or more anti-cantilevering structures will limit or prevent canting thereby applying an opposing force, pressure, or load to prevent further canting. The spacing between anti-cantilevering structures **62**, **64**, and **66** and upper housing **18** when no canting is occurring is a minimum spacing defined by tolerances in manufacturing and assembly of measurement system **10** to ensure a gap. In one embodiment, the spacing between anti-cantilevering structures **62**, **64**, and **66** and periphery **38** of upper housing **18** is 0.254 millimeters when the position of applied load is within the boundary of triangle **110**. The spacing between anti-cantilevering structure **42**, **44**, and **46** of structure **14** and periphery **40** of structure **14** is also 0.254 millimeters when the position of applied load is within the boundary of triangle **112**. In general, the point at which one or more anti-cantilevering structures **62**, **64**, and **66** will couple to periphery **38** can vary and is determined by the position of applied load as it moves outside the boundary of triangle **110**. Referring briefly to FIG. **5**, F.sub.applied **120** the position of applied load is shown outside the boundary of triangle **110**. F.sub.applied **120** cants structure **12** such that anti-cantilevering structure **64** of structure **12** couples to periphery **38** of structure **12**. In the example, anti-cantilevering structure **64** produces F.sub.reaction **132** in an area shown in FIG. **5** that prevents further canting. F.sub.reaction **132** is shown on the interior view of structure **12** that couples anti-cantilevering structure **64** to periphery **38** of structure **12**. In one embodiment, the entire anti-cantilevering structure **64** can be coupled to periphery **38** of structure **12** or a portion of anti-cantilevering structure **64** can be coupled to periphery **38** of structure **12** depending on the position applied load which causes structure **12** to cant. As mentioned previously, more than one anti-cantilevering structure can couple to periphery **38** of structure **12**. F.sub.reaction **132** is then divided between the one or more anti-cantilevering structures coupling to periphery **138** to generate a force that opposes canting of structure **12**.

(43) FIG. **7** is an illustration of a force being applied outside the boundary of the polygon in accordance with an example embodiment. A simplified view of a structure shows what occurs when a force is applied outside the boundary of the polygon on the surface of the structure in a measurement system. In the example, the polygon on the surface of structure **12** is triangle **110** as shown in FIG. **5** having vertexes **72**, **74**, and **76**. A first sensor, a second sensor, and a third sensor respectively underlie vertexes **72**, **74**, and **76** and are configured to measure a force, pressure, or load at each location. A computer **22** shown in FIG. **1** is configured to receive measurement data and calculate the position of applied load and the load magnitude at the position of applied load using the force, pressure, or load measurement data and the locations of vertexes **72**, **74**, and **76**. As mentioned previously, inaccuracies in measurement can occur when the position of applied load moves outside the boundary of triangle **110**. The inaccuracy will increase as the position of applied load moves farther from the boundary of triangle **110**.

(44) Enclosure **16** of FIG. **1** is hermetically sealed from an external environment. Upper housing **18** is coupled to lower housing **20** to form enclosure **16** in FIG. **1**. In one embodiment, upper housing **18** and lower housing **20** are coupled together by an adhesive. Structures **12** and **14** of FIG. **1** have a seal to isolate an interior of enclosure **16** from an external environment while allowing structures **12** and **14** to move relative to enclosure **16**. Movement of structures **12** and **14** relative to enclosure **16** support measurement of the position of applied load and the load magnitude at the position of applied load. Structure **12** of FIG. **7** is sealed to upper housing **18** of FIG. **5** by an O-ring **124**. O-ring **124** comprises a compressible and flexible material such as silicone that couples around structure **12** or structure **14**. O-ring **124** couples between a sidewall in the opening of upper housing **18** of FIG. **2**A and a sidewall of structure **12**. The spacing between the sidewall of upper housing **18** and the sidewall of structure **12** is less than the thickness of O-ring **124** to ensure O-ring **124** compresses to form a compression seal. O-ring **124** supports movement of structure **12** relative to enclosure **16** of FIG. **1** when a force, pressure, or load is applied to the surface of structure **12**. Enclosure **16** of FIG. **1** further includes a stop **126** as shown in FIG. **7** that is configured to protect sensor **122**. Sensor **122** underlies vertex **76** of FIG. **5**. In the example, stop **126** prevents movement

of structure **12** prior to F.sub.applied **120** being at a level that can damage sensor **122**. Conversely, stop **126** does not couple to structure **12** when F.sub.applied **120** is being applied to the surface of structure **12** that is in a normal operating range of sensor **122**. Stop **126** stops movement of structure **12** such that the loading to sensor **122** cannot be increased after a predetermined spacing is exceeded between structure **12** and stop **126**. In one embodiment, the predetermined spacing between structure **12** and stop **126** is 0.508 millimeters which is sufficient to protect sensor **122** from being damaged when a load is applied to structure **12** above the allowed maximum loading. In one embodiment, the stop **126** is coupled to lower housing **20** of FIG. **1**. In one embodiment, a plurality of stops are formed in lower housing **20** of FIG. **1** to protect each sensor coupled to structure **12** and each sensor coupled to structure **14** from over-excursion damage.

(45) Referring to FIG. **5**, the position of applied load to the surface of structure **12** is applied to region **82** near vertex **76**. F.sub.applied **120** is a force, pressure, or load applied to the surface of structure **12** outside the boundary of triangle **110** of FIG. **5**. Although a specific example is provided, any force, pressure, or load applied to the surface of structure **12** outside the boundary of triangle **110** of FIG. **5** will be calculated similarly. A sensor **122** as shown in FIG. **7** underlies vertex **76** and is configured to measure loading applied at vertex **76**. Note that sensor **122** acts as a pivot point when F.sub.applied **120** is outside the boundary of triangle **110** of FIG. **5**. Conversely, sensor **122** is not a pivot point that causes structure **12** to cant when F.sub.applied **120** is at the boundary or within the boundary of triangle **110** of FIG. **5**. In the example, F.sub.applied **120** is applied a distance **128** corresponding to d.sub.1 in FIG. **7** from vertex **76**. A distance **132** corresponding to d.sub.2 in FIG. **7** is a distance from vertex **128** to an opposing side of structure **112** having anti-cantilevering structure **64** of FIG. **6** overlying periphery **38** of structure **12**. F.sub.applied **120** applied as indicated in FIG. **6** will cause structure **12** to cant towards upper housing **18** ultimately coupling anti-cantilevering structure **64** to periphery **38** of structure **12** of FIG. **6**. As shown, in FIG. **7**, anti-cantilevering structure **64** has not coupled to structure **12**. F.sub.reaction **132** is a force applied by enclosure **16** and more specifically periphery **38** of upper housing **18** of FIG. **3** to prevent structure **12** from further canting. In general, an increase in F.sub.applied **120** will result in a corresponding increase in F.sub.reaction **132** applied by upper housing **18** to structure **12**. As mentioned previously, the predetermined distance between anti-cantilevering structure **64** of structure **12** and periphery **38** of upper housing **18** is 0.254 millimeters that is supported by the manufacturing and assembling tolerances of enclosure **16** of FIG. **1**.

(46) FIG. **8** is an illustration of structure **12** canting due to a force, pressure, or load being applied to the surface outside triangle **110** of FIG. **5** in accordance with an example embodiment. In the example, the force, pressure, or load is applied to region **82** of FIG. **5** near vertex **76** causing structure **12** to cant. In the example, F.sub.applied **120** is applied to the location indicated in FIG. **5** causing structure **12** to cant and coupling anti-cantilevering structure **64** to periphery **38** of upper housing **18**. More specifically, canting of structure **12** causes region **78** of FIG. **5** to lift or cant when loading is applied near vertex **76** in region **82**. As shown in FIG. **6** canting of structure **12** and more specifically region **78** of FIG. **5** results in anti-cantilevering structure **64** coupling to periphery **38** of upper housing **18** thereby preventing further canting of structure **12**. Structure **12** movement is limited by periphery **38** of upper housing **18** even if F.sub.applied **120** is increased. F.sub.reaction **132** is generated to oppose the canting of structure **12** corresponding to anti-cantilevering structure **64** of structure **12** coupling to periphery **38** of upper housing **18**.

(47) Measurement data from sensor **122** requires correction when F.sub.applied **120** is outside the boundary of triangle **110** in region **82** and periphery **38** of upper housing **18** of FIG. **3** couples to anti-cantilevering structure **64** of structure **12**. A first equation (1) relates F.sub.reaction **132** to F.sub.applied **120** as shown herein below. A second equation (2) relates F.sub.measured to F.sub.reaction and F.sub.applied and is shown herein below for the example. Note that computer **22** of FIG. **1** will calculate the position of applied load and the load magnitude at the position of applied load from the measurement data generated by the sensors underlying each vertex of the

polygon.

$$F_{reaction132}=F_{applied120}*d_1/d_2. \quad (1)$$

$$F_{measured}=F_{reaction132}+F_{applied120} \quad (2)$$

(48) In one embodiment, F.sub.measured can be estimated without having measurement data for F.sub.reaction **132**. The estimate used if the error is within a range that is acceptable for the surgeon or surgical team in monitoring the position of applied load and the load magnitude at the position of applied load over a range of motion. The worst error will occur at the farthest distance from a boundary in regions **78**, **80**, or **82** as shown in FIG. **5**. The farthest points within regions **78**, **80**, or **82** from the boundary of triangle **110** are respectively identified as location **84**, location **86**, and location **88** of FIG. **5**. In one embodiment, the error in measurement by measurement system **10** will be largest at locations **84**, **86**, and **88** of FIG. **5**. We can solve for F.sub.reaction using equation (1) and then use the results in equation 2 to determine F.sub.measured as a ratio of the distances d.sub.1/d.sub.2. Equation (3) relates measurement error at location **84** to F.sub.measured that is actually measured by measurement system **10**. Equation (4) relates measurement error at location **82** to F.sub.measured that is actually measured by measurement system **10**. Equation (5) relates measurement error at location **86** to F.sub.measured that is actually measured by measurement system **10**. Note that the error at the different locations within a region **78**, **80**, or **82** will vary because d.sub.1 and d.sub.2 differs in each region due to a difference in shape of each region. D.sub.1 is the distance from a vertex to the position of applied load at locations **84**, **86**, and **88**. D.sub.2 is the distance from the vertex to the anti-cantilevering structure that couples to upper housing **18** of FIG. **6** when structure **12** is canted.

$$\text{Error at Location 84}:=d_1/d_2*F_{measured} \quad (4)$$

$$\text{Error at Location 82}:=d_1/d_2*F_{measured} \quad (5)$$

$$\text{Error at Location 86}:=d_1/d_2*F_{measured} \quad (6)$$

(49) In the example shown in FIG. **5** for structure **12**, the maximum error (Max.sub.error) at location **84**, **82**, and **86** is (d.sub.1/d.sub.2) 15% at location **84**, (d.sub.1/d.sub.2) 13% at location **82**, and (d.sub.1/d.sub.2) 7% at location **86**. In one embodiment, the error is chosen as a constant for each region. In one embodiment, the error is chosen to be different for each region **78**, **80**, **82** of structure **12** and related to the maximum error at locations **84**, **86**, and **88**. In one embodiment, the error selected for calculating the measured loading outside the boundary of triangle **110** is less than the maximum error. In the example disclosed herein above, the error is selected to be half of the maximum error (0.5*Max.sub.error) to calculate an approximate load magnitude when the position of applied load is outside the boundary of triangle **110** of FIG. **5**. Computer **22** is used to calculate F.sub.approximate at the position of applied load as stated in equation (7).

$$F_{approximate}=F_{measured}(1+\tfrac{1}{2}(\text{Max}_{error}\text{ for region})) \quad (7)$$

(50) Thus, the correction increases the loading measured by measurement system **10** when the position of applied load is in regions **78**, **80**, or **82**. One half of maximum error (Max.sub.error) in regions, **78**, **80**, and **82** is respectively 7.5%, 3.5%, and 6.5%. Computer **22** determines the region in which the position of applied load is in and selects the appropriate Max.sub.error for the region. The F.sub.measured by measurement system **10** is used with equation (7) to calculate F.sub.approximate which is the calculated loading at the position of applied load. Note that F.sub.approximate is an estimated force. The error in the approximation of the load magnitude at the position of applied load in regions **78**, **80**, and **82** is respectively limited to an error less than or equal to 7.5%, 3.5%, or 6.5% of the F.sub.measured by measurement system **10**. In one embodiment, this error is acceptable for applications to support installation of one or more prosthetic components in a joint of the musculoskeletal system.

(51) In the example, computer **22** receiving measurement data from measurement system **10** would determine that the position of applied load is in region **82** of the surface of structure **12**. Computer **22** uses 13.5% as the error correction as disclosed above for that region. Computer **22** would also calculate the load magnitude at the position of applied load which is F.sub.applied **120**. Computer

then outputs the approximate loading in region **82** as stated in equation (8) herein below. The measurement error using this calculation method would be less than or equal to 6.5% of F.sub.approximate. Although disclosed for structure **12** of measurement system **10**, the calculation method can be applied similarly for structure **14**. Different polygons can be used to reduce the maximum error by reducing the distance outside the boundary of the polygon and the distance to a vertex. Computer **22** will have different maximum error (Max.sub.error) for each region outside the boundary of a polygon. For the calculation, the measurement error is minimized by adding 0.5*(Max.sub.error) to the measured force, pressure, or load as the position of applied load traverses outside the boundary of the polygon into any region. Each region can have a different (Max.sub.error) due to geometrical differences as disclosed herein. As mentioned, this measurement methodology is supported with the minimum number of sensors and provides accuracy suitable for monitoring musculoskeletal loading over a range of motion. Typically, the majority of the position of applied load will be within the polygon measurement system **10** but computer **22** will provide F.sub.approximate measurement data in regions outside the polygon of structure **12** or structure **14**. In one embodiment, a different multiplier other than 0.5 can be used to further reduce error if the typical paths outside the boundary of the polygon for the application does not extend to (Max.sub.error) as calculated herein above. Knowledge of the range of motion paths for measurement system **10** can be incorporated to further reduce error in measurement.

F.sub.approximate=*F*.sub.applied120*(1+½(0.135))   (8)

(52) Alternatively, the actual measurement can be corrected by knowing F.sub.reaction **132**. In one embodiment, a load sensor is coupled to structure **12** or upper housing **18** to measure when anti-cantilevering structures **64** to measure F.sub.reaction **132**. F.sub.reaction **132** is measured by the load sensor when anti-cantilevering structure **64** couples to upper housing **18**. More specifically this will occur when the position of applied load moves into region **82** outside the boundary of triangle **110** of FIG. **5**. Measurement system **10** transmits measurement data F.sub.reaction **132** and F.sub.applied **120** to computer **22** of FIG. **1** to calculate F.sub.measured using equation (2) that would be provided on display **24**. Since we are measuring F.sub.reaction **132** directly we do not need distances d.sub.1 and d.sub.2 for calculation. In general, each anti-cantilevering structure **62**, **64**, and **66** will have a force, pressure, or load sensor configured to measure F.sub.reaction when anti-cantilevering structure **62**, **64**, or **66** couples to periphery **38** of upper housing **18**.

(53) The second equation (2) supports measurement of F.sub.applied **120**. The calculation of the second equation requires the distance d.sub.1 and d.sub.2 to be calculated. The position of the vertexes **72**, **74**, and **76** are known by computer **22** of FIG. **1**. Similarly, the position of anti-cantilevering structures **62**, **64**, and **66** of FIG. **3** are known by computer **22** of FIG. **1**. Distances for d.sub.1 and d.sub.2 can be calculated by computer **22** using the known positions and measurement data received from measurement system **10** of FIG. **1**. Referring to FIG. **8**, measurement system **10** would identify that the position of applied load to the actual measured force, pressure, or load (F.sub.measured) to F.sub.reaction and F.sub.applied.

(54) The second equation is: F.sub.applied**120**=F.sub.reaction**132***d.sub.2/d.sub.1. The applied force at F.sub.applied **120** can be calculated by computer **22** and displayed on display **24** of FIG. **1**.

(55) Alternatively, an estimate can be provided by computer **22** and display **24** of FIG. **1**. The estimate is provided that provides a simple correction that improves the accuracy of the measurement data within acceptable tolerances required by a surgeon or surgical team reviewing the measurement data as the position of applied load moves outside the boundary of triangle **110** of FIG. **4**. Thus, measurements can be provided outside a polygon formed by the sensors located at vertexes of the polygon either by estimate or direct measurement as disclosed herein.

(56) FIG. **9** is an illustration of bottom housing **20** in accordance with an example embodiment. Bottom housing **20** is a component of measurement system **10** of FIG. **1**. Structure **12** and structure **14** are shown coupled to bottom housing **20**. An O-ring **124** is shown coupled around structure **12**. Similarly, an O-ring **124** is shown coupled around structure **14**. O-ring **124** is configured to support

movement of structure **12** or **14** when a force, pressure, or load is applied to a surface of structure **12** or **14**. O-ring **12** is also configured to form a hermetic seal between upper housing **18** (not shown) and structure **12** or **14** to isolate an internal environment of enclosure **16** of FIG. **1** from an external environment. Structure **12** and structure **14** can move independently. Bottom housing **20** has a glue channel **140** that corresponds to a glue channel of upper housing **18** of FIG. **3**. In the example, glue channel **140** forms a contiguous channel around the entire periphery of bottom housing **20**. Glue channel **140** is configured to hold a glue or adhesive prior to coupling upper housing **18** to bottom housing **20**. Glue or adhesive is placed in glue channel **140** around the entirety of glue channel **140** to ensure complete hermetic sealing of enclosure **16** of FIG. **1** when upper housing **18** is mated to bottom housing **20**.
(57) Sensors couple to and underlie structure **12** or structure **14** at vertexes of a polygon. Examples of sensors for measuring a force, pressure, or load are mechanical sensors, piezo-sensors, MEMs devices, capacitors, strain gauges, and other pressure sensitive components. The sensors can measure force, pressure, or load directly or indirectly. Computer **22** of FIG. **1** can include calibration data to reduce non-linearities over a range of measurement. In the example, a first sensor, a second sensor, and third sensor underlie and couple to structure **12** respectively at area **52**, **54**, and **56** of structure **12** of FIG. **3**. The first sensor, second sensor, and third sensor measure loading at vertexes **72**, **74**, and **76** as shown in FIG. **4**. Similarly, a fourth sensor, a fifth sensor, and a sixth sensor underlie and couple to structure **12** respectively at area **32**, **34**, and **36** of FIG. **3**. The fourth sensor, fifth sensor, and sixth sensor measure loading respectively at vertex **92**, **94**, and **96**. The position of applied load and the load magnitude applied to structures **12** or **14** can be calculated using measurement data from the first, second, third, fourth, fifth, or sixth sensors. In one embodiment, the measurement data from the sensors is transmitted from enclosure **10** coupled to a musculoskeletal system to computer **22** for calculating the position of applied and the load magnitude.
(58) FIG. **10** is a cross-sectional view of upper housing **10** illustrating O-ring **124** placed around structure **12** forming a hermetic seal between structure **12** and upper housing **18** in accordance with an example embodiment. Similarly, O-ring **124** placed around structure **14** forms a hermetic seal between structure **12** and upper housing **18**. As stated previously, structure **12** or structure **14** can move relative to the enclosure when a force, pressure, or load is applied to a surface of structure **12** or structure **14**. The O-ring **124** coupled to structure **12** is bounded and retained by features on upper housing **18** and structure **12**. In one embodiment, a ridge **144** is a feature formed on upper housing **18** on a sidewall of the opening in which structure **12** fits. Similarly, a ridge **148** is formed on structure **12** on a sidewall of structure **12**. O-ring **124** couples around structure **12** and is retained by ridge **148**. In one embodiment, there is a gap between a sidewall having ridge **144** and structure **12**. The gap between the sidewall having ridge **144** is less than the thickness of O-ring **124** to compress O-ring **124** thereby forming a hermetic seal when structure **12** is placed within the opening in upper housing **18**. The cross-sectional view shows structure **12** inserted within the opening in upper housing **18**. Note that O-ring **124** is bounded by ridge **144** and ridge **148** to retain O-ring **124** compressed between structure **12** and upper housing **18** to maintain the hermetic seal.
(59) Similarly, the O-ring **124** coupled to structure **14** is bounded and retained by features on upper housing **18** and structure **14**. In one embodiment, a ridge **146** is a feature formed on upper housing **18** on a sidewall of the opening in which structure **14** fits. A ridge **150** is formed on a sidewall of structure **14** that corresponds to ridge **146**. O-ring **124** couples around structure **14** and is retained by ridge **150**. In one embodiment, there is a gap between a sidewall having ridge **146** and structure **14**. The gap between the sidewall having ridge **146** of is less than the thickness of O-ring **124** to compress O-ring **124** when structure **14** is placed within the opening in upper housing **18**. The cross-sectional view shows structure **14** inserted within the opening in upper housing **18**. Note that O-ring **124** is bounded by ridge **146** and ridge **150** to retain O-ring **124** compressed between structure **12** and upper housing **18** to maintain the hermetic seal. Alternatively, O-ring **124** can be

replaced with a flexible glue or flexible overmold feature that creates a seal/linear bearing effect.

(60) Upper housing **18** couples to bottom housing **20** of FIG. **9**. In one embodiment, a glue channel **140** of FIG. **9** is configured to hold glue or an adhesive around the entire perimeter of the bottom housing **20** of FIG. **9**. Upper housing **18** has a corresponding glue channel **142**. Glue channel **142** is also formed around the entire perimeter of upper housing **18**. In one embodiment, glue channel **142** has a ridge configured to fit within glue channel **140** of FIG. **9**. The glue or adhesive is placed within glue channel **140** of FIG. **9**. Upper housing **18** is coupled to bottom housing **20** of FIG. **9** such that glue channel **140** couples to glue channel **142**. In one embodiment, glue channel **142** of upper housing **18** has a feature that extends into glue channel **140** of bottom housing of FIG. **9**. The feature of glue channel **142** is configured to couple to the glue or adhesive within and support alignment of upper housing **18** to bottom housing **20** of FIG. **9** to form enclosure **16** of FIG. **1** that is hermetically sealed. Thus, Enclosure **16** of FIG. **1** is hermetically sealed by glue channel **140** of FIG. **9**, glue channel **142** of FIG. **10**, O-ring **124** on structure **12** and O-ring **124** on structure **14**. Electronic circuitry and one or more sensors are housed within enclosure **16** of FIG. **1**. In one embodiment, enclosure **16** of FIG. **1** further includes a power source such as a battery or can acquire power or harvest energy from an external source to charge an energy storage device such as a super capacitor to perform a measurement sequence. Measurement data from enclosure **16** is transmitted to computer **22** of FIG. **1** and displayed on display **24**. In one embodiment, computer **22** and display **24** of FIG. **1** is configured to provide measurement data related to load magnitude at a position of applied load over the entire surface of structure **12** or structure **14**.

(61) In general, FIGS. **1-10** will be referenced herein below to support disclosure of the invention. More specifically, components of FIGS. **1-10** may be called upon to describe aspects of operation or structure herein below. A measurement system **10** is disclosed comprising an enclosure **16** and a computer **22**. A measurement device of measurement system **10** comprises enclosure **16**, at least one structure (structure **12** or structure **14**), electronic circuitry, a power source, and at least one sensor. In general, the measurement device is configured to couple to a musculoskeletal system to generate at least one measurement. In one embodiment, the measurement device is configured to be placed in a joint of the musculoskeletal system. The electronic circuitry, the power source, and the at least one sensor are housed within enclosure **16** and sealed from an external environment. In one embodiment, enclosure **16** comprises an upper housing **16** and a bottom housing **20** coupled together. In one embodiment, the at least one structure is configured to fit within an opening in the enclosure **16**. In one embodiment, at least a portion of the surface of the at least one structure is above an adjacent surface of upper housing **16**. The surface shape and height of the at least one structure reduces the position of applied load from leaving the at least one structure to the adjacent surface of upper housing **16**. In one embodiment, the surface of the at least one structure is non-planar. In one embodiment, the surface of the at least one structure is curved. The surface of the at least one structure is configured to couple to a musculoskeletal system. In the example, structure **12** and structure **14** are configured to fit within openings in enclosure **16** for coupling to a medial condyle and a lateral condyle of a femur. A plurality of sensors underlies and couples to the at least on structure for measuring a force, pressure, or load. Enclosure **16** and the structure are hermetically sealed to isolate an interior of enclosure **16** from an external environment. In one embodiment, an O-ring **124** is placed around the at least one structure (structure **12** or structure **14**) such that the O-ring **124** couples between enclosure **16** and the at least one structure to hermetically seal the at least one structure (structure **12** or structure **14**) to enclosure **16**. The O-ring also supports movement of structure **12** or structure **14** relative to enclosure **16** when a force, pressure, or load is applied to the surface of structure **12** or structure **14**. O-ring **124** is retained by two or more features configured to confine O-ring **124** within a predetermined area. In the example, a ridge **144** is formed in upper housing **18** and a ridge **148** is formed in structure **12** as retaining features for O-ring **124**. O-ring **124** is compressed between sidewalls of upper housing **18** and structure **12**. Ridge **144** and ridge **148** retains O-ring **124** from moving up or down thereby

maintaining a seal over the range of motion of structure **12** under a force, pressure, or load. In one embodiment, the plurality of sensors couple to the surface of the at least one structure at vertexes of a polygon. In one embodiment, the at least one structure includes at least three anti-cantilevering structures where at least one of the anti-cantilevering structures is configured to couple to the enclosure to limit canting of the at least one structure when the musculoskeletal system couples to the surface of the at least one structure outside a predetermined area. The measurement device of measurement system **10** transmits measurement data to computer **22**. Computer **22** calculates a position of applied load by the musculoskeletal system to the surface of the at least one structure of the measurement device and a load magnitude at the position of applied load from the sensor data from the measurement device. In one embodiment, computer **22** is configured to estimate the load magnitude at the position of applied load (by the musculoskeletal system) when at least one anti-cantilevering structure in enclosure **16** prevents canting of structure **12** or structure **14**. In one embodiment, anti-cantilevering structures are formed on structure **12** and structure **14** that couple to upper housing **18** to limit canting. Alternatively, anti-cantilevering structures can be formed on upper housing **18** or bottom housing **20**. In the example, anti-cantilevering structures **62**, **64**, or **66** are formed on structure **12** of enclosure **16** and anti-cantilevering structures **42**, **44**, or **46** are formed on structure **14** of enclosure **16**. Anti-cantilevering structure **62**, **64**, or **66** limit canting when a force pressure, or load is applied to the surface structure **12** in region **78**, **80**, or **82**. Similarly, Anti-cantilevering structure **42**, **44**, or **46** limit canting when a force, pressure, or load is applied to the surface of structure **14** in region **98**, **100**, or **102**.

(62) The measurement device is configured to be placed the musculoskeletal system such as in bone, a spine, a knee, a hip, a shoulder, an ankle, fingers, wrist, elbow, or toes. In the example, the measurement device is configured to be placed in a knee joint of the musculoskeletal system. Measurement system **10** is configured to measure a force, pressure, or load applied by a medial condyle and lateral condyle of a femur. In one embodiment, the surface of the at least one structure (structure **12** or structure **14**) couples within the joint and supports movement of the joint. In one embodiment, the measurement device includes at least three sensors are configured to measure a force, pressure, or load applied to the surface of the at least one structure. The electronic circuitry couples to the at least three sensors and is configured to control a measurement process and transmit measurement data. The at least one structure (structure **12** or structure **14**) is configured to move under loading to apply the force, pressure, or load to the at least three sensors. Computer **22** is configured to receive the measurement data from the measurement device. Computer **22** is configured to calculate a position of applied load on the surface of the structure (structure **12** or structure **14**) and a load magnitude at the position of applied load. In one embodiment the predetermined area of the surface of the structure (structure **12** or structure **14**) is the polygon defined by the at least three sensors that couple to the surface at vertexes of the polygon. In the example, the three sensors couple to the surface of the structure (structure **12** or structure **14**) at vertexes of a triangle.

(63) At least three regions exist outside the boundary of the polygon on the surface of the structure (structure **12** or structure **14**) defined by the at least three sensors underlying the surface that measure the force, pressure, or load applied to the surface. As previously mentioned, the at least three sensors are placed at vertexes of the polygon that can be related to the surface of the structure (structure **12** or structure **14**) as seen in FIG. **4**. In the example, a region **78**, a region **80**, and a region **82** are outside the predetermined area of the surface of structure **12**. In the example, the predetermined area is triangle **110** having vertexes **72**, **74**, and **76** shown on the surface of structure **12**. Computer **22** is configured to correct the load magnitude when the position of applied load is in region **78**, region **80**, or region **82**. In the example, computer **22** applies a first correction, a second correction or a third correction when the position of applied load is respectively in region **78**, region **80**, and region **82** to reduce measurement error. In the example, the first correction, the second correction, or the third correction is a constant. Alternatively, the first correction, the second

correction, or the third correction can be more complex to further reduce the error.
(64) One or more stop features are formed within enclosure **16**. A stop feature is configured to limit movement of structure **12** or structure **14**. In one embodiment, the stop feature prevents movement of structure **12** or structure **14** beyond a predetermined distance. In one embodiment, the stop feature prevents a force, pressure, or load from being applied to a surface of structure **12** or structure **14** that can damage the one or more sensors configured for measuring the force, pressure, or load applied to structure **12** or structure **14**. In the example, a stop **126** is formed in bottom housing **20** underlying structure **12** or structure **14**. In the example, stop **126** is configured to support compression of sensor **122** but prevents compression of sensor **122** beyond a predetermined distance. The predetermined distance between structure **12** and stop **126** is a function of the range of measurement by measurement system **10** and the limit of reliable sensing by sensor **122**. In general, the predetermined distance between structure **12** and stop **126** is selected to keep sensor **122** within a range of operation that is specified by the sensor manufacturer for sustainable and reliable performance. In one embodiment, stops can be formed in more than one location underlying structure **12** or structure **14**. In one embodiment, the predetermined distance between the stop and structure **12** supports a maximum measurement but can prevent measurement by sensor **122** above the maximum measurement as stop **126** prevents further movement of structure **12** and thereby further loading applied to sensor **122**.
(65) It should be noted that very little data exists on implanted orthopedic devices. Most of the data is empirically obtained by analyzing orthopedic devices that have been used in a human subject or simulated use. Wear patterns, material issues, and failure mechanisms are studied. Although, information can be garnered through this type of study it does not yield substantive data about the initial installation, post-operative use, and long term use from a measurement perspective. Just as each person is different, each device installation is different having variations in initial loading, balance, and alignment. Having measured data and using the data to install an orthopedic device will greatly increase the consistency of the implant procedure thereby reducing rework and maximizing the life of the device. In at least one exemplary embodiment, the measured data can be collected to a database where it can be stored and analyzed. For example, once a relevant sample of the measured data is collected, it can be used to define optimal initial measured settings, geometries, and alignments for maximizing the life and usability of an implanted orthopedic device.
(66) The present invention is applicable to a wide range of medical and nonmedical applications including, but not limited to, frequency compensation; control of, or alarms for, physical systems; or monitoring or measuring physical parameters of interest. The level of accuracy and repeatability attainable in a highly compact measurement device or surgical apparatus may be applicable to many medical applications monitoring or measuring physiological parameters throughout the human body including, not limited to, bone density, movement, position, orientation, force, pressure, load, viscosity, and pressure of various fluids, localized temperature, etc. with applications in the vascular, lymph, respiratory, digestive system, muscles, bones, and joints, other soft tissue areas, and interstitial fluids.
(67) 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 claimed invention, which is set forth in the claims. While the subject matter of the invention is described with specific examples of embodiments, the foregoing drawings and descriptions thereof depict only typical embodiments of the subject matter and are not therefore to be considered to be limiting of its scope, it is evident that many alternatives and variations will be apparent to those skilled in the art. Thus, the description of the invention is merely descriptive in nature and, thus, variations that do not depart from the gist of the invention are intended to be within the scope of the embodiments of the

present invention. Such variations are not to be regarded as a departure from the spirit and scope of the present invention.
(68) While the present invention has been described with reference to embodiments, it is to be understood that the invention is not limited to the disclosed embodiments. The scope of the following claims is to be accorded the broadest interpretation so as to encompass all modifications, equivalent structures and functions. For example, if words such as “orthogonal”, “perpendicular” are used the intended meaning is “substantially orthogonal” and “substantially perpendicular” respectively. Additionally although specific numbers may be quoted in the claims, it is intended that a number close to the one stated is also within the intended scope, i.e. any stated number (e.g., 90 degrees) should be interpreted to be “about” the value of the stated number (e.g., about 90 degrees).
(69) As the claims hereinafter reflect, inventive aspects may lie in less than all features of a single foregoing disclosed embodiment. Thus, the hereinafter expressed claims are hereby expressly incorporated into this Detailed Description of the Drawings, with each claim standing on its own as a separate embodiment of an invention. Furthermore, while some embodiments described herein include some but not other features included in other embodiments, combinations of features of different embodiments are meant to be within the scope of the invention, and form different embodiments, as would be understood by those skilled in the art.

Claims

1. A measurement device to measure loading applied by a musculoskeletal system comprising: an enclosure comprising an upper housing and a lower housing; a structure having a surface to couple to the musculoskeletal system, wherein the structure fits within an opening of the enclosure, wherein a plurality of sensors are coupled to a surface of the structure, wherein the structure includes an anti-cantilevering structure, wherein the anti-cantilevering structure couples to the enclosure to limit canting of the structure when the musculoskeletal system contacts the surface of the structure outside a predetermined area, wherein the anti-cantilevering structure overhangs a periphery of the upper housing, wherein a first region, a second region, and a third region of the surface of the structure are outside the predetermined area, wherein the anti-cantilevering structure is a first anti-cantilevering structure, wherein the measurement device further includes a second anti-cantilevering structure and a third anti-cantilevering structure, wherein the first anti-cantilevering structure, the second anti-cantilevering structure, or the third anti-cantilevering structure are configured to limit canting of the structure when a position of an applied load is in the first region, the second region, or the third region.
2. The measurement device of claim 1, wherein the measurement device is configured to be placed within a joint of the musculoskeletal system, and wherein the surface of the structure is configured to support movement of the joint.
3. The measurement device of claim 1, further including: electronic circuitry coupled to the plurality of sensors, wherein the electronic circuitry is configured to control a measurement process and transmit measurement data; and a computer configured to receive the measurement data, wherein the computer is configured to calculate a position of an applied load on the surface of the structure and a load magnitude at the position of the applied load.
4. The measurement device of claim 3, wherein the computer is configured to correct the load magnitude when the position of the applied load is in the first region, the second region, or the third region.
5. The measurement device of claim 4, wherein the computer applies a first correction, a second correction, or a third correction to the load magnitude when the position of the applied load is respectively in the first region, the second region, or the third region to reduce measurement error.
6. The measurement device of claim 1, wherein the plurality of sensors couple to the surface of the

structure at vertexes of a polygon, and wherein the predetermined area is the polygon.
7. The measurement device of claim 1, wherein the upper housing has the opening of the enclosure, and wherein an O-ring couples between the structure and the upper housing to support movement of the structure relative to the enclosure.
8. The measurement device of claim 7, wherein the O-ring is coupled between a retaining feature of the upper housing and a retaining feature of the structure.
9. The measurement device of claim 1, wherein a portion of the surface of the structure is above an adjacent surface of the enclosure.
10. The measurement device of claim 1, wherein the surface of the structure is curved.
11. The measurement device of claim 1, wherein the anti-cantilevering structure is positioned a predetermined distance from the periphery of the upper housing.
12. The measurement device of claim 1, wherein an overhang distance of the anti-cantilevering structure relative to the periphery of the upper housing varies based on the applied load, wherein the overhang distance of the anti-cantilevering structure is a distance the anti-cantilevering structure overhangs the periphery of the upper housing.
13. A measurement device configured to measure loading applied by a musculoskeletal system, the measurement device comprising: an enclosure; a structure configured to move relative to the enclosure, wherein the structure has a surface configured to couple to the musculoskeletal system and wherein the surface of the structure couples to a plurality of load sensors, wherein each of the plurality of load sensors define a vertex of a predetermined area of the surface; electronic circuitry within the enclosure, wherein the electronic circuitry is coupled to the plurality of load sensors, wherein the electronic circuitry is configured to control a measurement process and transmit measurement data; and a computer configured to receive the measurement data, wherein the surface of the structure is configured to couple to the musculoskeletal system, wherein the computer is configured to calculate (i) a position of an applied load to the surface of the structure and (ii) a load magnitude at the position of the applied load, wherein the computer is configured to determine when the position of the applied load is outside the predetermined area of the surface, and wherein the computer corrects the load magnitude at the position of the applied load when the position of the applied load is outside the predetermined area of the surface, wherein the enclosure includes a plurality of anti-cantilevering structures, wherein the plurality of anti-cantilevering structures are configured to limit canting of the structure when the position of the applied load is outside the predetermined area of the surface, and wherein the enclosure includes at least one stop feature.
14. The measurement device of claim 13, wherein the measurement device is configured to be placed within a joint of the musculoskeletal system, wherein the surface of the structure is configured to support movement of the joint, wherein the computer is configured to utilize a constant to correct the load magnitude, and wherein the constant is used by the computer to adjust the load magnitude when the position of the applied load is outside the predetermined area of the surface.
15. The measurement device of claim 13, wherein the enclosure has an opening, wherein an O-ring couples between the structure and an upper housing to support movement of the structure within the opening, and wherein the O-ring is coupled between a retaining feature of the enclosure.
16. The measurement device of claim 13, wherein a portion of the surface of the structure is above an adjacent surface of the enclosure.
17. A measurement device configured to measure loading applied by a musculoskeletal system, the measurement device comprising: an upper housing; a lower housing, wherein the upper housing and the lower housing are configured to couple together to form an enclosure to house electronic circuitry and a plurality of load sensors; and a structure having a surface configured to couple to a joint of the musculoskeletal system, wherein the structure is configured to fit within an opening in the upper housing, wherein the structure couples to the plurality of load sensors, wherein an O-ring

couples between the upper housing and the structure, wherein the upper housing and the structure each include at least one retaining feature to retain the O-ring between the upper housing and the structure, wherein the surface of the structure is configured to couple to the musculoskeletal system, wherein the structure is configured to move relative to the enclosure, wherein the surface of the structure is above an adjacent surface of the upper housing, and wherein the enclosure includes one or more anti-cantilevering structures to prevent canting that can unload at least one of the plurality of load sensors.

18. The measurement device of claim 17 further including: the electronic circuitry within the enclosure coupled to the plurality of load sensors, wherein the electronic circuitry is configured to control a measurement process and transmit measurement data; and a computer configured to receive the measurement data, wherein the computer is configured to calculate a position of an applied load to the surface of the structure and a load magnitude at the position of the applied load, wherein the computer is configured to determine when the position of the applied load is outside a predetermined area of the surface, and wherein the computer corrects the load magnitude at the position of the applied load when the position of the applied load is outside the predetermined area.