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(54) **PROSTHETIC LIMB TEST APPARATUS AND METHOD**

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See application file for complete search history.

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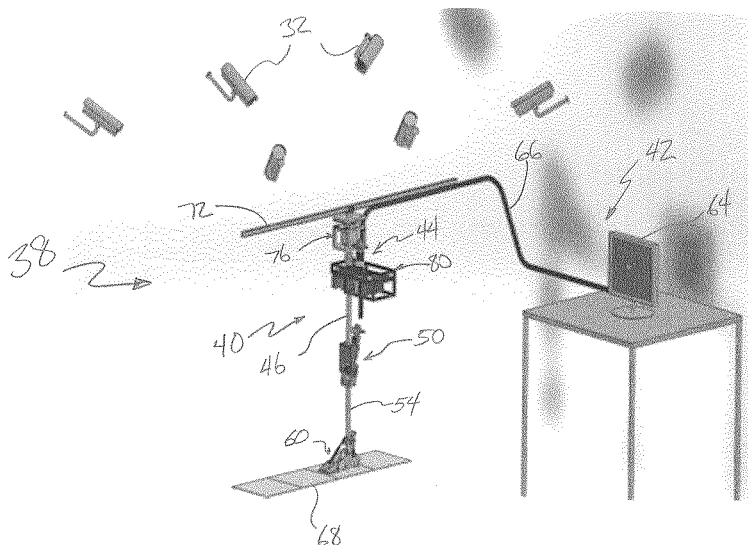
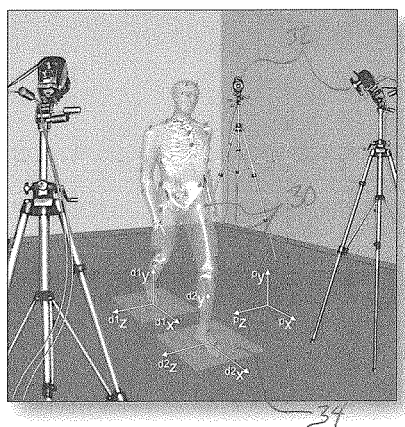
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(57) **ABSTRACT**

A prosthetic limb test fixture is configured to mimic a human stride. An electronic management system can control the test fixture to follow the position and pattern of a particular selected gait cycle during testing. A proposed prosthesis can be attached to the test fixture. Sensor data collected during testing can be evaluated to determine whether the proposed prosthesis is likely to appropriately fit an amputee patient. Iterative adjustments may be made to the prosthesis based on test data in order to maximize the likelihood of a good fit.

12 Claims, 15 Drawing Sheets



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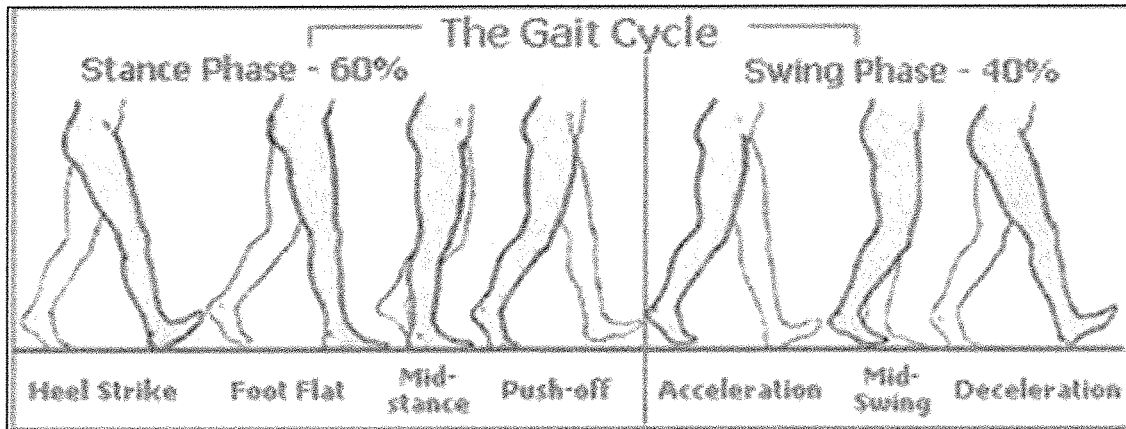


Fig. 1

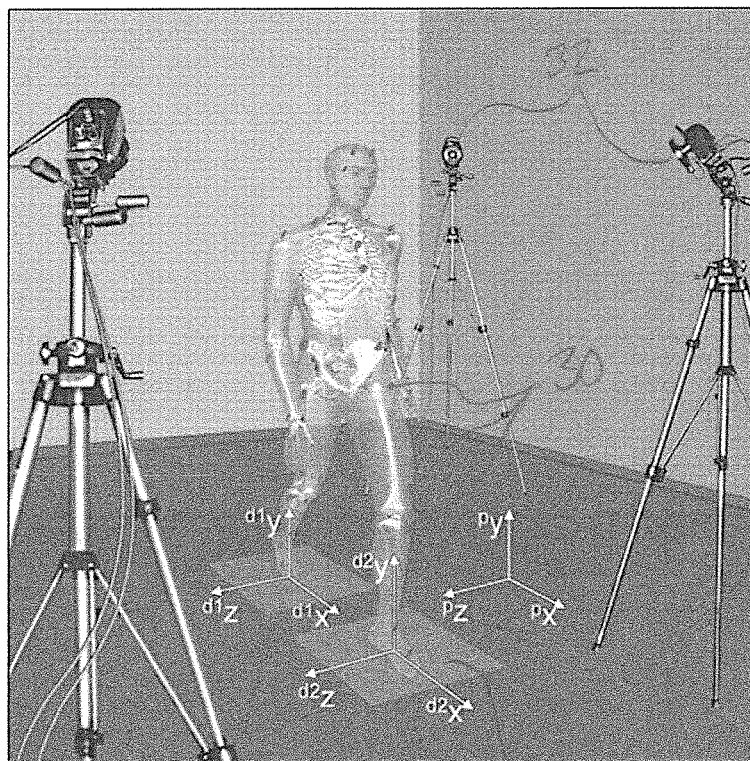


Fig. 2

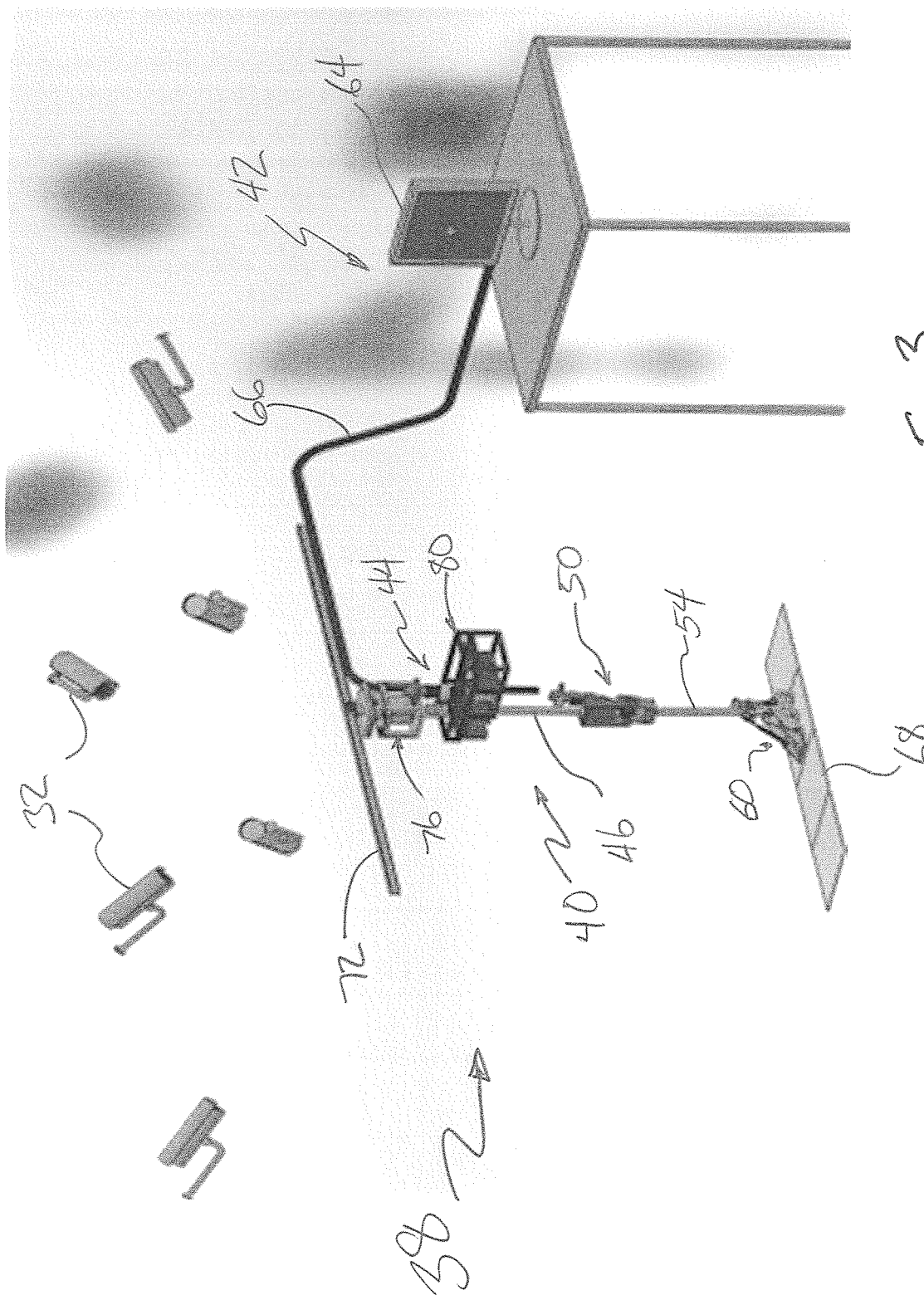


Fig. 3

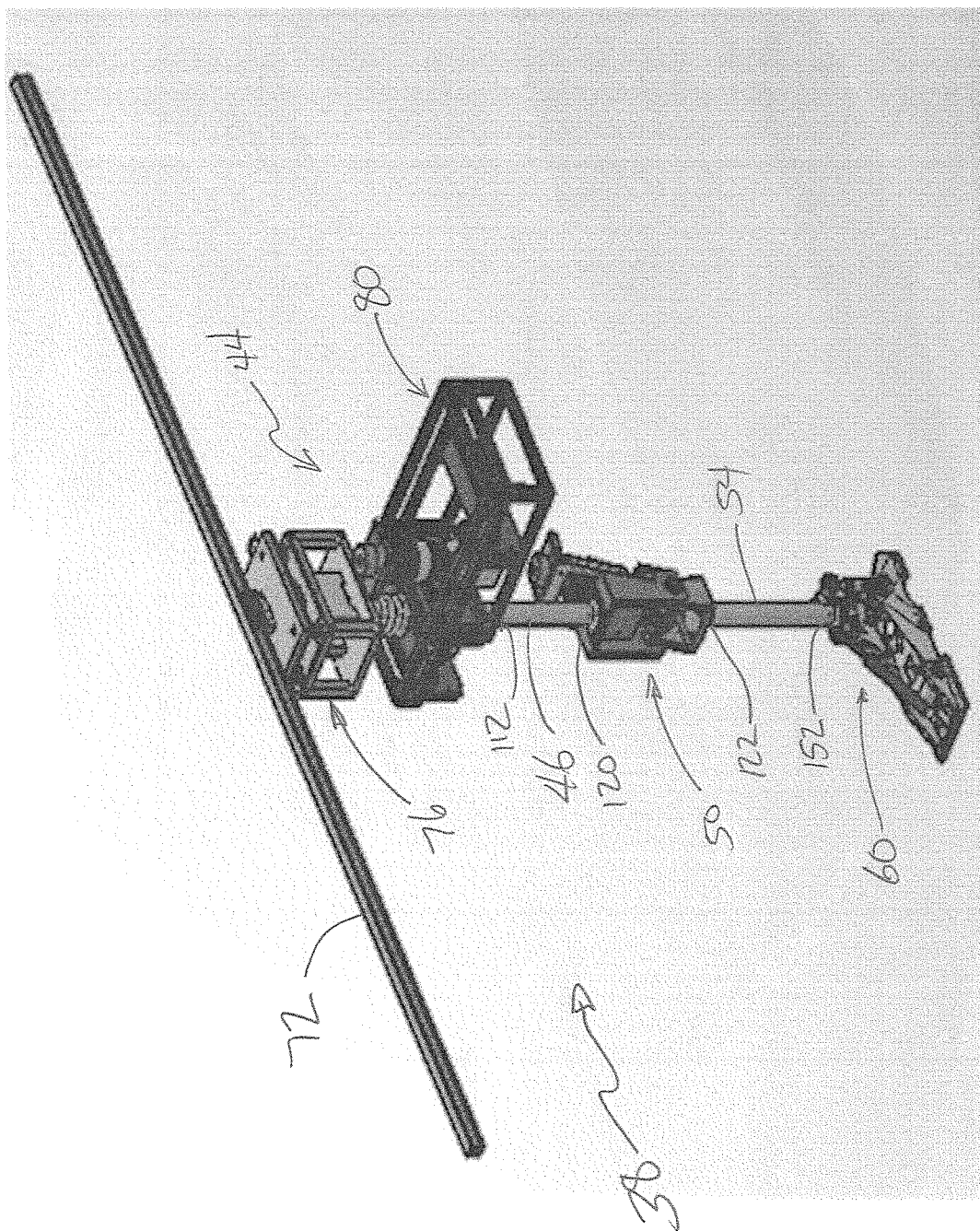
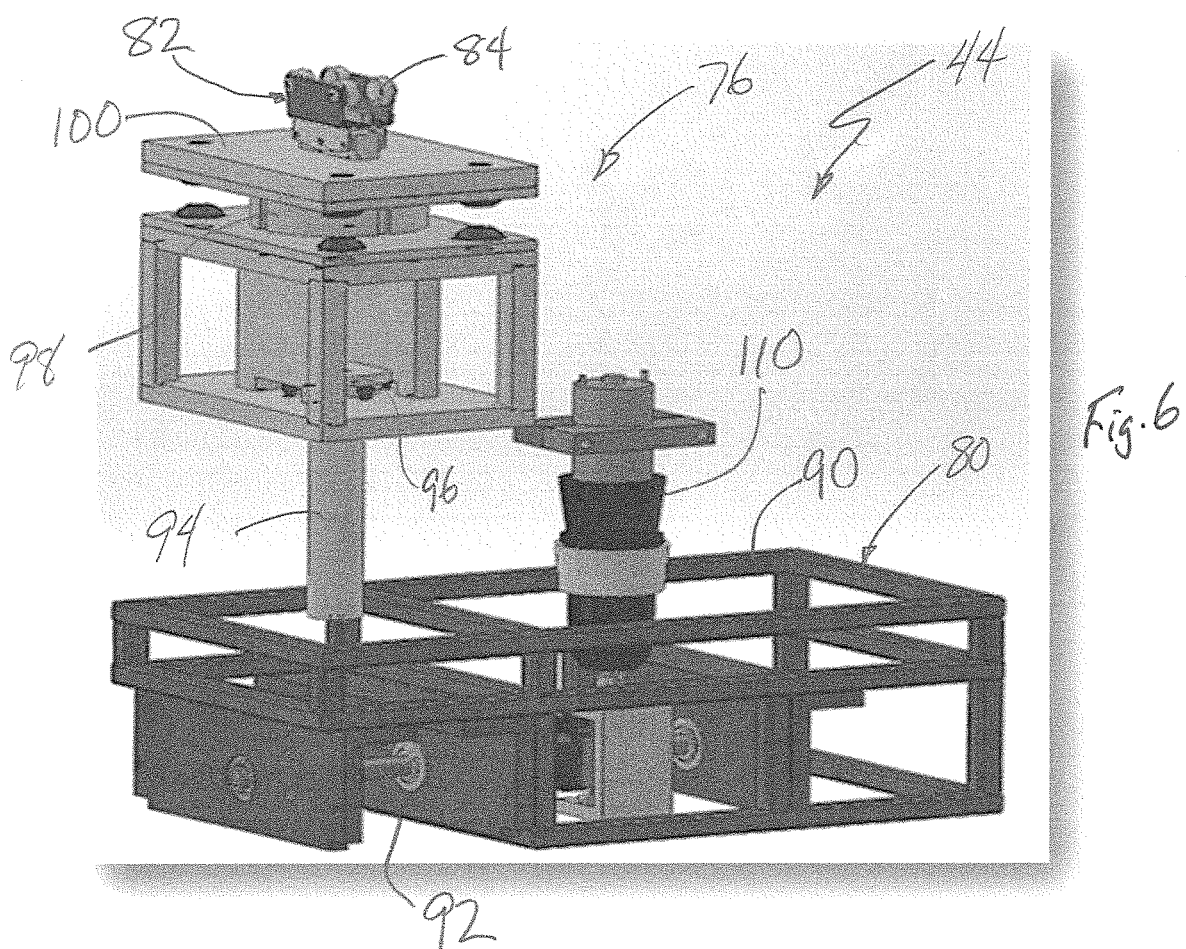
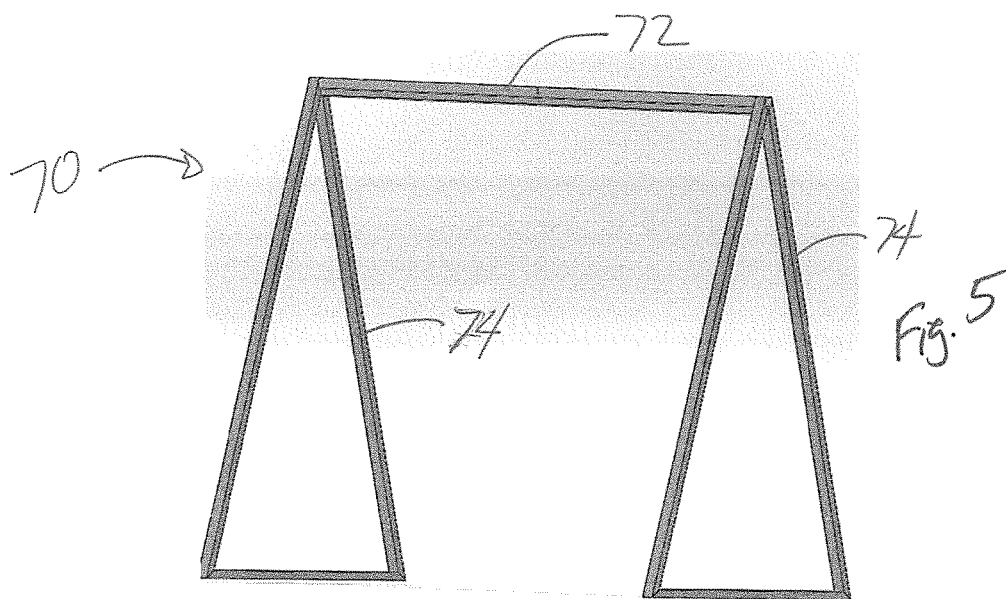
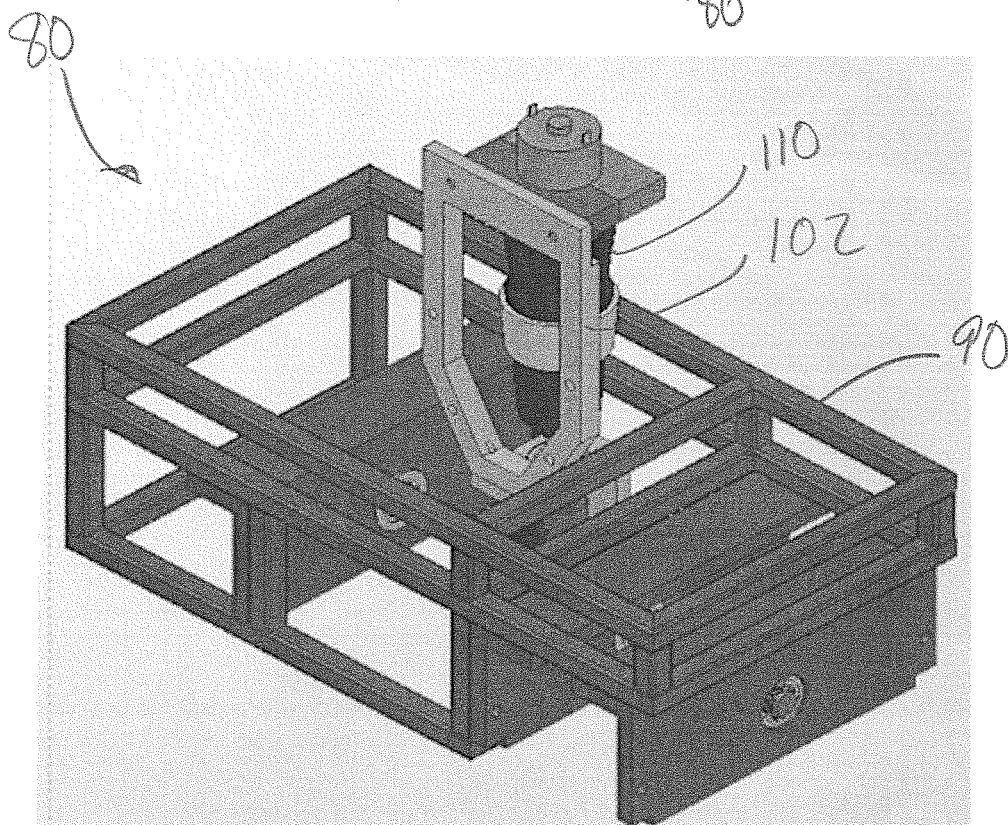
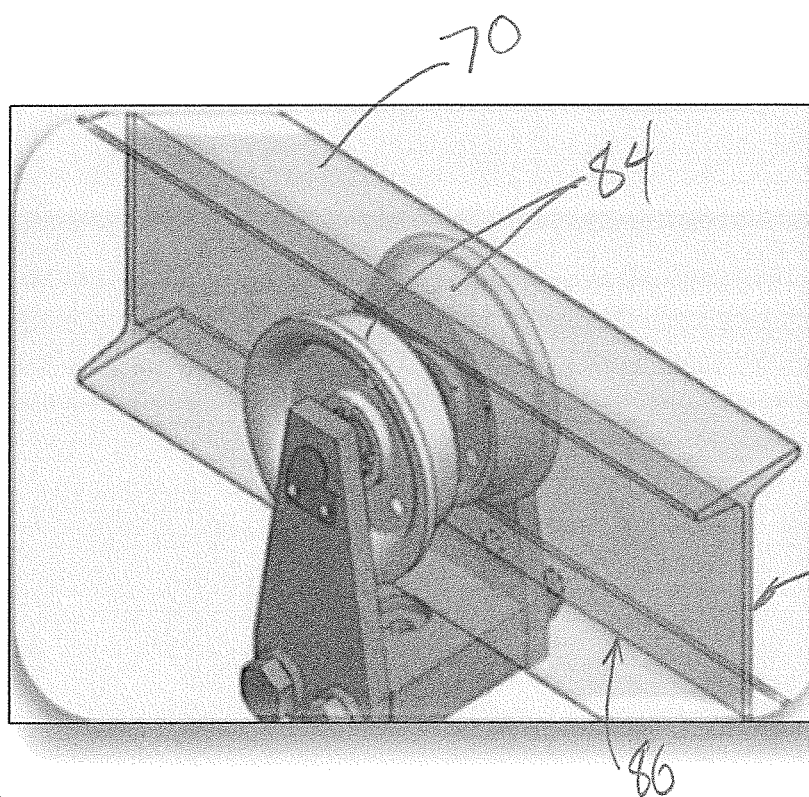


Fig. 4





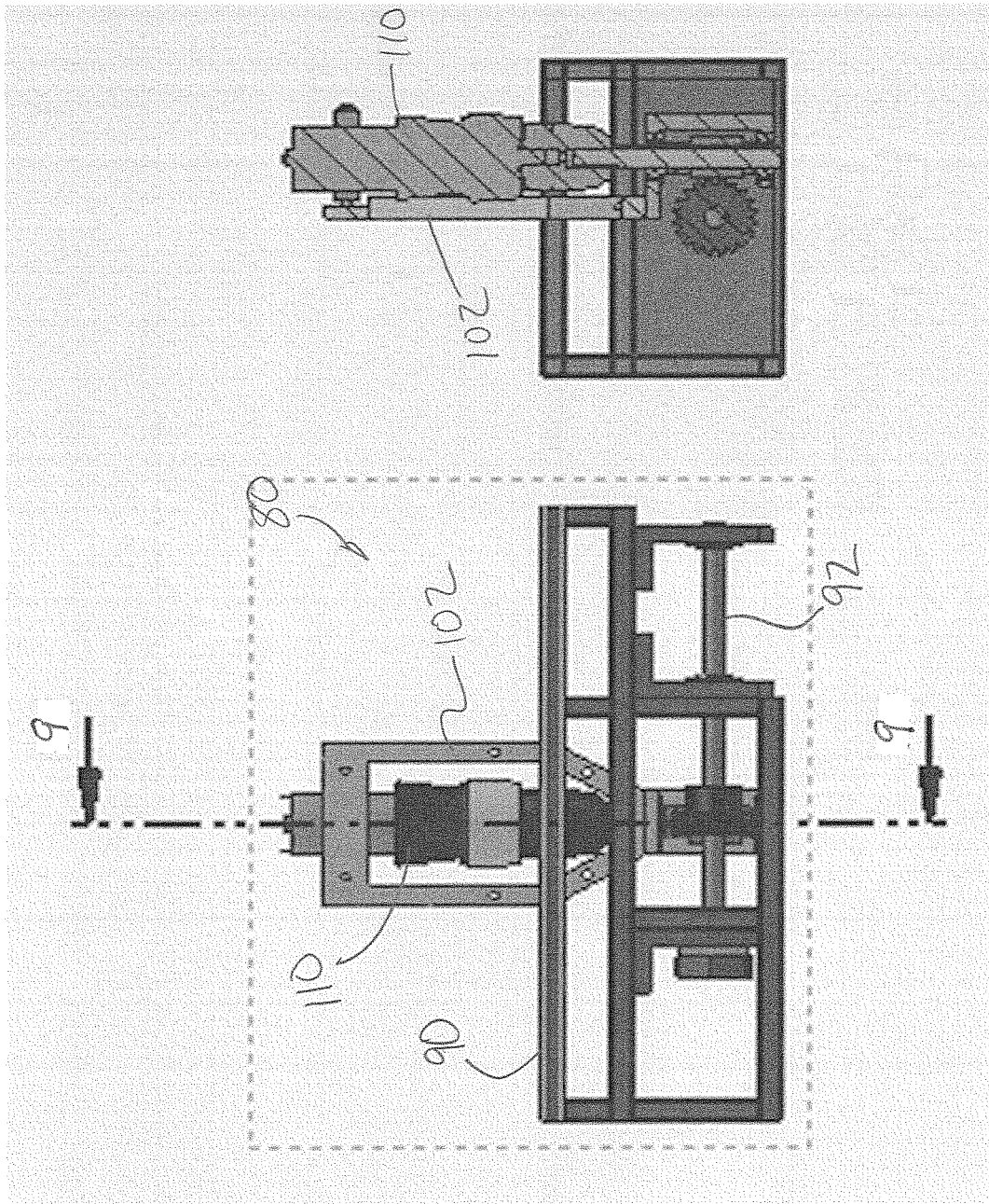


Fig. 9

Fig. 8

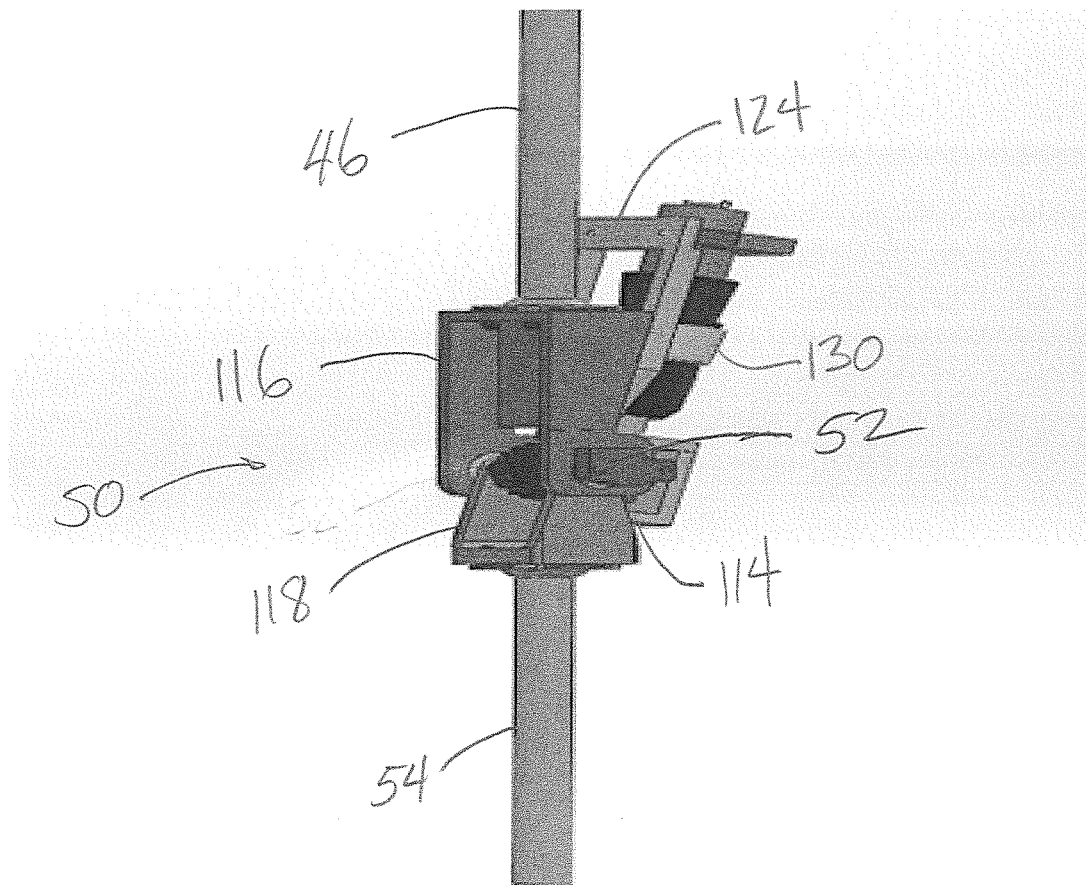


Fig. 10

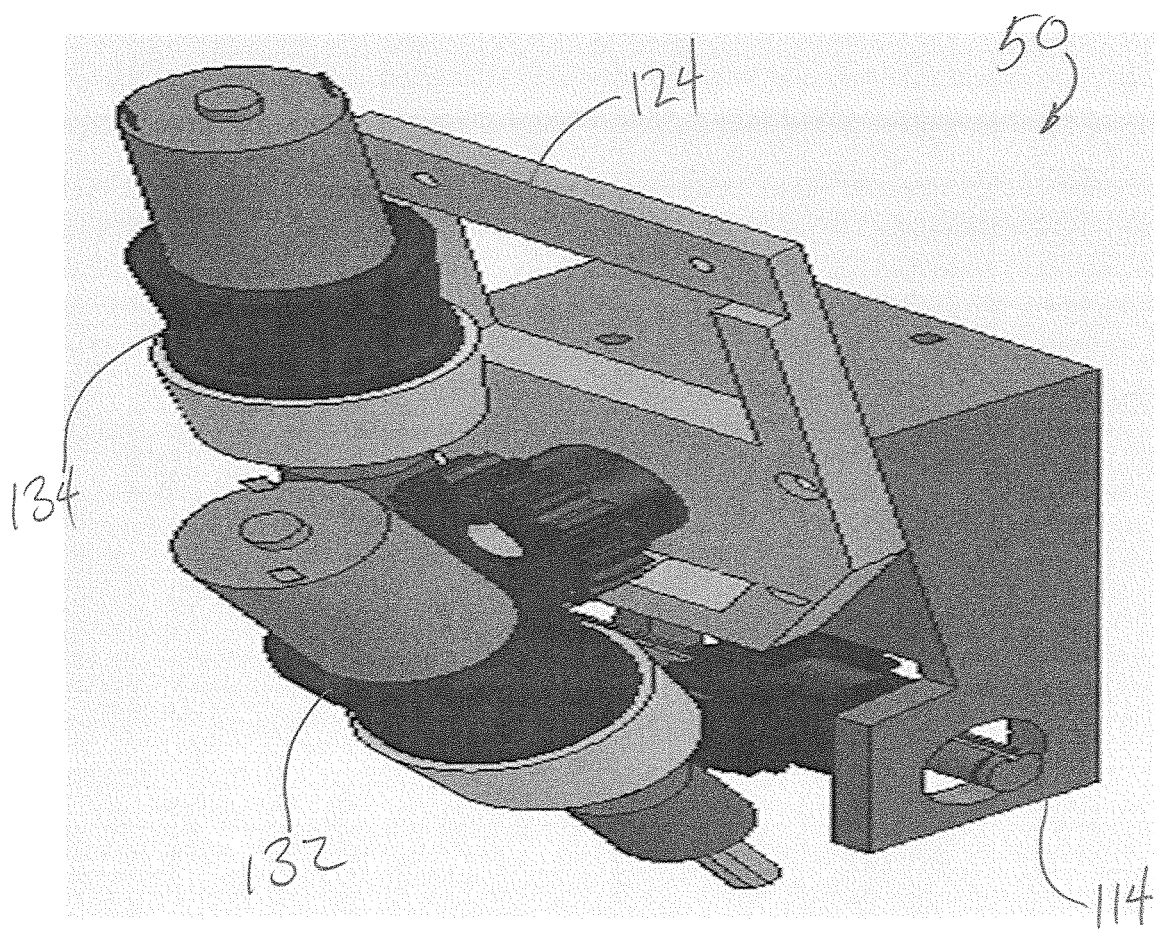


Fig. 11

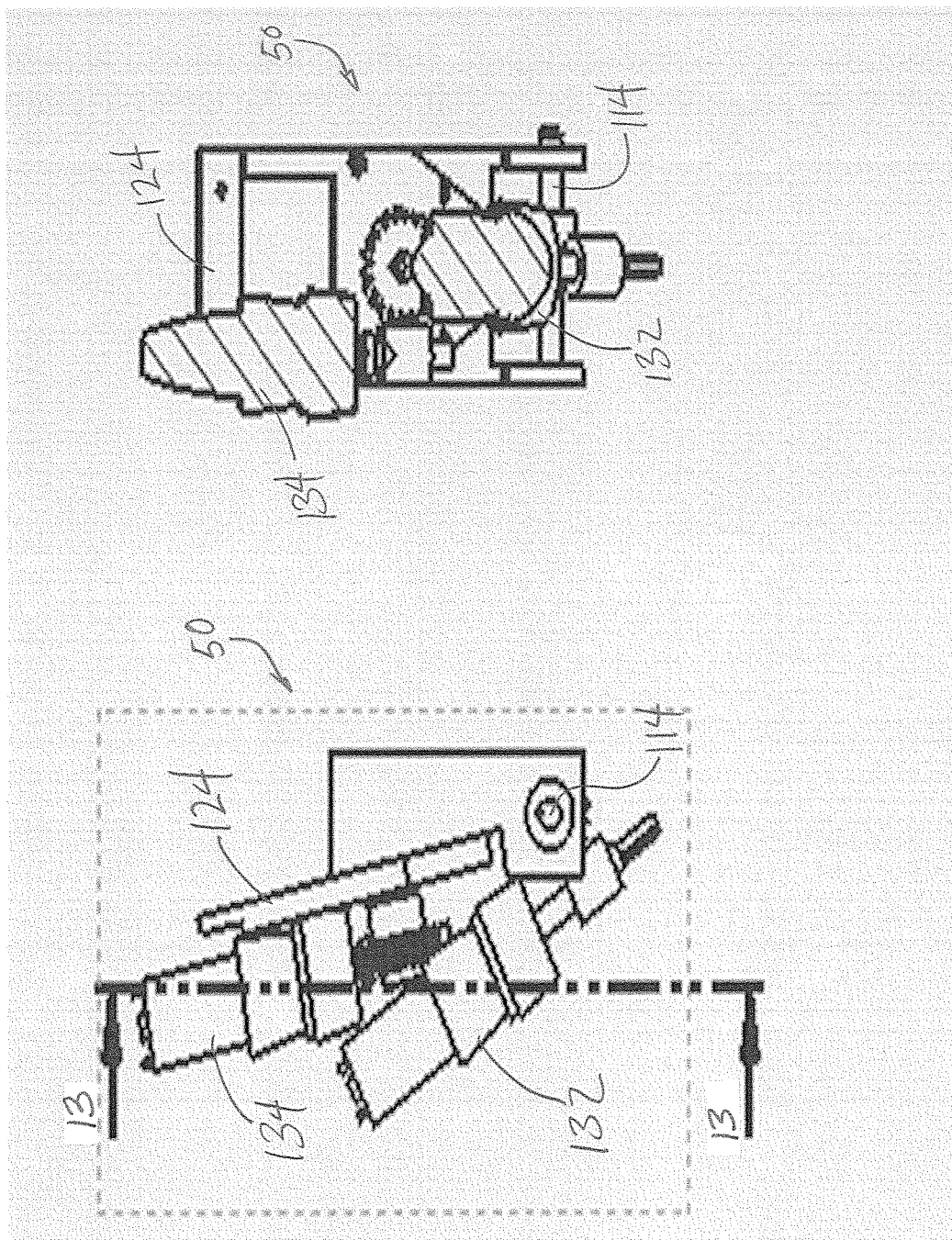


Fig. 13

Fig. 12

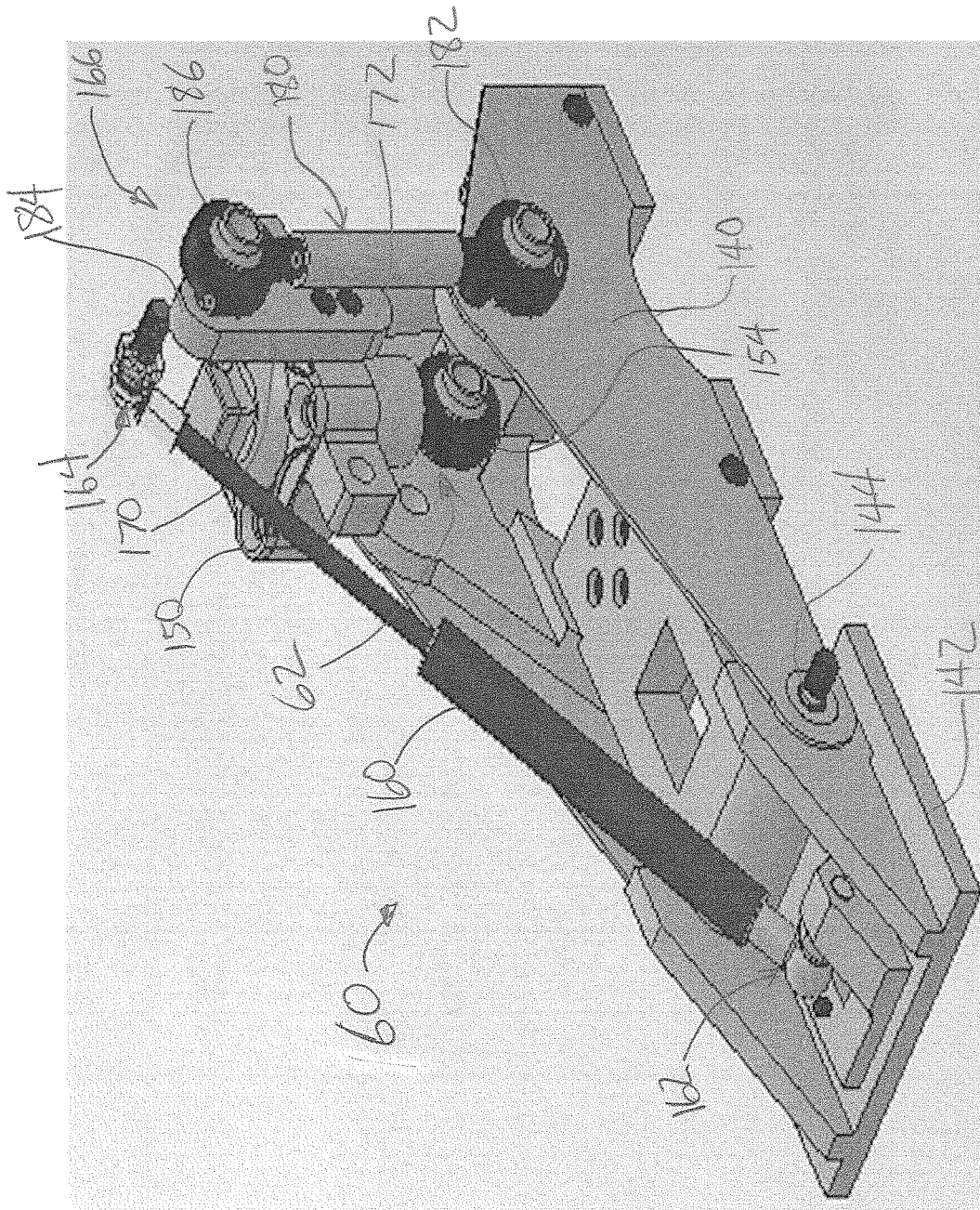


Fig. 14

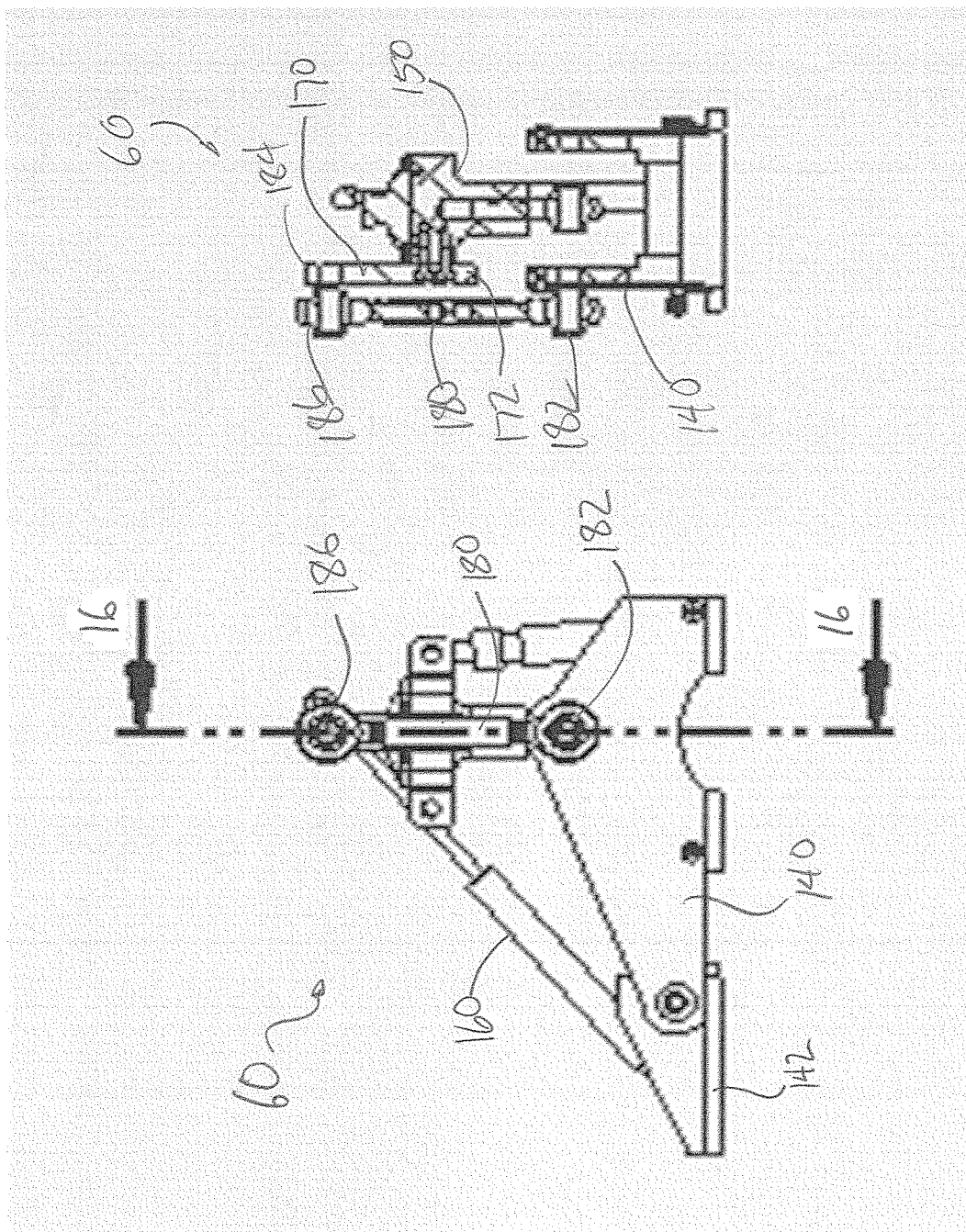


Fig. 16

Fig. 15

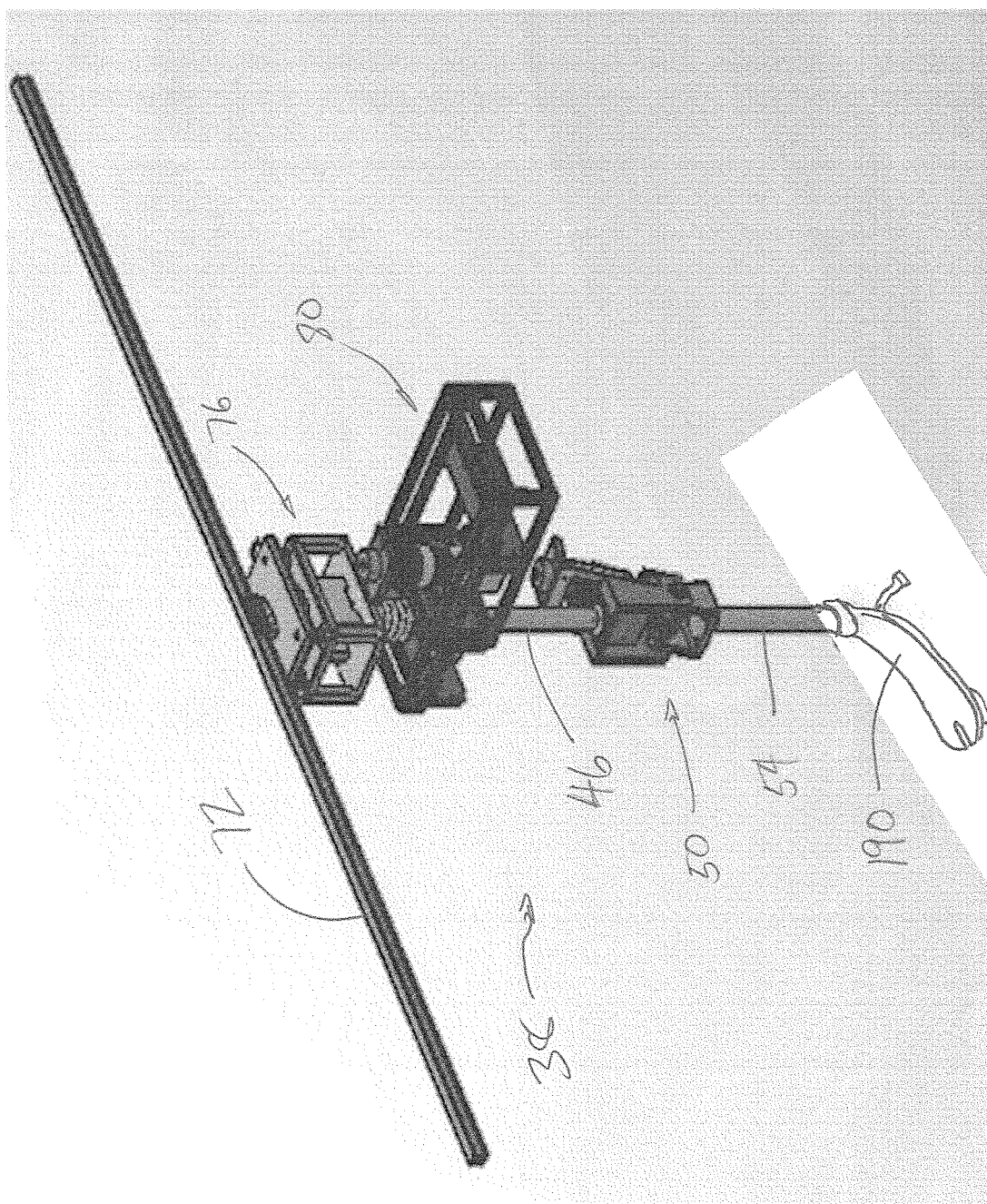
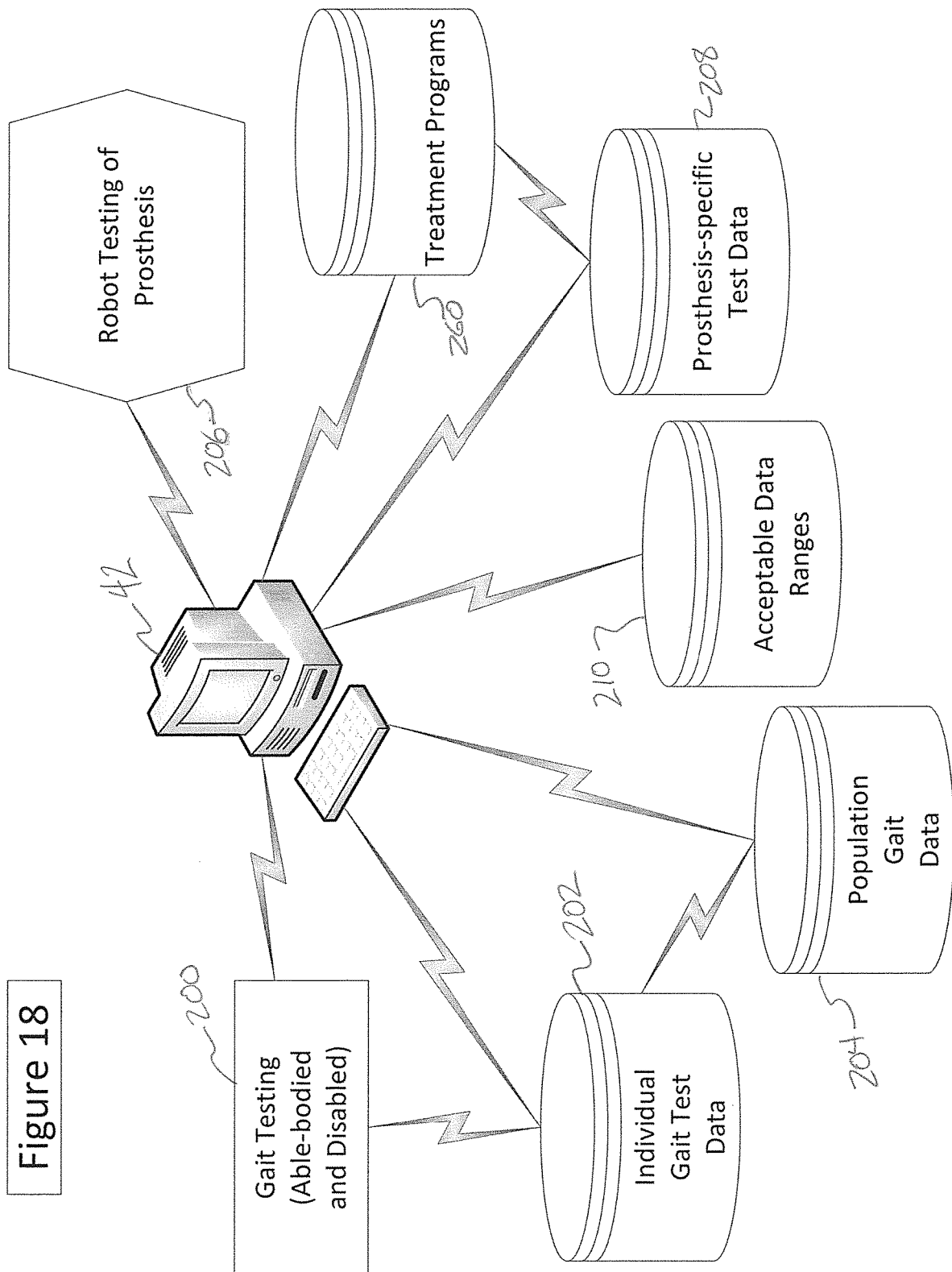


Fig 17



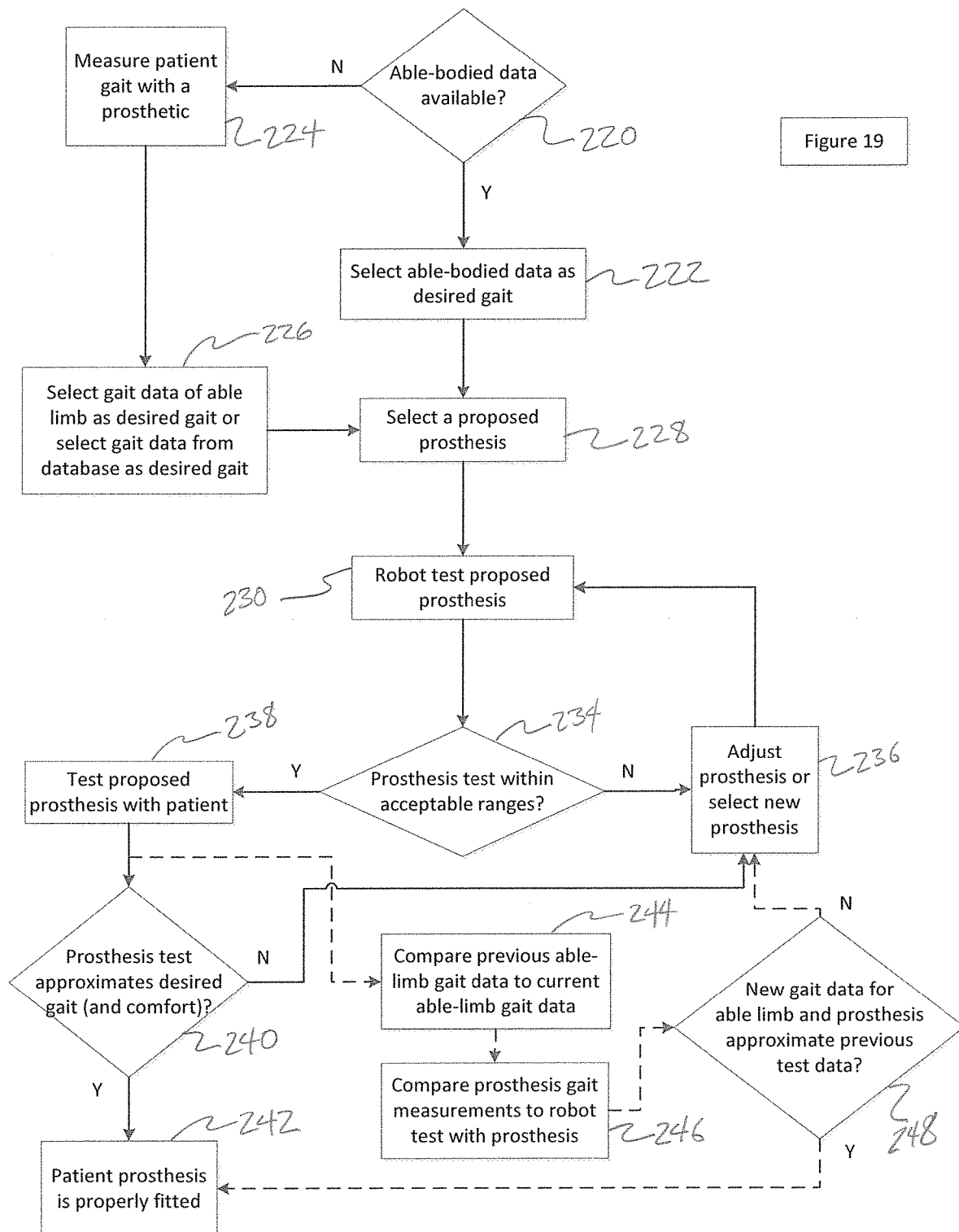
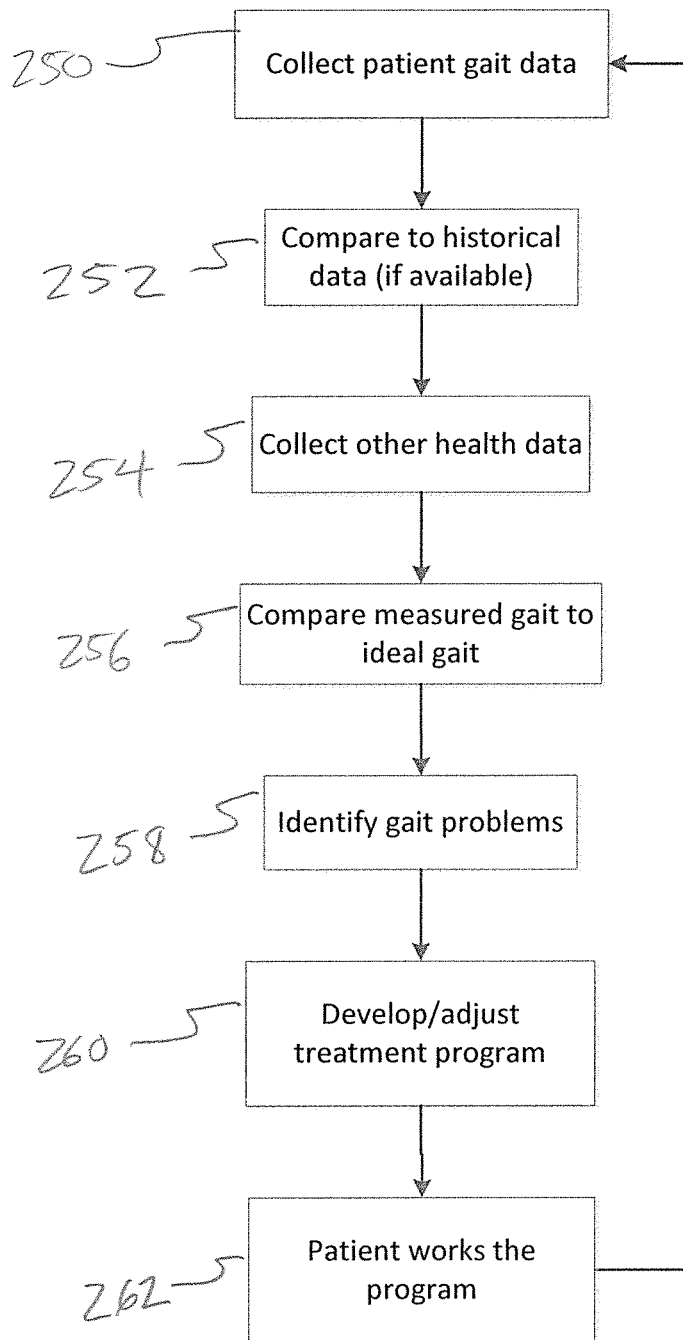


Figure 20



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PROSTHETIC LIMB TEST APPARATUS AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

The application claims the benefit of U.S. Provisional Application No. 62/002,722, which was filed May 23, 2014, the entirety of which is hereby incorporated by reference.

BACKGROUND

The present disclosure relates to the field of therapy for correcting or improving a human stride, and more particularly to correctly fitting prosthetic limbs or braces.

As simple and typical as it may seem, walking is actually a complex motion involving multiple joints. As a person completes one complete stride, from one heel strike to the next heel strike on the same foot, the person's hips, knee, ankle and toe joints move through various planes and angles. Also, each person walks in a manner that is unique to them. A person's gait cycle is a measurement that quantifies such motion during a person's typical stride. Although there are average patterns in gait cycles, each person has a unique gait cycle.

Many people have flawed or irregular gait cycles. Biomechanical abnormalities can be caused by flaws in a person's gait cycle. Sometimes a person's gait cycle can be evaluated and corrected by treatment in order to correct or relieve such abnormalities.

Patients who have had lower limbs amputated or substantial injuries typically experience major alterations in their gait cycles. Many patients will alter their striding motion to compensate for their disability. This modified gait can potentially cause stress and long term damage to other areas of the body.

For amputees, in particular, the process of fitting a prosthesis often relies heavily on the judgment of the technician performing the fitting. Although such technicians can develop substantial skill with experience, they still must substantially rely on subjective judgment rather than empirical data. As such, optimizing the fit of a prosthesis, and particularly a lower-limb prosthesis, can be time-consuming and inexact.

SUMMARY

Accordingly, there is a need in the art for a system and method that can provide empirical data to assist in correctly fitting prostheses and/or braces with unique patients. There is also a need in the art for a method of using such empirical data in the selection and fitting of a prosthesis. There is a further need in the art for a system and method that can provide empirical data to assist in devising treatment programs for patients having flawed gait cycles.

In accordance with one embodiment, the present disclosure provides a prosthesis fitting apparatus. A test fixture comprises a hip module and a knee module, the hip module being connected to the knee module by an elongate thigh pylon, the knee module being releasably attachable to a prosthesis. An electronic controller has access to a desired gait cycle data, the gait cycle data comprising a dataset of positions of components of a human lower limb during a complete stride. The hip module comprises a hip joint configured to mimic movement of a human hip, the hip module comprising one or more hip motors connected to the electronic controller and configured to move the hip joint in

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a manner directed by the electronic controller. The knee module comprises a knee joint configured to mimic movement of a human knee, the knee module comprising one or more knee motors connected to the electronic controller and configured to move the knee joint in a manner directed by the electronic controller. The test fixture is configured to complete a stride in a manner directed by the electronic controller. The electronic controller is configured to direct the hip and knee motors to mimic the desired gait cycle data when the prosthesis is attached. A plurality of force sensors are configured to measure forces exerted at one or more of the hip and knee modules when the test fixture completes a stride as directed by the electronic controller, and to communicate measured force data to the electronic controller.

In one such embodiment, the knee module is releasably attachable to a proximal end of an elongate shin pylon, and a distal end of the elongate shin pylon is releasably attachable to a foot prosthesis. Another embodiment additionally comprises a foot module comprising an ankle joint. The foot module is configured so that the ankle joint mimics the movement of a human ankle, and the distal end of the elongate shin pylon is releasably attachable to the foot module.

In another embodiment, a length of one or more of the thigh and knee pylons can be adjusted.

In yet another embodiment, the test fixture is configured to mimic a patient weight associated with the desired gait cycle.

In accordance with another embodiment, the present disclosure provides a method of fitting a lower-limb prosthesis to a patient. The method includes receiving and electronically storing a set of patient parameters including a patient weight and a patient height, and also receiving and electronically storing a test gait cycle. The test gait cycle comprises kinematic and position data regarding one or more joints of a patient's lower limb during a test walking stride. The method includes operating a test fixture through the test walking stride while a lower-limb prosthesis is mounted on the test fixture. Operating the test fixture through the test walking stride comprises directing the test fixture to apply the patient parameters and to move in accordance with the test gait cycle. The method further includes receiving force sensor data regarding the measured forces at one or more joints of the test fixture. The force sensor data comprising forces measured at the one or more joints while the test fixture is operated through the walking stride of the patient. The method still further includes comparing the force sensor data to desired force parameters.

In another embodiment, if the force sensor data exceeds one or more of the desired force parameters additionally comprising making an adjustment to the prosthesis and again operating the test fixture through the test walking stride.

In yet another embodiment, the test walking stride simulates a desired gait cycle of a patient.

Still another embodiment additionally comprises iteratively adjusting the prosthesis and again operating the test fixture through the test walking stride until the force sensor data is within a defined desirable range of a desired force parameter.

In some embodiments, the desired gait cycle of the patient comprises a healthy gait cycle of an amputee patient. The desired gait cycle can reflect a gait cycle measurement taken when the amputee patient was whole.

Yet another embodiment additionally comprises measuring an amputee patient's gait cycle of the amputee patient's whole leg.

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In a further embodiment the desired gait cycle is taken from a database of average human gait cycles.

A still further embodiment additionally comprises receiving angular position sensor data regarding measured angles at one or more locations on the prosthesis. The angular position data comprises angular positions measured at the one or more locations on the prosthesis.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagram depicting a human gait cycle;

FIG. 2 is a schematic perspective view depicting a system for obtaining gait cycle data;

FIG. 3 is a perspective view of a prosthesis testing system in accordance with one embodiment;

FIG. 4 is another view of the test fixture of FIG. 3;

FIG. 5 depicts a track portion of the test fixture of FIG. 3;

FIG. 6 is a perspective view of a track interface module and hip module in accordance with the embodiment of FIG. 3;

FIG. 6A is a close-up perspective view of wheels of the embodiment of FIG. 6 engaged with a track of the embodiment of FIG. 5;

FIG. 7 is another perspective view of a hip module in accordance with the embodiment of FIG. 3;

FIG. 8 is a side view of the hip module of FIG. 7;

FIG. 9 is a cross section view of the hip module of FIG. 8 taken along lines 9-9;

FIG. 10 is a perspective view of a knee module in accordance with the embodiment of FIG. 3;

FIG. 11 is a perspective view of another embodiment of a knee module in accordance with the embodiment of FIG. 3;

FIG. 12 is a side view of the knee module of FIG. 11;

FIG. 13 is a cross section of the knee module of FIG. 12 taken along lines 13-13;

FIG. 14 is a perspective view of a foot module in accordance with the embodiment of FIG. 3;

FIG. 15 is a side view of the foot module of FIG. 14;

FIG. 16 is a cross sectional view taken along lines 16-16 of FIG. 15;

FIG. 17 shows an embodiment in which the test fixture of FIG. 3 has a foot prosthesis mounted thereon for testing;

FIG. 18 is a chart depicting the interrelationships of various data;

FIG. 19 depicts a method of using the test fixture for fitting a prosthesis; and

FIG. 20 depicts a method of treating gait problems in accordance with another embodiment.

DESCRIPTION

Gait analysis is the study of human motion by using instrumentation and human observation. Gait analysis involves tracking and analysis of movement and forces during a single sequence of functions of one lower limb, known as the gait cycle. When analyzing gait movements, the stride of the limb is evaluated. A stride is defined as the linear distance between corresponding heel strikes of the same foot, in the movements taken by the lower limb while walking through that linear distance. A stride is comprised of two components: the stance phase, and the swing phase. With reference to FIG. 1, the stance phase is the first portion of a stride, and the swinging phase is the second.

With continued reference to FIG. 1, the stance phase comprises four subdivided categories. The first category is the initial contact sub-phase, which is the instance that the

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heel strikes the ground. The second is the loading response sub-phase, which includes a flat foot position and the time period instantly following the lift of the opposite extremity off the ground. Weight shift occurs during this time. The third part of the stance sub-phase is the mid-stance and includes the time interval from when the opposite extremity leaves the ground until the ankles of both legs align when being viewed from the side plane. The fourth part of the stance sub-phase is the push off. This is the time interval from when the ankles of both legs are aligned to the time just prior to initial ground contact of the swinging leg. This symbolizes the time interval from initial contact of the swinging leg to just before the other leg reaches the ground.

Continuing with reference to FIG. 1, the swinging phase of a human stride in the context of gait analysis comprises three sub-phases. The first sub-phase is the initial swing, which is the lifting of the leg from the ground to the position of maximum knee flexion. The second sub-phase is the mid swing, which involves the swinging of the leg immediately following the knee flexing until the tibia of the leg is in a vertical position. The third and final sub-phase of the swing phase is the terminal swing which is the motion following when the tibia is in a vertical position until just before the heel comes in contact with the ground completing one stride.

By analyzing a patient's gait, doctors are able to identify causes for issues the patient may be experiencing and work to find corrective solutions to potential problems. With reference next to FIG. 2, a patient's gait can be recorded and analyzed by attaching reflective markers 30 in several strategic locations to the patient. A test is then conducted in a lab equipped with cameras 32 and sensors, including force-measuring sensors built into floor panels 34, to capture movement and force data. During the test, the patient will walk, preferably taking at least one and potentially a plurality of complete strides. The cameras 32 and sensors are linked to a computer, which receives data from the cameras and sensors, electronically stores the data, and uses software to analyze the data and, in some instances, create a 3D digital model of the patient and the respective motion.

With reference next to FIG. 3, an embodiment of a system 38 for testing a lower-limb prosthesis is shown. With reference also to FIG. 4, the system comprises a test fixture 40, or robot leg, and an electronic management system 42.

With continued reference to FIGS. 3 and 4, the test fixture 40 is configured to "walk" for one complete stride from one heel strike to the next heel strike on the same foot while mimicking the movement of a patient's actual lower limb during that stride. The illustrated test fixture 40 is self-supporting during the process of making the stride. Preferably, the test fixture 40 includes structure that mimics each of the structures of a human leg. More specifically, the test fixture 40 includes a pelvic section 44 configured to mimic the movement of a patient's pelvis, including the patient's hip. An elongate thigh section or thigh pylon 46 connects the pelvic section 44 to a knee module 50 which includes a knee joint 52 configured to mimic the movement of a natural human knee joint 52. The knee module 50 is connected via an elongate shin section, or shin pylon 54, to a foot module 60, which includes an ankle joint 62, and which is configured to mimic the movement of the foot and ankle of a patient. Preferably each of the modules, and joints within the modules, are configured to be able to rotate in each of the x, y, and z axes in order to be capable of replicating a particular patient's gait cycle through a complete stride.

Preferably, the test fixture 40 is proportioned in accordance with average anthropometric data, such as the proportion of the length of the thigh pylon 46 relative to the

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length of the shin pylon **54** being consistent with typical human leg proportions. In some embodiments, the lengths of the thigh and shin sections can be adjusted so as to match measured data taken from a particular patient. Similarly, in some embodiments the length of the foot module **60** can be modified to match measured data taken from a particular patient.

Preferably, a plurality of sensors are arranged on the test fixture **40**. Such sensors can include reflective markers **30** so that the actual motion of various parts of the test fixture **40** can be tracked; angle measurement sensors, which can track angular movement of each joint, preferably in each of the x, y and z axes, during the test; and force sensors configured to measure forces in several different directions, including shear forces, in each of the joints and elsewhere throughout the test fixture **40**.

With particular reference again to FIG. **3**, the electronic management system comprises a computer system **64** having software for data acquisition and analysis, as well as for controlling operation of the test fixture **40**. A data acquisition system of the electronic management system acquires data generated by the test fixture **40** during a test. For example, a wire **66** from the test fixture **40** delivers data generated by the various sensors to the electronic management system **42**. The wire **66** also communicate instructions from the electronic management system **42** to the test fixture **40**. Of course, it is contemplated that other communication means, such as Wi-Fi or other wireless communication, can be employed between the electronic management system **42** and the test fixture **40** or any data acquisition structure that may be employed.

In the illustrated embodiment, the electronic management system **42** comprises several cameras that track movement of the test fixture **40**, such as by tracking movement of reflective markers **30**, and relay data regarding such movement to the electronic management system **42**. Similarly, in the illustrated embodiment, a test floor **68** comprises several pressure sensing plates and/or pressure sensors disposed at a particular locations along the test route. The sensors detect pressure resulting from contact of the test fixture **40** with the floor, including the location of such contact, and relay such information to the electronic management system **42**.

With reference next to FIG. **5**, an embodiment of a track system **70** is illustrated. The illustrated track system **70** comprises an elongate track **72** having supports **74** disposed at each end. The track **72** is configured to support the test fixture **40** during operation. More specifically, in the illustrated embodiment the track system **70** remains stationary while the test fixture **40** moves during test operation. The elongate track preferably is sufficiently long to accommodate a full stride of the test fixture **40**, which in one embodiment is about six feet. In the illustrated embodiment, the track comprises an I-beam, and thus provides a secure support for the test fixture **40**.

With reference next to FIG. **6**, an embodiment of the pelvis section **44** of the test fixture **40** is illustrated. The pelvis section **44** comprises an interface module **76** and a hip module **80**. The interface module **76** includes a connector **82** that is adapted to connect to the track **72**. With additional reference to FIG. **6a**, in the illustrated embodiment the connector **82** includes a plurality of wheels **84** that are configured to fit within C-shaped channels **86** formed on opposing sides of the track **72** I-beam. As such, the connector **82** rolls along the track **72**, but does not rotate about the axis of the track **72**. Preferably the I-beam is configured so that there is a substantially close fit between the upper and lower portions of the C-shaped channels **86** and the wheels

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84 of the connector **82**. As such, the track **72** can provide both upwardly-directed forces to support the test fixture **40** and downwardly-directed forces to press down upon the test fixture **40** to simulate a human's weight.

It is to be understood that various other structures can be employed for connecting the test fixture **40** to the track **72**, and other embodiments of structures can be used for the track **72**. For example, in another embodiment the connector **82** of the interface module **76** may comprise a linear bearing **96**, and the track **72** can be shaped to specifically fit the linear bearing **96**. Furthermore, preferably the connection between the connector **82** and track **72** is such that it will allow linear movement along the length of the track **72** but the connector **82** will not substantially rotate about the axis of the track **72**. Instead, preferably such movement is controlled by and through the test fixture **40**.

It is to be understood that the illustrated track system **70**, and the manner in which it connects to the test fixture **40**, can vary in other embodiments. For example, in another embodiment, the support system may be substantially rigidly attached to the test fixture **40**, and the support system can be configured to move linearly during operation of the test fixture **40** through a stride. In one such embodiment, the support system rolls upon a plurality of wheels which may, in some embodiments, be confined to a track **72**. In another embodiment, the support system may be supported by and directed by one or more linear bearings.

With reference next to FIGS. **6-9**, the hip module **80** comprises a frame-like hip box **90** that supports a horizontal rotating shaft **92**. A pin **94** of the interface module **76** can be attached to the hip box **90**. The pin **94** preferably is configured to move vertically relative to a linear bearing of the interface module **76**, and thus the hip box **90** can move vertically relative to the interface module **76**. In the illustrated embodiment, a turntable **98** is disposed adjacent a base **100** of the connector **82** and is configured to rotate 360° about a vertical or Y axis.

The hip box **90** supports a motor support **102** which in turn supports a motor **110** such as a servo motor that is linked to the rotating shaft **92**. A proximal end **112** of the elongate thigh pylon **46** preferably is attachable via a connector (not shown) to the rotating shaft **92** and is thus configured to rotate with the rotating shaft **92**. As such, actuation of the hip motor **110** prompts movement of the thigh pylon **46** in accordance with the human stride. In additional embodiments other structures may be employed, including one or more additional servo motors. For example, in one embodiment a motor can be applied to rotate the hip module **80** at the turntable **98**. Further, a servo motor **110** can be applied to regulate forces as the hip box **90** moves vertically relative to the interface module **76**. In another embodiment, an axle and associated motor can cooperate to apply and control tilt of the hip box **90**.

With reference next to FIG. **10**, a knee module **50** comprises a horizontal axis **114** and upper and lower mount brackets **116**, **118** having connectors that attach to a distal end of the thigh pylon **46** and a proximal end **122** of the shin pylon **54**, respectively. A mount bracket **124** supports a servo motor **130** that is configured to bend the knee joint **52** at the horizontal axis **114** to simulate a human knee joint **52**.

In another embodiment, such as the embodiment illustrated in connection with FIGS. **11-13**, the knee module **50** may employ first and second knee servo motors **132**, **134**. The first motor **132** may be attached and configured to rotate the knee about the horizontal axis **114**, which is a substantially horizontal x axis. The second knee motor **134** can be configured to rotate the upper bracket **116** about a y axis

parallel to the x axis. As depicted in FIG. 11, the horizontal axle 114 can be mounted so as to allow some measure of y axis rotation.

It is to be understood, of course, that other specific structures can be employed to simulate a patient's knee joint, and that other structures may employ more or less motors in order to control the knee joint to mimic, or more truly mimic, a natural human gait cycle.

With reference next to FIGS. 14-16, the illustrated foot module 60 comprises a foot bracket 140 configured to simulate a human foot. A toe plate 142 is attached to the foot bracket 140 at a horizontal pin 144 so that the toe plate 142 can rotate relative to the foot bracket 140. An ankle bracket 150 is configured to attach to the distal end 152 of the shin pylon 54 and further to attach to the foot bracket 140. In the illustrated embodiment, the ankle bracket 150 engages a bearing 154 supported by the foot bracket 140. The bearing 154 enables the foot bracket 140 to have a 360° range of motion relative to the ankle bracket 150, thus simulating a human ankle.

In the illustrated embodiment, a damper 160, such as a hydraulic cylinder, has a first end 162 attached to the toe plate 142 and a second end 164 attached to a damper arm assembly 166. The damper arm assembly 166 in the illustrated embodiment comprises an ankle bracket arm 170 having a first end 172 rotatably connected to the ankle bracket 150 and a foot arm 180 having a first end 182 connected to the foot plate 140. Second ends 184, 186 of the ankle bracket arm 170 and the foot arm 180 are connected to one another and are also connected to the second end 164 of the damper 160. In this manner the damper 160 is tuned so as to be biased towards a fully extended position as shown in the figures but to apply resistance to mimic the behavior of human toes while the test fixture 40 is taking a stride.

In the illustrated embodiment, the foot module 60 is passive, and does not include any motors. It is to be understood, however, that in other embodiments the foot module 60 may include one or more motors to control ankle joint 62 motion and forces in any direction as well as toe motion and force application, and can be controlled by the electronic management system 42.

As discussed above, each of the hip, knee and foot modules 80, 50, 60 include connectors adapted to connect to portions of one or both of the thigh and shin pylons 46, 54. Preferably, such connectors are configured to comply with standard connectors of various prostheses. Thus, the test fixture 40 can be used to test any of multiple prostheses. For example, a knee prosthesis can be attached to the thigh and shin pylons 46, 54 in place of the knee module 50, or a below-knee prosthesis can be attached to the knee module 50 in place of the shin pylon 54 and foot module 60. In FIG. 17, a foot prosthesis 190 is depicted attached to the distal end of the shin pylon 54 in place of the foot module 60.

Additionally, in some embodiments the shin and/or thigh pylons 54, 46 can be configured to have an adjustable length in order to more closely approximate a specific patient's dimensions. In additional embodiments, several pylons of various lengths can be provided, and selectively attached to the test fixture 40 to more closely approximate a specific patient's dimensions.

As discussed above, many sensors, including force sensors, angular location sensors, position sensors or markers; or the like preferably are attached to the test fixture 40. Similarly, multiple sensors can be attached to a prosthesis that is attached to the test fixture 40. As such, during

operation of the test fixture 40 as it takes a full stride, sensor data will be collected and sent to the electronic management system 42.

In one preferred embodiment, the electronic management system 42 will operate the test fixture 40 to perform a walking stride in accordance with all the position data of a selected desired gait cycle. In some embodiments desired patient parameters such as weight and height can also be replicated during the test.

In a preferred embodiment, the selected desired gait cycle is the patient's own gait cycle from when he was able-bodied. However, the selected desired gait cycle can also be selected from a database of gait cycles of able-bodied individuals or average gait cycles of able-bodied individuals. Further, the desired gait cycle can be obtained by measuring the gait cycle of the patient's own able-bodied lower limb and mirroring that gait cycle to determine the desired gait cycle.

As also discussed above, an ill-fitting prosthesis may alter an amputee patient's stride so that unnatural forces are applied to the patient's able joints. Over time, such forces can cause substantial damage to the joint and pain for the patient. Thus, forces measured during a test help a clinician determine the suitability of the tested prosthesis for the patient. In accordance with one embodiment, after a proposed prosthesis has been tested, force sensor data indicating forces experienced by the test fixture 40 joints are evaluated to determine whether they fall within an acceptable range of forces for that particular joint. In some instances a target force for a particular direction on a particular joint may be zero, but a range of a number of pounds of force around the target may be acceptable. In other instances, target forces may be nonzero, and acceptable ranges of forces can be determined based upon experience.

In a preferred embodiment, to properly size a lower limb prosthesis for a specific patient, a clinician may review patient data and select a desired gait cycle that best matches the patient. The clinician may also select a proposed prosthesis for testing. After testing, the clinician will review sensor data to gauge compliance with acceptable ranges of forces for particular joints. Acceptable ranges of angular data may also be evaluated, both of the test fixture 40 and of the prosthesis itself to determine whether the sensor data from the test falls within acceptable operational ranges. If one or more sensed measurement falls outside a range of compliance the clinician may either select a different prosthesis, or make an adjustment to the proposed prosthesis, after which the clinician may run another test. In this manner a clinician may use objective data to iteratively tune a prosthesis to a patient.

With reference to FIG. 18, in some embodiments, able-bodied individuals undergo gait cycle testing 200 in order to obtain kinematic, position and force data corresponding to the gait cycle for their able-bodied stride. Test data can be saved for that individual, and can also contribute to a database 202, 204 of test data for able-bodied individuals. Such test data can be categorized, such as by gender, height, weight, age, dimensions of leg segments, health, athleticism, etc.

Disabled individuals can also undergo gait cycle testing 206. Typically they will wear a prosthesis in such testing, which can record measurements relating to the gait cycle of the disabled leg, and also the gait cycle of the able-bodied leg. Gait cycle data can be saved in individual and population gait cycle databases 202, 204. Also, gait cycle testing data can be saved in prosthesis-specific databases 206, tied

to a particular prosthesis **208**, and qualified by data about the patient such as weight, height, age, health, complaints regarding fit, discomfort, ancillary joint problems, etc. As such, a history of problems with particular prostheses, as well as a pattern of a particular prosthesis's strengths and weaknesses, and patterns of the type of people it works best with, can be accumulated. In this manner, ranges of acceptable (healthy) forces, angular position and the like can be established.

Testing can also be performed for well-fitting prostheses that are comfortable and do not lead to damage to amputee patients' able-bodied joints. Testing such prostheses will help to further define the ranges of acceptable forces, angular position and the like. Such acceptable ranges can be provided to a database **210**.

FIG. **19** presents an embodiment of a method for fitting a lower-limb prosthesis to a patient. If able-bodied gait cycle data **220** for the patient is available, the able-bodied data is selected **222** as a desired gait. If able-bodied data is not available, the patient can be given a temporary prosthesis, and gait data can be measured **224**, including data concerning the patient's able limb. Preferably the gait of the able limb is selected as a desired gait **226**.

Based on the technician's experience, manufacturer specifications, the selected gait data, and/or prosthesis-specific gait cycle data, a technician selects a proposed prosthesis **228**. The proposed prosthesis is tested **230** by the robot leg test fixture **40** with other parameters (height, weight, etc.) of the patient considered and applied by the electronic management system **42**. In the test, the test fixture **40** will take a walking stride in accordance with the desired gait cycle. Data such as forces on test fixture joints or the prosthesis and also angular position data are examined to see if the data is within acceptable parameters defining a well-fitting prosthetic **234**. As discussed above, if the test fixture **40** reveals data that does not fall within the desired force or angular parameters, the technician either adjusts the prosthesis **236** (with identification of areas of adjustment generally made apparent from the test data) or may select a different prosthesis. Testing and comparing is then repeated iteratively until the proposed prosthesis complies with acceptable force and angular parameters during tests.

Once a proposed prosthesis appears to conform with acceptable parameters, the patient can be brought in to test the proposed prosthesis in person **238**. If the prosthesis is comfortable, and/or if the prosthesis (as worn by the patient) is measured during patient gait testing **240** and determined to have a gait cycle consistent with the selected desired gait cycle, the patient is considered properly fitted to the prosthesis **242**. In this manner, a patient can be fitted with a prosthesis based on objective measurements rather than subjective judgments. Also, a proposed prosthesis can be prepared and adjusted prior to the patient coming in, further streamlining the fitting process.

If, when fitted with the prosthesis, the patient is measured via gait cycle testing, and does not have a gait cycle that approximates the selected desired gait cycle, or if the prosthesis is uncomfortable, the technician may again adjust the proposed prosthesis, or select a new prosthesis **236**, and go through the iterative testing program again.

Continuing with reference FIG. **19**, in some embodiments, when the proposed prosthesis is tested with the actual patient, the patient's able-limb gait cycle while wearing the proposed prosthesis will be tested and compared to the patient's able-limb gait cycle with the temporary prosthesis from the previous test **244**. Also, the prosthesis-side gait cycle measurements will be compared to the gait cycle

measurements from the test fixture test **246**. If such new gait data for the able limb and/or prosthesis do not approximate prior test data **248**, the technician may make further adjustments, or a different prosthesis may be selected **236**. Through further selections and testing, a prosthesis can be selected and adjusted to provide gait cycle data approaching the patient's natural or desired gait. Of course, in some embodiments, a desired gait cycle can be selected from a database of average gait cycles of comparable patients.

With reference next to FIG. **20**, gait cycle data can be used to treat various gait problems, both for amputees and able-bodied people. This may include able-bodied people that have been injured or have gait problems from other causes, and need physical therapy. In some cases athletes seeking to improve or optimize their gait cycle may seek such treatment. In such embodiments, a clinician may have a sensor apparatus to collect gait cycle data of the patient **250**. The clinician may have access to and interact with databases such as in FIG. **18**, to store patient gait data and to access population gait cycle data.

If the patient has historical gait data, such as his own able-bodied gait cycle data (for example from before an accident), the patient's current gait cycle data can be compared to the historical data **252**. Also, other health problems, particularly problems such as back pain, hip pain, etc., which can be related to or affect gait, can be investigated **254**. The clinician can determine an ideal gait cycle, and can compare the current gait cycle to the ideal gait cycle **256**. Such a comparison can help identify gait problems **258**. Additionally, or alternatively, upon entering patient data, servers in the cloud having access to gait cycle databases can calculate an ideal or desired gait cycle for the patient. A treatment program **260** (see FIG. **18**) can be developed, including goal waypoints for the patient's gait cycle, and even suggesting apparatus (such as braces or wraps) or exercises (such as for targeted strengthening) to help the patient achieve an ideal or goal gait cycle. For prosthesis-wearing individuals, the treatment program may include a suggested adjustment to the prosthesis that may urge or force the patient to develop new, healthier, walking habits.

The patient may then work the program **262**. Periodically, the patient's gait cycle data will be remeasured, and the patient will be reevaluated for progress in the treatment program, and adjustments to the treatment program may be made. The patient's progress can be maintained in the cloud-based server and database. Levels of treatment success can also be maintained in databases to help improve treatment prescriptions for future patients.

The embodiments discussed above have provided a good context for disclosing and discussing inventive subject matter. Other embodiments may employ different specific structural shapes and interactions. For example, the above discussion focusses on lower-limb prostheses. Such prostheses can include foot-only, foot and shin, knee, and above or below-knee prostheses, and even can apply to treatment of able-bodied individuals. These principles may also apply to other limbs and motion, such as arm motions.

Also, it is to be understood that the particular, structure of the test fixture **40** discussed above has been given by example only. Other specific structures can be employed to practice the principles of the invention. It is therefore anticipated that various types and styles of test fixture **40s** can yield force sensor data, angular data, or other types of data that will help the clinician determine how well a prosthesis will fit a patient having a particular set of physical parameters.

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The embodiments discussed above have disclosed structures with substantial specificity. This has provided a good context for disclosing and discussing inventive subject matter. However, it is to be understood that other embodiments may employ different specific structural shapes and interactions.

Although inventive subject matter has been disclosed in the context of certain preferred or illustrated embodiments and examples, it will be understood by those skilled in the art that the inventive subject matter extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. In addition, while a number of variations of the disclosed embodiments have been shown and described in detail, other modifications, which are within the scope of the inventive subject matter, will be readily apparent to those of skill in the art based upon this disclosure. It is also contemplated that various combinations or subcombinations of the specific features and aspects of the disclosed embodiments may be made and still fall within the scope of the inventive subject matter. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed inventive subject matter. Thus, it is intended that the scope of the inventive subject matter herein disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the claims that follow.

What is claimed is:

1. A method of fitting a lower-limb prosthesis to a patient, comprising:

receiving and electronically storing a set of patient parameters including a patient weight and a patient height; receiving and electronically storing a test gait cycle, the test gait cycle comprising kinematic and position data regarding one or more joints of the patient's lower limb during a test walking stride;

mounting a proposed lower-limb prosthesis onto a test fixture having one or more joints and being configured to simulate an able portion of the patient's lower limb;

identifying desired force parameters for the one or more joints of the test fixture, the desired force parameters comprising ranges of acceptable forces at the one or more joints of the test fixture during a gait cycle;

performing an iterative pre-fitting test, comprising:
operating the test fixture through the test walking stride while the proposed lower-limb prosthesis is mounted on the test fixture, operating the test fixture through the test walking stride comprising directing the test fixture to apply the patient parameters and to move in accordance with the test gait cycle;

receiving force sensor data regarding the one or more joints of the test fixture, the force sensor data comprising forces measured at the one or more joints of

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the test fixture while the test fixture is operated through the test walking stride;

comparing the force sensor data to the desired force parameters;

when the force sensor data exceeds one or more of the desired force parameters, making an adjustment to the proposed lower-limb prosthesis and again performing the iterative pre-fitting test; and

when the force sensor data is within the desired force parameters, installing the proposed lower-limb prosthesis onto the patient.

2. The method as in claim 1, wherein the test walking stride simulates a desired gait cycle of a patient.

3. The method as in claim 2, wherein the desired gait cycle of the patient comprises a healthy gait cycle of an amputee patient, the desired gait cycle reflecting a gait cycle measurement taken when the amputee patient was whole.

4. The method as in claim 2 additionally comprising measuring an amputee patient's gait cycle of the amputee patient's whole lower limb and defining the desired gait cycle as the measured amputee patient's gait cycle of the amputee patient's whole lower limb.

5. The method as in claim 2, wherein the desired gait cycle is taken from a database of average human gait cycles.

6. The method as in claim 1, additionally comprising receiving angular position sensor data regarding measured angles at one or more locations on the prosthesis while operating the test fixture through the test walking stride, the angular position data comprising angular positions measured at the one or more locations on the prosthesis.

7. The method as in claim 1, wherein the desired force parameters comprise acceptable parameters for a well-fitting prosthesis.

8. The method as in claim 1, additionally comprising obtaining a retest gait cycle of the amputee patient's whole lower limb by observing the amputee patient performing the test walking stride while wearing the lower-limb prosthesis.

9. The method as in claim 8 additionally comprising comparing the retest gait cycle with the test gait cycle.

10. The method as in claim 9 additionally comprising installing the lower-limb prosthesis onto the test fixture and performing a retest by directing the test fixture to apply the patient parameters and to move in accordance with the retest gait cycle, receiving retest force sensor data comprising forces measured at the one or more joints during the retest, and comparing the retest force sensor data to the desired force parameters.

11. The method as in claim 1 additionally comprising selecting a second proposed lower-limb prosthesis when the force sensor data exceeds one or more of the desired force parameters.

12. The method as in claim 1, wherein the one or more joints of the test fixture comprise one or more of a hip joint and a knee joint.

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