An apparatus and the method of using of an instrumented orthopedic restraining device (2") includes an ambulatory housing (4") having restraining means for restraining movement of the first and second distal end portions (4aa", 4ab") of the ambulatory housing (4") relative to one another. The restraining means includes an elongated restraining bar (6a", 6b") equipped with a stress sensing mechanism (8") for sensing stress on the restraining bar (6a", 6b"), and an adjustable hinge (21a, 21b) interconnecting distal end sections (6aa", 6ab", 6aa", 6bb") of the elongated restraining bar (6a", 6b"), wherein the angle between the respective distal end sections can be adjusted relative to one another. A control unit (10") includes a recording mechanism (68, 70) and a microprocessor mechanism (64), which is provided for indicating sensed stress based upon outputs from the stress sensing mechanism (8"). Preferred embodiments include a plurality of strain gauges (8a", 8b") attached to the elongated restraining bar (6a", 6b") and interconnected with control unit (10"), and the adjustable hinge (21a, 21b) is an electromechanical hinge which can be at least partially controlled by software.
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"ORTHOPEDIC RESTRAINING DEVICE AND METHOD OF USE"

Field of the Invention
The present invention relates to ambulatory orthopedic restraining devices such as casts, braces and the like.

Background of the Invention
It is known that both muscles and bones should be exercised to maintain strength. It is also known that healing fractures, exposed to permissible weight bearing stress, often heal more predictably and more rapidly than fractures which are not stressed at all. This is probably also true for connective tissues, such as ligaments and articular cartilage.

When an individual sustains a physical injury which involves damage to bones, muscle tissue, connective tissue or the like, the physician treating the individual will make a determination as to whether exercise will be allowed. The physician will allow exercise if the physician can obtain assurances that the exercise will be performed in a controlled manner within specific parameters wherein the injured bone and/or tissue will remain stable. Unfortunately, however, the physician is generally unable to obtain adequate information or assurances about the manner in which a particular patient will conduct prescribed exercise. Furthermore, because the physician is also unable to obtain adequate feedback after the patient performs any specific prescribed exercise, the physician generally does not feel he or she has sufficient access to information about the exercise to permit or recommend anything but the most basic exercise. Without some way to obtain information about exercise events, the physician cannot maintain sufficient control of the exercise. The physician does not know how much stress the patient can or will exert voluntarily, and does not know how well the patient will adhere to a schedule of repetitive exercise events.
Since the physician is not able to obtain adequate feedback regarding the patient's exercise, the most prudent course of action for the physician is to limit the amount of exercise which the patient is allowed to perform by immobilizing the portions of the body proximate the injury. This is often accomplished by using a cast which is the simplest and crudest method of protecting an injury. The cast allows virtually no movement at all and is widely used to insure against reinjuries. Unfortunately, this method of protecting the injury often does not provide adequate means for exercising the body portions proximate the injury. For instance, a cast is often not strong enough, without additional reinforcement, to permit isometric exercising. Furthermore, casts are not equipped to provide feedback to the physician or the patient with respect to any exercising.

Accordingly, a need exists for a personal orthopedic restraining device which will permit and encourage a range of exercise during rehabilitation and provide sufficient feedback to the prescribing physician to allow the physician to evaluate the patient's progress in regard to the exercise the physician has prescribed. A need also exists for a personal restraining device which is equipped to give the patient immediate feedback respecting exercise events. Although it has been known that exercise is helpful in rehabilitating patients and others having orthopedic disabilities, inadequacies, or the like, adequate devices for methods of restraining respective body parts and monitoring the exercise thereof have not been provided which adequately address this problem.

The present invention provides a solution to these and other problems, and offers other advantages over the prior art.

Summary of the Invention

Accordingly, a novel orthopedic restraining device is now proposed. The present invention provides a personal orthopedic restraining device for use to restrain flexibly
connected body portions of an individual. The present restraining device comprises an ambulatory housing, including first and second distal end portions, and restraining means for restraining movement of said first and second distal end portions relative to one another. Each of the respective distal end portions is configured to receive flexibly connected body portions of the individual, whereby movement of the respective body portions relative to one another can be restrained by the housing. The present restraining device also comprises stress sensing means for sensing stress on said restraining means and stress indicating means for indicating a quantitative stress value based upon an output from said stress sensing means. Said stress sensing means is attached to said restraining means and said stress indicating means is interconnected with said stress sensing means for receiving the output from said stress sensing means. In preferred embodiments, said restraining means include an elongated restraining bar having first and second distal end sections, wherein said first and second distal end sections are fixedly secured to said first and second distal end portions of the housing, respectively. In the most preferred devices, the restraining device is preferably an ambulatory appliance which can be worn by the individual to prevent specific movements of respective body portions restrained thereby. Certain stress placed upon said restraining means can be monitored with said indicating means. Preferably, the present restraining device further includes recording means for recording an output from said stress sensing means, wherein said recording means is interconnected with said stress sensing means for receiving the output from said stress sensing means. A preferred restraining device of the present invention further includes control means including said indicating means and said recording means and being interconnected with said stress sensing means for receiving the output from said stress sensing means.
Preferably, said control means further include microprocessor means for processing outputs from said stress sensing means. The elongated restraining bar can include an adjustable hinge interconnecting said distal end sections, wherein the angular position of the respective distal end sections can be adjusted relative to one another. In preferred embodiments, the adjustable hinge includes position sensing means for sensing the relative angular position of the first and second distal end sections. In certain preferred embodiments, the adjustable hinge is an electromechanical hinge and the restraining device includes control means interconnected with said stress sensing means and said position sensing means for receiving outputs therefrom. Preferably, said control means further include recording means for recording outputs from said stress sensing means and said positioning sensing means. Said stress sensing means preferably include a strain gauge, more preferably a plurality of strain gauges, attached to said restraining means, preferably attached to the elongated restraining bar. In a preferred embodiment, stress sensing means include four strain gauges attached to the elongated restraining bar and being interconnected with one another in a wheatstone bridge circuit arrangement. Preferably, the present restraining device will have two elongated restraining bars disposed on opposite sides of the flexibly connected body portions when the housing is engaged therewith.

Alternate embodiments of the present invention provide methods of rehabilitating or conditioning an individual having orthopedic or musculoskeletal disabilities or deficits and of monitoring and regulating patient musculoskeletal rehabilitation and/or conditioning. Each of these methods preferably comprise the steps of providing a preferred restraining device of the present invention, engaging flexibly connected body portions in the device and exercising, or requesting the individual to
exercise, the respective flexibly connected body portions by exerting a measurable force against said restraining means. Further steps including monitoring stress placed upon said restraining means. In preferred embodiments of the present method claims, the step of providing includes providing a preferred restraining device including an elongated restraining bar having an incrementally adjustable hinge interconnecting the first and second end sections, wherein the incrementally adjustable hinge permits the relative angular position of the first and second end sections to be adjusted incrementally such that the relative angular relationship of the respective body portions restrained thereby can be varied. When the adjustable hinge is used, physicians and physical therapists can direct a patient to adjust the hinge so that a series of sets of isometric exercises can be conducted at different degrees of flexion or extension, thereby allowing the patient to take advantage of the overlapping strength gains which are generally believed to be associated with isometric exercise events completed at any particular series of degrees of flexion.

Still other embodiments of the present invention include the step of providing a variety of other preferred embodiments of the restraining device of the present invention, including embodiments which incorporate a capacity for recording data generated by sensing means attached to an elongated restraining bar or bars. That data can be monitored by the patient and/or the physician or physical therapist during exercise and can also be stored and manipulated to allow the physician or physical therapist to monitor the patient's exercise at a later time and place, so that the patient's progress can be easily monitored and evaluated on an on-going basis, and substantive patient interviews can be conducted to reinforce the patient's exercise behavior and response thereeto. Control means (e.g., software) has also been developed to provide the patient with ideal exercise
models or goals toward which the patient can strive. These models and/or goals can be used to enhance the patient’s devotion to conditioning and/or rehabilitation, as well as to reinforce the patient’s confidence in exercise generally and in the use of the preferred restraining device itself.

The present invention provides many advantages over the prior art methods of orthopedic immobilization. A more refined technique of immobilization is provided wherein the maximum strains exerted by a patient may be monitored, both by the patient and by the physician. Because the physician is able to obtain data regarding the patient’s exercise ability and/or progress, the physician may permit the patient to exercise tissue surrounding an injury. The ability to retrieve information regarding such exercise gives the physician a degree of control over the exercise performed. For instance, after a review of the exercise conducted by the patient, the physician can prescribe more exercise when more exercise is believed to be appropriate, or less exercise when a patient is too aggressive. The physician can also advise and encourage the patient as to ways to modify the exercise routine so as to further benefit the patient and speed recovery or rehabilitation.

The injured body portions need only be immobilized as much as it is deemed to be required by the physician. As the physician obtains more information with respect to the exercise being conducted by the patient, the degree of immobilization and the exercise routine, can be varied to speed the patient’s recovery and to suit a patient’s immediate needs.

Significant cost savings may be realized with the availability of the present restraining device because frequent visits to the physical therapist for exercise therapy may no longer be required. Therapy programs for rehabilitation and/or conditioning following certain injuries can commonly cost the patient and society
thousands of dollars. The present invention would provide a significant improvement over such therapy programs because the patient could exercise at home by following an exercise routine. The patient would be able to monitor his or her progress as would the physician when the preferred restraining device including recording means is used. It is envisioned that an exercise routine could be programmed directly into preferred embodiments of the present invention so that the patient could simply follow a preselected exercise routine at the same time that he or she monitors the effort being exerted. In other embodiments, it is envisioned that the patient's progress could be monitored locally or remotely by the physician or therapist entirely by electronic means, and that the exercise program could be varied in response to events, such as the completion of particular requirements.

Another significant advantage of the preferred embodiments of the present invention is that patient compliance is likely to be much higher. Because patients provided with preferred embodiments of the present invention will be able to monitor their own exercise routines, and will know, in certain cases, that their progress will be monitored by others, they are more likely to exercise as suggested by the physician. Forgetfulness could be obviated by a reminding device such as an alarm or a message system. Control means, preferably a computer program, can be provided which will provide a variable message system which can direct the patient's activity in either a set format or in a format which is responsive to the patient's success or failure with respect to specific goals or levels of exercise achievement. Patient confidence and devotion to rehabilitation efforts are also likely to be higher due to a knowledge that their efforts to rehabilitate their injury are being closely supervised.

In addition, patient comfort level would undoubtedly be improved because of this increased confidence and devotion to rehabilitation, thereby lowering mental stresses which
ordinarily result from fears that their injury is not being closely monitored or that progress with respect to rehabilitation is too subjective to identify. Furthermore, patients would probably have less pain due to unnecessary immobilization, and they would be able to retrieve hard data respecting their exercise routines which they could discuss objectively with their physician or physical therapist either in the office, or, in all likelihood, over the telephone subsequent to independent reviews of the data by each party.

The biggest advantage, however, is that patients will be able to recover from injuries quicker and will be able to avoid debilitating deterioration in strength of the tissue proximate the injury during periods of limited immobilization. The value of the present invention in this regard cannot be over emphasized. Physicians and therapists of the future will now have a means for obtaining feedback respecting patient exercise activity, which will permit them to allow constructive rehabilitative and maintenance conditioning which has, heretofore, been viewed as being too uncontrolled to be permitted in most cases.

It is also believed that patients will be able to perform exercise which they could not otherwise perform because of the availability of feedback when using preferred embodiments of the present invention. For instance, as a patient is able to achieve a certain level of exercise, they will be reinforced with respect to their ability to perform the exercise. The exercise requirement can then be increased following the reinforcement, and the patient will then be given a further opportunity to obtain similar reinforcement with respect to reaching the next set of exercise requirements. Because the preferred embodiments of the present invention allow both the patient and the physician to monitor the patient's progress, the physician is more equipped to offer objective support and review of the patient's progress.
As used herein, an "isometric" exercise is an exercise wherein one exerts force against a restraining device having a set and substantially unchangeable configuration for the duration of the specific isometric exercise event. "Isometric" force means force which is exerted by pressing against a relatively immovable object, or two or more objects or elements of an apparatus or device which are relatively immovable with respect to one another. The incrementally adjustable hinge of an alternate embodiment of the present invention is designed to be adjustable between separate exercise events. As used herein, the phrase "angular position of the respective distal end sections" is used to describe an angular relationship or an angle or angles between the longitudinal axes of the respective first and second end sections of an elongated restraining bar or a pair of elongated restraining bars having reciprocating angular relationships between their respective distal end sections. Although it is envisioned that the primary emphasis for use of the present invention will be with human beings, particularly patients recovery a wide assortment of injuries or disabilities, as used herein an "individual" can be a human or an animal such as a horse, cat, dog, or any other domestic or wild animal. An "ambulatory" housing, or an "ambulatory" appliance, as used herein, is a housing or an appliance which may be engaged with flexibly connected body portions of an individual such that the individual can move from place to place wearing the housing or appliance which is so described. As used herein, "flexibly connected body portions" of an individual are flexibly connected body parts such as an upper leg and a lower leg which are flexibly interconnected at the knee, an upper arm and a forearm which are flexibly interconnected at the elbow, a forearm and a hand which are flexibly interconnected at the wrist, separate portions of one's torso which are flexibly interconnected at any one of the flexible joints between any two vertebra, and the like. Elements of the
present invention which are "interconnected for receiving outputs" include elements which are interconnected electrically or are interconnected by means such that signals and/or information or outputs can be transmitted and received between said elements via a wired or wireless connection. As used herein in connection with the terms "indication" and "indicator", "audible" means an indication or indicator capable of being sensed using one's sense of hearing; "visual" means an indication or indicator capable of being sensed using one's ability to see; and "palpable" means an indication or indicator capable of being sensed using one's sense of feeling. The term "instrumented", as used herein, means "including mechanisms for monitoring outputs".

These and various other advantages and features of novelty which characterize the present invention are pointed out with particularity in the claims annexed hereto and forming a part hereof. However, for a better understanding of the invention, its advantages, and the objects obtained by its use, reference should be made to the drawings which form a further part hereof and to the accompanying descriptive material, in which there is illustrated and described preferred embodiments of the present invention.

**Brief Description of the Drawings**

In the drawings, in which like reference numerals refer to corresponding parts of preferred embodiments of the present invention throughout the several views,

Figure 1 is a side view of an orthopedic restraining device in accordance with the present invention;

Figure 2 is a schematic illustration of the orthopedic restraining device shown in Figure 1 showing elongated restraining bars located on either side of the device;

Figure 3 is a side view of an alternate orthopedic restraining device in accordance with the present invention;
Figure 4 is a schematic illustration of elements of the alternate orthopedic restraining device of Figure 3 showing elongated restraining bars located on either side of the device;

Figure 5 is an enlarged side view of an incrementally adjustable hinge shown in Figure 3;

Figure 6 is a top view of the adjustable hinge shown in Figure 3 when its respective engaging members are engaged;

Figure 7 is a sectional view of the adjustable hinge from the line 7-7 of Figure 5 when the respective engaging members are engaged;

Figure 8 is a sectional view of the adjustable hinge from line 8-8 of Figure 5 when the respective engaging members are disengaged;

Figure 9 is a side plan view of a first engaging member of the adjustable hinge shown in Figure 6;

Figure 10 is a side plan view of a second engaging member of the adjustable hinge shown in Figure 6;

Figure 11 is a side view of an alternate orthopedic restraining device having an electromechanical hinge;

Figure 12 is a schematic illustration of elements of the alternate orthopedic restraining device shown in Figure 11;

Figure 13 is a sectional view of the electromechanical hinge shown in Figures 11 and 12 from the line 13-13 of Figure 12;

Figure 14 is a sectional view of the electromechanical hinge of Figures 11 and 12 as seen from the line 14-14 of Figure 13;

Figure 15 is a functional block diagram of the orthopedic restraining device shown in Figures 11-14; and Figures 16A through 16C are functional flow diagrams of control logic for an orthopedic device in accordance with the principles of the present invention.
Detailed Description of the Preferred Embodiments

Referring now to the drawings, and to Figures 1-2 in particular, a personal orthopedic restraining device 2 in accordance with the present invention is illustrated when engaged with upper and lower leg portions of a right leg 3 of an individual 1. The restraining device 2 includes a housing 4. The housing includes first and second distal end portions 4a and 4b which are configured to receive upper and lower leg portions 3a and 3b of the individual's right leg 3 which are flexibly connected at the knee. The housing 4 further includes a pair of elongated restraining bars 6a and 6b disposed on opposite sides of the individuals right leg 3. Each of the elongated restraining bars 6a and 6b have first and second distal end sections 6aa and 6ba, and 6ab and 6bb, respectively. Each of the distal end sections is fixedly secured to the respective end portion of the housing proximate thereto. Attached to opposite edges of each of the elongated restraining bars 6a and 6b are separate strain gauges 8a and 8b respectively. In preferred embodiments the strain gauges 8a and 8b are foil type strain gauges, each consisting of two strain gauges such that each elongated bar member 6a and 6b are equipped with four strain gauges which are interconnected in a wheatstone bridge circuit arrangement to provide superior sensing capabilities. The strain gauges are capable of sensing stress on the elongated restraining bars and provide an output which is indicative of a quantitative stress level. The strain gauges 8 are electrically interconnected with a programmed microprocessor control unit 10 which includes a mechanism for indicating a quantitative stress value based upon an output from the strain gauges 8 which sense stress on the respective elongated bar members 6a and 6b to which the individual strain gauges are attached. The device 2 also includes a pressure sensing mechanism or load cell 14 which senses pressure placed on the cell 14 when the individual places weight on the leg 3. The load cell 14
is interconnected by a wire 17 with the control unit 10 which can monitor and record outputs from the load cell 14.

An isometric restraining device 2 in accordance with the present invention includes a restraining mechanism 4 including an elongated restraining bar 6a, two strain gauges 8a attached to the restraining bar 6a, and a control unit 10, including a stress indicating mechanism, interconnected to the strain gauges 8a by interconnecting wires 12a. The restraining device 2 also includes a second elongated restraining bar 6b proximate the inside of the subject's leg such that it roughly mirrors the image of the restraining bar 6a which is shown on the outside of the subject's leg in Figure 1. The other restraining bar 6b is also equipped with two strain gauges 8b which are attached to the bar and electrically interconnected to the control unit 10 in a similar manner to that shown in Figure 1. Both restraining bars 6a and 6b are shown in Figure 2.

Now referring also to Figures 3 and 4, the present invention also provides an alternate personal orthopedic restraining device 2' including elements corresponding to those of the previously described restraining device 2. In addition, however, each of the elongated restraining bars 6a' and 6b' include an incrementally adjustable hinge 20a or 20b interconnecting the respective distal end sections 6aa' and 6ab' or 6ba' and 6bb'. The first and second distal end portions 4a' and 4b' of the housing 4' are interconnected by the elongated restraining bars 6a' and 6b' which are fixedly secured thereto. The respective first distal end sections 6aa' and 6ba' are fixedly secured to the first distal end portion 4a' and the second distal end sections 6ab' and 6bb' (not shown) are fixedly secured to the second distal end portion 4b' so that these elements of the alternate restraining device 2' move as though they were separate portions of an integral unit. The plurality of strain gauges 8a' and 8b', respectively,
are attached to the elongated restraining bars 6a' and 6b'. These strain gauges 8a' and 8b' are electrically interconnected with a control unit 10'. It will be appreciated that the present invention may be made with a single strain gauge attached to a single elongated bar. However, it is preferable to include an elongated bar on either side of a point of flexion such as a knee, an elbow or the like. Similarly, it is preferable to include at least two strain gauges 8 on each of the elongated bars 6 and, preferably, four strain gauges in an unbalanced wheatstone bridge circuit arrangement or configuration.

Referring now also to Figures 5-10, the adjustable hinge apparatus 20a includes a first engaging member 22a which is engagable with a second engaging member 24a. The first engaging member 22a is interconnected with the first distal end section 6aa of the elongated restraining bar 6a and the second engaging member 24a is interconnected with the second distal end section 6ab of the elongated restraining bar 6a. Each of the respective engaging members include engaging teeth, 23a and 25a respectively, which engage one another in a reciprocal relationship when the respective engaging members 22a and 24a are tightened or screwed together as shown in Figures 6 and 7. When the respective engaging members 22a and 24a are not tightened together, as shown in Figure 8, they are free to turn or pivot with respect to one another on a bolt portion 28a of a securing member 26a which is retained within a bolt receiving opening 29a in the second engaging member 24a. The bolt receiving opening 29a is located in the circumferential center of the second engaging member 24a so that the bolt portion 28a of the securing member 26a provides an axial pivot point for the respective engaging members 22a and 24a, with respect to one another, when they are not secured together.

The bolt portion 28a of the securing member 26a is retained in the bolt receiving opening 29a by a retaining clip 30a which is attached to the bolt portion 28a such
that the bolt portion 28a cannot be removed from the bolt receiving opening 29a. This prevents the securing member 26a from becoming entirely disengaged from the second engaging member 24a when the securing member 26a is unscrewed to free the engaging teeth 23a of the first engaging member 22a from the engaging teeth 25a of the second engaging member 24a. When the securing member 26a is unscrewed as far as the retaining clip 30a will allow the bolt portion 28a to go a coil spring 31a encircling the bolt portion 28a will bias the first engaging member 22a away from the second engaging member 24a so that the respective engaging teeth 23a and 25a are disengaged and the respective engaging members 22a and 24a can turn or pivot about the bolt portion 28a of the securing member 26a.

The bolt receiving opening 29a of the second engaging member 24a includes a reciprocating screw hole 34a which receives and reciprocates the right-handed screw turns on the bolt portion 28a of the securing member 26a. The bolt receiving opening 29a also includes a recess 36a. When the securing member 26a is turned clockwise, the right-handed screw turns of the bolt portion 28a are drawn into the second engaging member 24a by the reciprocating turns of the reciprocating screw hole 34a, and the respective engaging teeth 23a and 25a are gradually drawn closer together. When the securing member 26a is turned as far as it can go in this direction, the coil spring 31a will be tightened together as shown in Figure 7, and the respective engaging teeth 23a and 25a will be tightened together and engaged such that the respective engaging members 22a and 24a can no longer turn or pivot with respect to one another.

When the engaging members 22a and 24a are tightened together in this manner, as shown in Figures 6 and 7, an angle between the respective distal end sections 6aa' and 6ab' of the elongated restraining bar 6a' will be fixed and the device 2' can then be used to restrain an
individual wearing or engaged in the device 2' conducting isometric exercises at a series of different degree of flexion generally corresponding to this angle. This device 2' can also be used to restrain an individual conducting isometric exercises at a series of different degrees of flexion. This can be accomplished by conducting isometric exercises at one degree of flexion when the respective distal end sections 6aa' and 6ab' are set at one particular angle with respect to one another, and subsequently at a second, third, fourth and/or fifth degree of flexion when the respective distal end sections 6aa' and 6ab' are reset at different angles. It will be understood that this will mean resetting the angle between the respective end sections of each of the restraining bars 6a' and 6b' in a preferred device 2' which has two restraining bars. This is done by loosening the respective securing members 26a and 26b (not shown) on each side of the device 2', allowing the individual to adjust the flexion of the joint manually, and resecuring the respective engaging members 22a and 24 and 22b and 24b of the respective adjustable hinge apparatus 20a and 20b, such that the respective engaging teeth 23a and 25a and 23a and 25a of both of the adjustable hinges 20a and 20b are fully engaged as shown in Figures 6 and 7. When the engaging teeth are fully engaged, and the respective engaging members can no longer pivot with respect to one another, the angle between the respective distal end sections will be fixed and the subsequent isometric exercising can begin.

Preferred embodiments of the present invention also include a control unit 10. The control unit is interconnected with the respective strain gauges and the incrementally adjustable hinges in order that the control unit 10 can receive electrical outputs therefrom. The incrementally adjustable hinge 20a preferably includes a potentiometer-like mechanism 39a which is part of a position sensing device 60 for determining the angle of
the respective distal end sections of the respective elongated restraining bar 6 in respect to one another. It will be appreciated that because the angle between respective end sections of respective restraining bars will generally be roughly equivalent, it is not required to have more than one potentiometer mechanism in any device 2’. However, because the elongated restraining bars 6a and 6b of the present device 2’ are identical mirror images of one another, each includes the adjustable hinge apparatus 20a and 20b, respectively, including a potentiometer mechanism 39 which is interconnected with the control unit 10’. Each potentiometer mechanism has the same elements. Further embodiments of the hinge mechanism may include modification to better approximate the specific anatomic motion of the respective joint partially immobilized or protected by the specific device.

The potentiometer mechanism 39a shown in Figures 7 and 8 includes a conductive wiper 40a attached or adhered to an inner surface 42a of the second engaging member 24a, a resistive element 44a and a conductive element 46a which are interconnected with the control unit 10’ in order that outputs from the potentiometer mechanism 39 can be monitored, and preferably, recorded, by the control unit 10’ (See Figures 9 and 10 also). The wiper 40a has two resilient contact arms 52a and 54a which extend outwardly from the inner surface 42a of the second engaging member 24a to contact the resistive element 44a and the conductive element 46a, respectively, so that the position of the wiper 40a with respect to the resistive element 44a can be sensed by the control unit 10’ reading the electrical output from the potentiometer mechanism 39. In embodiments where there are two hinges only one of the potentiometer mechanisms, if there are two, needs to be interconnected with the control unit 10’, although both can be connected.
Referring now also to Figures 11-14, yet another embodiment of the present personal orthopedic restraining device 2'' includes a pair of electromechanical hinges 21a and 21b which are incrementally adjustable. This embodiment of the restraining device 2'' can include all of the elements of the restraining device 2' shown in Figures 3 and 4, except that the incrementally adjustable hinge apparatus 20a and 20b have been replaced by the electromechanical hinge 21a and 21b, which are mirror images of one another. The elements of the electromechanical hinge 21a are shown in Figures 13 and 14. The electromechanical hinge 21a is also an incrementally adjustable hinge and includes an alternate potentiometer-like mechanism 39a' which is part of an alternative position sensing device 60' (not shown) for sending an output to a control unit 10'', and also includes other elements corresponding to similar elements included in the adjustable hinge apparatus 20a. In the preferred embodiment shown in Figures 11-14, the electromechanical hinge 21a is partially controlled by the control unit 10''. The electromechanical hinge 21a includes an electromechanical brake and/or clutch mechanism 41a similar to those which are standard in the art. The preferred electromechanical clutch mechanism 41a is interconnected with the control unit 10'' by lead wires extending from leads 43a which are electrically interconnected with a stator coil 45a within a stator housing 56a which is designed to attract a magnetically attractable armature 47a when a sufficient magnetic field is created by an electric current passing through the stator coil 45a. The current is derived from a source of electricity within the control unit 10''. Separate lead wires connect the potentiometer-like mechanism 39a' of the position sensing device 60' (not shown) to the control unit 10'' so that the electrical output, which provides an indication of the angle between the respective distal end
sections 6aa'' and 6ab'', can be monitored and/or recorded by the control unit 10''.

The electromechanical hinge 21a shown in Figures 11-14 includes a clutch housing 48a which is secured to the first distal end section 6aa'' or 6ba'' of the respective elongated restraining bar 6a''. A similar hinge 21b is incorporated into the other restraining bar 6b'. In Figure 13, a cross-sectional view of the electromechanical hinge 21a interconnected to the elongated restraining bar 6a'' is shown. The second end section 6ab'' is an integral unit including an extended restraining bar segment 7a and a shouldered pin or bolt segment 9a. The shouldered pin segment 9a includes a plurality of pin portions 9aa, 9ab, 9ac, 9ad and 9ae. The first pin portion 9aa is integrally connected to the proximate end of the extended restraining bar segment 7a. Together with the second pin portion 9ab, the first pin portion 9aa defines a first shoulder upon which the first distal end section 6aa'' can rest as it turns about the second pin portion 9ab when the respective distal end sections are allowed to pivot with respect to one another by the electromechanical hinge 21a. The third pin portion 9ac has a threaded exterior for receiving a nut 11a for securing the first distal end section 6aa'' to the second distal end section 6ab'' over the shouldered pin segment 9a. The nut 11a secures a washer 13 against the first distal end section 6aa'', such that the first distal end section 6aa'' can turn freely about the second pin portion 9ab when it is permitted to turn by the electromechanical brake/clutch. The fourth pin portion 9ad is received by an opening (not shown) in the magnetically attractable armature 47a. The armature 47a includes a spline 51a which fits into an armature groove 16a for receiving the spline 51a, located in the fourth pin portion 9ad, so that the armature 47a will only turn in a common rotary movement with the shouldered pin segment 9a. The fourth pin portion 9ad and the fifth pin portion 9ae define a
fourth shoulder against which a wiper arm 50a' is secured. The fifth pin portion 9ae includes a threaded exterior for receiving a second nut 49a which secures the wiper arm 50a' against the fourth shoulder. The fifth pin portion 9ae also includes a flat side which provides a key to turn a molded insulating element portion 50aa' of the wiper arm 50a' which is bonded to the conductive element 50ab' thereof. The insulating element 50aa' is made of a suitable polymeric material which insulates the shouldered pin segment 9a from the electrical current which normally flows through the conductive element 50ab' of the wiper arm 50a'. This is essential to the integrity of the potentiometer circuit. Because the wiper arm 50a' is keyed to the fifth pin portion 9ae, it will turn in a common rotary movement with the entire shoulder pin segment 9a. As the wiper arm 50a' turns, it remains in contact with a contact arm 52a' which is connected to one of the leads 43aa which is in turn electrically interconnected with the control unit 10'''. The other lead 43ab is interconnected with a resistive slide line element 53a and also with the control unit 10'''. The potentiometer-like mechanism 39a' is electrically interconnected with the control unit 10''' to provide an output to the control unit 10''' which can be calibrated to indicate the relative position of the contact point between the resistive slide line element 53a and the wiper arm 50a', and also the angle between the respective distal end sections 6aa'' and 6ab'' of the restraining bar 6a'.

The electromechanical break/clutch mechanism 41a of the electromechanical hinge 21a can be controlled by pushing either a release or a brake button (not shown) on the control unit 10''' which will respectively free the armature 47a to turn with respect to the stator coil 45a or attract the armature 47a to the stator coil 45a thereby preventing the armature 47a from turning with respect to the stator coil 45a. When the release button is pushed,
the armature 47a is free to turn with respect to the coil 45a and the angle between the respective distal end sections 6aa'' and 6ab'' or 6ba'' and 6bb'' may be manually adjusted. In preferred embodiments, the change of the angle between the respective distal end sections can be monitored by watching an LCD readout display (not shown) on the control unit 10''. As the angle is adjusted. When the angle reaches the desired angle, the brake may be applied by pushing the brake button, wherein a circuit is completed allowing an electric current to pass through the stator coil 45a, thereby creating a magnetic field which attracts the armature 47a and prevents the armature 47a from turning with respect to the coil 45a.

When the armature 47a is attracted to the coil 45a, as shown in Figure 13, a pair of free riding annular disks 55aa and 55ab are gripped between the armature 47a and a stator housing 56a within the clutch housing 48a. The outer annular disk 55ab is preferably made of a suitable metal and the inner annular disk 55aa is preferably made of a suitable polymeric material to provide for a smooth gripping action between the respective surfaces and to prevent wear therebetween. The free riding disks 55aa and 55ab encircle a center portion of the armature 47a. A coil spring 31a' biases the armature 47a away from the stator housing 56a when the magnetic attraction between the coil 45a and the armature 47a is insufficient to overcome the mechanical force of the coil spring 31a' which biases the armature 47a away from the stator housing 56a.

In a preferred embodiment of the present invention, the electromechanical brake/clutch mechanism 41a is controlled by a microprocessor 64 (see Figure 15) in the control unit 10'' which is programmed to release the brake/clutch mechanism 41a after the completion of a specified number of isometric events or repetitions when the device 2'' is set at a specific angle with respect to the respective distal end sections. Upon achieving a
required number of isometric repetitions, the programmed microprocessor will release the brake and the angle between the respective end sections can be manually adjusted to a different angle. The program may further dictate how much the angle may be changed prior to breaking the electromechanical hinge 21a again and requiring further isometric repetitions at the new setting. In this manner an entire exercise routine can be controlled by the programmed microprocessor. Preferably, the mechanical movement of the electromechanical hinge 21a will be generated by force placed upon the device 2'' by the individual engaged therein. However, the programmed microprocessor can be designed to place controls upon what movement will be allowed and when that movement will be allowed (i.e., after certain isometric event requirements have been met). It will be appreciated that such a system may be used to create a variety of exercise requirements which an individual will be encouraged to follow by his physician in order to conduct a proper exercise or rehabilitative routine.

Illustrated in Figure 15 is a functional block diagram of the control unit 10'' of the orthopedic restraining device 2'' shown in Figures 11-14. The control unit 10'' preferably controls certain aspects of the operation of the orthopedic restraining device 2''. The housing 4'' of the orthopedic restraining device is represented by the broken line 4'' and the control unit 10'' is represented by the broken line 10''. The various components of the control unit 10'' are illustrated as being suitably electrically connected. The control unit 10'' receives analog input signals from the position sensor 60', configured and arranged for sensing the relative angular position of the first and second distal end sections of the orthopedic restraining device 2'', and the control unit 10'' also receives signals from a stress sensing mechanism, in the embodiment shown the strain gauges 8'', for sensing stress on the orthopedic restraining device
2. The signals received from the position sensor 60 are representative of the sensed relative angular position and the signals received from the strain gauges 8 are representative of the sensed stress. In the embodiment shown, control unit 10 shown thus receives two general types of input signals: one representative of the angular position of the orthopedic restraining device 2 and a second representative of the strain on the orthopedic restraining device. The position sensor 60 is suitably electrically connected to an analog to digital converter 62 which converts analog signals to digital signals. The strain gauges 8 are suitably electrically connected to the analog to digital converter 62. In the embodiment shown, the strain gauges 8 are illustrated as being interconnected to an amplifier 63 for amplification of the output signals from the strain gauges 8. In addition, the amplified signals output from the amplifier 63 are passed through a low pass filter 65 for filtering out background noise and other unwanted signal interference.

The signal frequency output from the low pass filter 66 is roughly four hundred (400) hertz (Hz). The output from the low pass filter function 65 is transferred to sample/hold circuitry 67 which periodically samples the output from the low pass filter 65 and then outputs the sensed electrical signal value to the analog to digital convertor 62. The electrical connection between the strain gauges 8 in the housing 4 and the amplifier 63 in the control unit are represented by the reference numeral 12 while the electrical interconnection between the position sensor 60 and the analog to digital convertor 62 is represented by the line 61. It will be appreciated that the amplifier, low pass filter, sample/hold, and analog to digital convertor functions 63, 65, 67, 62 might be achieved by conventional well known circuitry.

The control unit 10 is further illustrated in figure 15 as including a microprocessor 64. It will be appreciated that numerous microprocessors might be
utilized in keeping with the present invention; e.g., Intel 8088 and 8086, Motorola 6800, etc. The microprocessor 64 is shown as including a power supply 66 and a nickel cadmium battery 69. In addition to providing power to the control unit 10” in its operational state, and to a lesser degree, in its idle state, the power supply 66 also provides power to the electromechanical hinge 21, the position sensor 60’ and the strain gauge or gauges 8’’. The microprocessor is also illustrated as including non-volatile data memory 68 for storing data and non-volatile memory 70 for storing a control program. The memory 68 might be low power CMOS memory which can be read and written into and is powered by the battery 69. The memory 70 might be electrically programmable read only memory (EPROM). The control unit 10” is further illustrated as including a real time clock 72 including an alarm function. In alternate embodiments, a speaker and a voice synthesizer might be used to provide voice commands and information to the user. In addition, the control unit 10” is illustrated as including a keypad 74 for user input into the control unit. It will be appreciated that any number of user input devices might be utilized; e.g., a keypad having individual keys, a touch sensitive pad, etc. The control unit 10” is further illustrated as including a graphic liquid crystal display 76 for displaying graphics and text information and suitable user alerts. The display 76 can have various resolutions; e.g., a 240 by 120 pixel display might be used. Once again, it will be appreciated that numerous display apparatus might be utilized in keeping with the present inventions. Additionally, the control unit 10” is illustrated as including a piezo alarm 78 for providing audible alerts to the user.

The control unit 10” is further illustrated as including an ETA 232C asynchronous communications port 80 on the microprocessor 64 for enabling communications with the devices remote from the control unit 10”. It will be
appreciated that more than one communications port might be present and/or that multiple communication protocols might be utilized. There are several uses to which the communications port capability can be applied. For example, information can be downloaded from the microprocessor memory 68 to a printer/plotter for printout of selected information. In addition, data might be downloaded from the memory 68 of the microprocessor 64 to an external storage device having removable media so as to enable transfer of the data to a remote location. Yet in other embodiments, a communications port might provide for wireless transmissions from the microprocessor 64 to a remote host such as a microcomputer in the doctor's office or clinic. The communications port 80 might provide for interconnection to a modem such that the user patients can download data into their doctor's computer system by use of to modem from their home or office. Still another application for a communications port would be to enable direct electrical connection between the microprocessor 64 and another computer. This would allow downloading of data from the memory 68 of the microprocessor 64 by interconnecting the microprocessor 64 to a suitable computer. For example, the user patient might come into the clinic on a periodic basis and have a technician connect the control unit 10′′ to a suitable computer in the clinic and download the data for analysis by the doctor while the user patient was at the clinic or at some later time. It will be appreciated that while the elements shown in Figure 15, and discussed hereinabove, are described in terms of the embodiment shown in Figures 11-14, similar elements can be incorporated in the embodiment shown in Figures 3-10, and also in the embodiment shown in Figures 1 and 2 to the degree such elements are individually or collectively applicable thereto.

Referring now to Figures 16A through 16C there is illustrated a functional flow diagram of control logic for
an orthopedic device in accordance with the principals of the present invention. It will be appreciated that numerous embodiments of the control logic might be implemented and yet be in keeping with the principals of the present invention. Moreover, various levels of capabilities and features can be incorporated into the control logic so as to provide the orthopedic restraining device 2' with a wide range of features and applications. In the embodiment shown, the control logic is embodied in a control program 82 stored in the memory 70 of the microprocessor 64. In the embodiment shown, thirty-two kilobytes (32kB) of memory storage is used for both data and the control program 82.

During typical operation, the control unit 10' will be in an idle state requiring minimal power. During this idle state, the control program 82 will periodically check the real time clock 72 to see if the elapsed time is such that it is time for the user patient to exercise. This is best illustrated in Figure 16A wherein the control program starts at block 84. At block 86 the control program will go into an idle loop for a predetermined period of time. A check is then made at block 88 to see if the elapsed time is such that it is time for the user patient to exercise. If this is the case, then at block 90 the control program 82 will summon the patient by use of an audible, palpable and/or a visual alarm. The audible alarm might be executed by use of the piezo alarm 78 as illustrated in Figure 15. The visual alarm might take the form of a flashing indicator or the like on the display 78. A palpable alarm could take the form of a common electromechanical vibrator 77. After summoning the patient at block 90, the control program 82 at block 92 then calls on a start subroutine illustrated in Figure 16B. At block 88, if it is not yet time to summon the patient, the control program 82 at block 94 checks to determine if the user patient has initiated an exercise. If at block 84 the user has requested initiation of an
exercise then the control program 82 calls on the start subroutine at block 92. However, if the user has not initiated an exercise, then the control program 82 returns to the idle loop. It will be appreciated that in some embodiments of the present invention, both of the function represented by blocks 94 and 88 may not be present. For example, if the doctor does not want the patient to initiate his/her own exercise, the function represented by block 94 might be deleted from the control program 82. In this case, at block 88, if it is not yet time to summon the patient, the control program once again returns to the idle loop 86. In yet other embodiments, the user patient might be allowed to initiate exercise only if the torque (foot pounds of force) selected by the user patient to be applied by the user is within a predetermined limit. If this were the case, there would be an additional logic clock to see if the related torque was within the guided limit. It will be appreciated that various alternative scenarios might be utilized and still be in keeping with the principles of the present invention.

The control logic for an embodiment of the start subroutine 92 is illustrated in figure 16B. The start subroutine begins at block 96. At block 98 the control unit 10" powers up to a full operational power level and initializes the hardware including the sensors of the orthopedic restraining device 2". At block 99, the control program 82 enters a subroutine named MAIN which is a menu display subroutine for displaying various menus on the display 76. At block 100 a main menu selection displaying various user patient options/modes of operation is displayed on the display 76. In the embodiment shown, the following options are displayed as the main menu: Help, Setup, Exercise and Statistics. The control program 82 then checks if the user patient has made a selection within a predetermined period of time; e. g., one minute, at block 102. If no user patient selection occurs within this predetermined time interval, the control program 82
then turns off the control unit 10′′, i.e., powers the control unit 10′′ down to its idle state, at block 104. At block 106 the control program 82 returns to the idle state and will remain there until it is time to summon the user patient for a scheduled exercise or until the user patient initiates an exercise. At block 108 a check is made if the user patient has selected the help option. If the user has selected the help option, then at block 110 the control program 82 displays the various help screens one at a time. The help screens will provide the user patient with the information necessary to operate the control unit 10′′. If the help option was not selected by the user at block 108, then at block 112 the control program 82 checks to see if the user patient selected the setup option. If the user patient has selected the setup option at block 112, then at block 114 the display prompts the user patient to select the number of exercise repetitions, which the user patient does at that time.

At block 116 the display prompts the user to select the force (torque) to be applied, which the user does at that time. In alternate embodiments, the force (torque) to be applied is preset by the prescribing professional. The number of repetitions and torque preferably have a default value which is preset by the doctor or prescribing professional. In some embodiments, after being preset, the user will not be able to change these default values. It will be appreciated that various parameters and restrictions might be placed on the setup functions of the control program 82. For example, the patient might be allowed to select from within predetermined parameters the number of repetitions and the force (torque) to be applied. The control program 82 might be programmed to vary the number of repetitions and force (torque) requirement throughout the user patient’s recovery/exercise term. The setup options might be limited such that the patient can only select additional exercise and not less than that prescribed by the doctor.
Moreover, the patient might be forced to select within a range of force (torque) values. In the preferred embodiment, the orthopedic restraining device 2 has an operational torque range of from zero to one thousand foot pounds. It will be appreciated that, in alternate embodiments, this range might vary depending upon the joint being exercised and/or the parameters specified by the healthcare professional. The keypad 74 will preferably include numeric keys, direction keys, and other predetermined function keys such as an enter key to enter the selected value. The selected number of repetitions, number of exercise times per day, time of day to exercise, etc. might be selected by using up, down, and sideways keys with the enter key being used to enter a selected value into the system.

Next the control program 82 checks to see if the exercise option is selected by the user patient at block 118. If the exercise menu is selected at block 118, then at block 120 the control program 82 calls on an exercise subroutine, an embodiment of which is illustrated in Figure 16C. If the exercise option is not chosen at block 118, then at block 122 the control program 82 checks if the statistics option is selected by the user patient. If the statistics option is chosen by the user patient, then at block 124 various statistical information is displayed on the display 76 with sensed stress data obtained from a prior exercise. If the statistics option was not chosen at block 122, then at block 123, the control program 82 checks to see if the user patient has selected the off option so as to exit the menu display subroutine. If so, at block 125, the control program 82 powers the control unit 10'' down to its idle state. At block 127, the control program 82 returns to the idle state. The control program 82 will then return to displaying the main menu at block 99. It will be appreciated that numerous types of statistical displays might be provided to the user on the display 76. For example, a curve might be displayed
wherein the area under the curve represents the work done (total energy exerted) by the patient during a particular exercise cycle. Yet another type of statistical display might be a display of the variance between the exercise goal and the actual exercise accomplished. Moreover, much more elaborate statistical analysis might be provided at a host computer such that upon down loading the data from the control unit 10′′, the host computer can provide a number of different statistical analyses.

An embodiment of the exercise subroutine is illustrated in Figure 16C the exercise subroutine begins at block 126. At block 128, the control program 82 initializes the exercise display presentation which is displayed on the liquid crystal display 76. At block 130, the control program 82 checks if the user patient has begun an exercise repetition. This is determined by sensing a force (torque) being exerted by the user patient in the proper direction. Once the user patient has started a repetition at block 132 the control program 82 will take a predetermined quantity of signal readings as received from the analog digital convertor 62 and average them. At block 134, the control program 82 will display the readings from the strain gauges as the strain sensed by the strain gauges 8. In one embodiment, the signal readings are averaged. The averaged signals are then displayed as a bar graph or a histogram on the display 76. At block 136, the control program 82 sounds a tone at a frequency corresponding to a percent of the targeted exercise force (torque) be exerted by the user patient and will sound a continuous tone if the user patient achieves the targeted exercise force. At block 138 the control program 82 will check to see if the user patient has finished a particular repetition. If not the control program 82 will continue to take readings and averaging them. If the repetition is finished, then at block 140, the control program 82 will check if the user patient has completed the number of repetitions designated by the
doctor and/or selected by the user patient. If the user patient has not finished his/her repetitions, then at block 142 the repetition counter is incremented and the control program 82 continues taking readings. Between repetitions, the control program 82 calculates the work or energy exerted by the user patient and might display the energy exerted as a percentage of the targeted energy amount. Stress data obtained during the exercise is saved or recorded for subsequent statistical analysis, displaying, recording and/or downloading to another computer. If the user patient has finished the designated number of repetitions, then at block 144 the exercise program 82 returns to the start program in Figure 16B at the location where it initiated the exercise program such that the start program continues its normal execution and will check at block 122 to see if the statistics option was chosen.

From the above discussion it will be appreciated, that the control unit 10'' might have various levels of functions. In the most basic configuration the control unit 10'' might simply indicate sensed stress, display data and/or store data. Additionally, although in the preferred embodiment of the control unit 10'' mounted on the housing 4'' includes all the features shown in Figure 15, it will be appreciated that some of these features might not be present and/or that other features might be contained in a separate ambulatory housing which is interconnected to the control unit 10'' when desired. For example, the keyboard and display features might be present in a separate hand held housing. Alternatively, the entire control unit 10'' can be wired or wirelessly interconnected for receiving outputs from the strain gauge or gauges 8'', and/or other elements of respective embodiments of the present restraining device, only when desired by the user.

A primary problem in orthopedic surgery is the complexity with which weakness, muscle weakness in
particular, compounds pain or other injury. A person who has, for example, a patellofemoral problem may be able to tolerate the pain which the patellofemoral problem causes, but they cannot tolerate the long-standing weakness which results from a patellofemoral problem, especially when that complicates the pain. The person in this circumstance is then in a double bind. They cannot use the knee for active daily living because it is weak, and they cannot do exercises to strengthen the knee because it is painful.

The concept behind the present invention is the separation of motion from pain so that effective exercise can be accomplished. In the example discussed immediately above, exercise is performed with the knee at rest, taking advantage of the knowledge that an isometric exercise performed at a series of different degrees of flexion will result in effective strength improvement throughout the entire range. This basic concept is applicable to other joints as well, including but not limited to the ankle and elbow.

In order to gain a fuller understanding of the problem and the proposed solution, we will continue with a discussion of a patient who has sustained an injury to the anterior cruciate ligament of his or her knee. A specific twisting mechanism ruptures a ligament within the knee; some bleeding and pain result. Common treatment for this injury is to immobilize the entire knee in an attempt to protect the knee from (1) further ligament injury; and (2) the pain and disability which result from the secondary swelling and fluid collection. However, total knee immobilization will result in deterioration or disuse changes in the muscles, connective tissues and surrounding bone. Strictly speaking, immobilization of the knee is unnecessary so long as the ligament is not further damaged. Therefore, what is really necessary is to maintain control of the knee while it is being exercised. It is for this reason the present proposal is advanced.
A further example is illustrated by a six-year old child with a long oblique fracture of the distal tibia. This fracture must be immobilized and protected from weight bearing. However, because of the nature of a child, simple instructions to avoid bearing weight on the leg, can go unheeded, thereby resulting in possible deformity and disability. A device to remind the child that such stresses are not allowed would be very helpful. If the present invention is provided with a load cell to sense such a load, a signal from a control device interconnected with the load cell could be programmed to alert the patient and/or the physician that inappropriate stress has been placed on the leg. Data from the load cell can also be recorded. The device 2 shown in Figure 1 includes such a load cell 14 which can have the specific characteristics of any of the commonly available commercial load cells.

Another example would be an isolated medial collateral ligament tear of the knee. This is inherently a stable injury when appropriately protected. Some motion would be allowed and some muscle contraction would be allowed. However, at this time, no method is known to both support the extremity and provide the patient and doctor with enough feedback to allow cautious, protected strengthening and motion exercises to proceed.

An additional example would be an upper tibial fracture or osteotomy. If this were of the stable type, it would be surrounded by healthy tissues and healthy muscles at the outset of the injury or surgery, and motion and strengthening exercises could be allowed. What is currently keeping a patient from doing such motion and strengthening exercises is the lack of a sophisticated device to both maintain position and to monitor strengthening exercises.

An upper tibial fracture theoretically could be formed in several ways. It could open like a book, it could be distracted, or it could rotate one fragment upon the
other. Current treatment for this injury is to immobilize the extremity in a cast. This prevents translation and rotation, and the normal muscle contraction prevents distraction of the injury.

The ankle is a similar situation. The mortise of the ankle is actually a stable configuration. There is a buttress medially and laterally, and there is a curved surface into which the talus dome fits snugly. A person who inverts or rolls on the ankle may tear the ligaments on either side but normal muscle tension prevents translation of the talus. This is because the talus sits within these conforming structures. Treatment for such an injury is to immobilize the entire extremity in a cast. This results in atrophy of the calf muscles, atrophy of the surrounding bone, weakness and probably some slower healing of the injured ligaments. Clearly such strict immobilization is not necessary and probably is detrimental. It would be much preferable if such an injured ankle could be placed in a device which would both support the injury, encourage cautious protective motion or strength and finally monitor the degree of motion or strength as it occurs and any gains which may result from exercise.

It is known that bone should be exercised. It is believed that weight bearing applied to certain healing fractures may cause the fractures to heal faster and more predictably than if the fracture is not stressed at all. Similar responses are also believed to be expectable for connective tissues such as ligaments and articular cartilage. Following his or her evaluation of an injury or disability, the doctor or prescribing professional makes a determination as to whether or not exercise will be allowed. Exercise is allowed when it is known that the injured tissue is stable and that exercise can be performed in a controlled manner. The problem which arises is that the physician or prescribing professional does not have adequate data to be assured that proper
control can be maintained. The amount of force the patient can exert voluntarily is unknown and mechanisms for monitoring the exertion of force have, heretofore, been inadequate or nonexistent.

There are also injuries which are unstable. The cast applied to an unstable fracture cannot always protect it from deformity and collapse. Comminuted fractures of the tibia are an example of this. Such a proposed device would not apply to comminuted fracture of the tibia or similar injury unless it would be to surrounding structures which could safely be moved or exercised. The converse of such a device may be useful in that it would detect unwanted strains or stresses placed upon a potentially unstable injury reminding the patient and protecting from deformity which might otherwise occur.

The simplest and crudest method of protecting an injury at this time is the cast. This allows no movement, it allows no strengthening and it provides no data to the physician or patient. The cast is used when motion is not allowed, it is true that motion is most physiological for connective tissues but it is not always possible when control of the healing injury is necessary. Casts are associated with what is called cast or fracture disease. This is weakness of the muscles, atrophy of the muscles and bond and stiffness of the related joints. Some of these problems may be permanent. Other problems with cast immobilization include a possibility of developing phlebitis (the formation of blood clots), pressure sores or skin pressure changes. The resulting atrophy of connective tissue muscle or bone proximate the joint or injury, further results in weakness and/or stiffness of the joint and, finally, pain. It is not comfortable to have an extremity unnecessarily immobilized in a brace.

The next simple step in the mobilization of injuries has been to add a hinge to a cast. This does allow movement but it does not allow the patient to perform any strengthening and again it has not provided the patient or
physician with any data. It would therefore be helpful if a cast brace could be instrumented in such a way that stresses within the brace could be monitored. It has always been a problem that the patient could not make the distinction between exercising the extremity without motion but still derive the benefits of exercise as if it had been performed with motion. The joint can be moved carefully but it cannot be moved forcefully.

Another example would be the debility and pain which follows a meniscus tear. The meniscus normally is a wedge-shaped structure which sits within the knee. It moves out of the way with flexion and extension of the knee. This, however, cannot occur if there is a tearing of the meniscus or some other type of joint damage. This tear of the meniscus results in pain, mechanical blockage or possibly retearing and further injury. Therefore, when the patient attempts to rotate the femur against the tibia, the tear in the meniscus results in abnormal joint stresses and possible further injury. The same problem exists following repair of such a torn meniscus. The patient attempting to move the knee under unprotected and unmonitored conditions may redisplace the sutured meniscus tear. On the other hand, the knee may be able to bear the weight of certain types of exercise without motion or it may be able to bear the motion of certain types of exercise without weight or compressive force even though, it cannot bear the compressive forces and the motion together. There are two components of exercise, compressive force and motion. The present method would assist the patient to separate these two components.

An additional problem exists within the failure of longitudinal structures. A patellar tendon, for example, if it is disrupted, is not adequately protected by surrounding the leg with a cast. It is a common problem in patellar tendon disruptions (or quadriceps disruptions or similar injuries) that the patient will attempt to move the extremity with a contraction of the associated muscle.
even though the tendon is damaged. This can result in further damage or can result in disruption of an attempted repair. At this time, it is simply suggested to the patient and they are reminded that they should not attempt to elevate the extremity. However, this is often not adequate. Normal reflex mechanisms cause the quadriceps muscle (in this case) to contract with hundreds of pounds of force which can cause these casted repairs to disrupt in the cast. For this reason, then, a device is necessary which could remind the patient that the extremity is being stressed in an impermissible way. It needs voluntary protection but it can only get that protection if the patient understands and is reminded in some way that the stresses are occurring.

An additional problem is that which results from the collection of blood within an immobilized extremity. Blood clots result and sometimes embolize to the lungs, creating serious medical problems. It would be of benefit to the patient if some type of reminding device could be placed in the cast or adjacent to the cast so that they could be reminded to exercise the calf muscle (in this case) pumping the blood, maintaining flow and preventing some of these serious medical problems. This could be done with certain types of stable injuries.

Oftentimes, the patients simply forget to do the exercises which are considered important. Patients are distracted by their activities of daily living and it is simply possible to forget about the extremity within the immobilization. When it is determined that exercise within protection is necessary, it would be most effective if the patient was both reminded by the protecting device and monitored as they execute the necessary activity.

It is known that patients who have fracture of the distal radius, adjacent to the wrist, may have long-term stiffness resulting from the immobilization of the fracture itself. In other words, if a patient has a wrist fracture and a cast only goes to the wrist leaving the
fingers exposed, because of swelling which results from the injury, because of the pain which prevents active use, because of the forgetfulness of the patient and possibly because of the ignorance of the patient in understanding how important most exercises are: permanent stiffness can result. The fracture of the distal radius is particularly common in elderly patients who have osteoporosis. These elderly patients commonly have degenerative changes of the adjacent finger joints and the failure to move these joints during a period of protection (even when the fingers are not immobilized) results in permanent stiffness.

In summary, the physician would determine when stress can safely occur. This would be allowed when the injury is stable, when pain is controlled, and if the stress and motion to the area are controlled. Under these conditions, the doctor or medical professional would almost certainly conclude that stress to the tissues can occur safely and should be permitted. Controlled stress to injured tissue has been shown to result in facilitation of healing, less muscle atrophy, and the prevention of scar tissue with maintenance of normal, healthy connective tissue. Current methods have often failed. Rehabilitation is often forgotten while a patient is in a cast. The cast immobilizes the patient unnecessarily, resulting in atrophy, tissue damage, debility and stiffness.

The simplest solution to address these problems would be to provide a cast with elongated restraining bars, a strain gauge and some type of recording device. The device 2 would include a strain gauge 8 interconnected to an electronic monitoring or control unit 10. The electronic monitoring or control unit 10 would preferably allow the patient and the physician or therapist to monitor the following:

1. Maximum stress exerted.
2. The quality and duration of contraction.
3. The improvement of the person's strength over time.
4. Any unwanted movement (if flexion was occurring when only extension was desired or when translation of the bone was occurring when protection from translation was desired).

The present invention will be further described in accord with the following Examples.

I. THIRD DEGREE MEDIAL COLLATERAL LIGAMENT SPRAIN

The term third degree medial collateral ligament strain signifies complete disruption of the medial collateral ligament. It is a significant injury. The normal hinge motion of the knee is no longer constrained side to side. This is usually treated by a cast or immobilization for three to six weeks (leg is at rest). This treatment program has the disadvantage that the patient's cartilage and muscle are not exercised.

In accord with the present invention an instrumented cast similar to the restraining device shown in Figures 1 and 2 would be provided as follows:

- Application of a cylinder or long leg cast incorporating two elongated restraining bars, generally as shown in Figures 1 and 2, with the knee at approximately 35 degrees of flexion. Each of the elongated restraining bars is equipped with a plurality of strain gauges in the same general configuration as shown in Figures 1 and 2. The strain gauges are interconnected with a control unit across the knee of the cast which monitors and records outputs from the strain gauges reflecting minute deformations of the elongated restraining bars and the cast. The control unit will remind the patient to exercise at certain times and will allow the patient to monitor the results of the exercise. The control
unit will also process the outputs from the strain gauges to provide the following information: (1) Maximum quadriceps contraction (which initially may be small in light of the patient's pain, but desirable); and (2) Maximum strain to signify the degree of contraction that the patient is able to exert.

Advantages of such a device include but are not limited to the following:

(1) It would encourage the patient to begin using the extremity in this very controlled circumstance right away. Some benefit to healing the fracture has been demonstrated once exercise can be accomplished.

(2) A person at the end of a period of cast immobilization would be expected to have more quadriceps strength, less measurable atrophy and some improvement in their low speed extension of the muscle of the knee.

(3) Preferably, the device could be set up to monitor both quadriceps and hamstring function. A second alternate device could also be placed at the ankle for those patients in a long leg cast to exercise the calf, both anterior and posterior muscle groups.

II. PATELLAR TENDON DISRUPTION

Patellar tendon disruption is a special problem in that absolute rest of the quadriceps muscle is necessary. The quadriceps is a very powerful muscle and its tendon, whether surgically repaired or allowed to heal without surgery, should have no tension placed through it. This is because tension may disrupt the healing. It is difficult to prevent the patient from contracting the muscle because it is so normal to do so. Even slight contractions can exceed the amount of allowable force.
This injury is ordinarily treated in a cast or immobilization (with the knee near full extension) to rest the tendon. Such treatment is usually necessary for approximately six weeks with physical therapy to follow. Treatment for such an injury would include:

- Application of a long leg cast including elongated restraining bars, with the knee near full extension. A strain gauge or similar device to detect and warn the patient of unwanted strains coming across the knee. It is desired that the patient not contract the quadriceps muscle, but some patients will do this anyway since it is easy to lift the leg into bed, or lift the leg when they begin to stand. This produces an unwanted contraction of quadriceps muscle, therefore, it would produce unwanted deformation of the cast which could be detected by such a device.

Benefits to the patient: The strain gauge would be placed at the knee to monitor this unwanted quadriceps contraction. The computerized device monitoring the strain gauge would emit some type of warning tone or signal to the individual should they contract the quadriceps muscle against the physician's advice. A patient treated in this fashion would stand less chance of accidentally disrupting their patella tendon. This is particularly important following surgery, when all that may support the repaired tendon is suture. Such sutures cannot hold up against the several hundred pounds of contractile force which the quadriceps muscle may exert.

III. SEVERE BIMALLEOLAR ANKLE SPRAIN

Bimalleolar ankle sprain is an injury of both collateral ligaments at the ankle. The sprained ankle is held together under normal tension by contraction of the anterior and posterior muscle groups but cannot support
sideways force (such as one exerts on a twisted ankle) because of disruption of the ligaments. It is usually treated for four weeks in a cast to allow the severe tissue damage to heal. With the prior art method of treatment, weakness of the surrounding musculature may result. It would, however, be desirable to exercise the ankle while it is in the cast.

An instrument cast to treat such an injury would include the following features:

(1) A strain gauge type restraining device including a pair of opposing restraining bars across the ankle joint.

(2) A monitoring device in the form of small electronic circuit which would remind the patient to forcibly extend the ankle (bring the foot up) or plantar flex (push the foot down into the toe point position).

(3) The patient would be reminded at various periods of the day that it would be important for them to exercise the various muscle groups. Some muscle groups such as the peroneal muscle group or posterior tibial muscle group whose functions cannot be isolated to a simple anterior or posterior deforming course could also be encouraged by such a device. The patient treated in such a cast would have the advantage that they will have exercise for their muscles during the course of their immobilization and it would not easily be forgotten that these exercises are necessary and important. The patient would have the benefit of the additional muscle strength at the end of the period of immobilization and further recovery would be hastened.

IV. LONG LEG CAST, ANKLE EXERCISE DESIRED

The patient with a tibia fracture or foot and ankle injury which may be in a long leg cast would be
optimally treated if they could exercise the calf musculature (both anterior and posterior musculature) to minimize stiffness and optimize venous flow. Exercise of the musculature has the effect of "pumping" the blood through the veins. This prevents venous stasis and theoretically should lessen the incidence of thrombophlebitis and venous obstructive problems. An example would be a stable transverse distal tibia fracture. Such a person is ordinarily in a significant amount of pain following such a fracture, and would probably be in a cast for three to four weeks before an alternate form of immobilization, either in the weeks before a removable brace or a short leg cast, is appropriate.

A person treated for a distal transverse tibia fracture would be treated in the following manner. A long leg cast would be applied with the knee at approximately 35° of flexion and the ankle at neutral dorsi/plantar flexion. Restraining bars would be incorporated into the cast, and strain gauges would be attached thereto and interconnected to a control unit. The cast could incorporate elongated restraining bars crossing both ankle and knee. In this case, a separate strain gauges would be placed at the ankle in addition to those at the knee. The patient would exercise the ankle when suggested by an alarm mechanism in the form of a vibration or a tone in the cast. The patient would attempt to dorsiflex the foot or ankle in this example; five or ten repetitions upwards, followed by five or ten repetitions downwards. This would cause the deep calf musculature to pump the blood through the veins, the course of which is normally augmented by muscle contraction.

The patient using this device would benefit from it in the following ways:

1. The patient would derive some direct strengthening of the calf musculature by the
effect of an isometric exercise in this protected situation.

2. Improvement in the patient's strength would be monitored by the electronic or mechanical measuring device. Such information could be stored over time to develop long-term trends.

3. The patient would likely have less chance of venous stasis and subsequent thrombophlebitis. Calf pumping exercises are commonly used when a patient is recumbent in bed following many types of surgeries such as total hip surgery, and its effect is generally recognized.

Use of such a monitoring device should improve the care of the tibia fracture by minimizing the chances of complications such as thrombophlebitis and maximizing the chance of early rehabilitation through strengthening.

V. STABLE COLLES' FRACTURE OF THE WRIST

Colles' fracture is a transverse fracture of the distal radius, usually defined as within two inches of the distal joint surface. It is a common fracture and often results from a fall on the extended forearm. Patients are often immobilized for a period of six weeks following such an injury. Very few other forms of protection and treatment are available. Stiffness in the wrist and weakness of the forearm musculature are common problems following treatment of Colles' fractures. Stiffness of the hand and fingers is a problem as well.

The patient treated in an instrumented cast or restraining device of the present invention would have either a long arm or a short arm cast applied across the wrist for this fracture. A restraining bar including a strain gauge of some type would be placed at the wrist, possibly dorsal, possibly volar, possibly radial or ulnar.
The patient attempting to extend the wrist in either palmar flexion or dorsiflexion could be monitored. Certain stable injuries should be very amenable to attempts at forceful muscle contraction. The patient treated in this fashion would benefit from treatment in the following ways:

1. They would tend to have less muscle atrophy because the forearm musculature would be exercised in a monitored fashion within the cast.

2. The patient and physician would have the benefit of monitoring any strength gains by the availability of the direct digital readout.

3. Circulation through the forearm may be enhanced by the pumping action of the forearm musculature.

4. Attendant accessory musculature such as the tendons extending to the fingers, would be exercised as a result of the reminding mechanism. This should forestall much of the hand stiffness which commonly occurs with treatment of these fractures.

VI. MENISCUS REPAIR

A person with a repairable meniscus sometimes undergoes a surgical procedure where the meniscus is sewn back to its bed. The meniscus is normally a c-shaped wedge of tissue which is attached at the outside edge to the ligaments surrounding the knee. Certain types of meniscus tears result in pulling away of the meniscus from its attachment. The meniscus provides a weight bearing function as well as a lubricating function and shock absorbing function within the knee. Disruption of the meniscus is a serious long-term problem. In the past several years, meniscus repair has been advised as a method of preserving its function. This involves a surgical procedure where the meniscus is sewn back, usually by arthroscopy. Twelve weeks of protection for the meniscus are necessary. The first six weeks of this
are usually in a cast. The second six weeks may allow motion of the knee, but without weight bearing. The repaired meniscus can bear cautious motion of the knee but cannot bear any motion of the knee under weight bearing. Weight bearing and combination of motion may wrench the meniscus and tear it from its bed.

In accordance with the present invention this person would be equipped with a restraining device or brace including a pair of elongated restraining bars including strain gauges and adjustable hinges. The brace would have a configuration with the following features:

- The brace would be applied to the knee, which would be adjustable at various points of knee flexion. The brace would be applied so that the patient can hold the knee securely at 5 degrees. He may then unlock the hinges and move reset them at some pre-determined point of flexion. Such a device would allow points of knee flexion at 5 degrees, 20 degrees, 35 degrees, 50 degrees, 65 degrees, 80 degrees and 90 degrees. A computerized monitoring device would both remind the patient and monitor the contractions as they occur.

The patient would use the device in the following way. At various times through the day, depending upon the literature and the experimental information, the patient will be reminded to perform a series of isometric contractions. The patient would, for example, perform 5 maximum extension contractions (using the quadriceps) with the knee at 5 degrees of flexion. The patient would then disengage the hinges and engage them again and perform 5 more extensions. He or she would work up the degrees of flexion in this fashion, until they had finally reached 90 degrees and done 5 repetitions there. A similar series of contractions could be done for the hamstring muscles.

In this way, the meniscus is protected because there is no motion which might tear the meniscus, but the
muscles are being exercised during this period of immobilization and protection. At the end of such a period of immobilization, the patient has benefited from treatment in this device. The patient's knee has been allowed movement, and should, therefore be less stiff. The patient's thigh muscle and hamstring muscle have been exercised and he should have less atrophy of the quadriceps and the hamstring muscle. Based on available information, it is suggested that the patient will have more success and easier rehabilitation from that point when motion is allowed without weight bearing. The patient is allowed to contract the muscles, but the motion and muscle action are done as separate exercises, protecting the meniscus but allowing each component of the rehabilitation to occur.

VII. SEVERE CHONDROMALACIA OR PATELLOFEMORAL DEGENERATIVE ARTHRITIS

The patient with severe chondromalacia or degenerative arthritis of the patellofemoral joint cannot actively extend their knee under resistance. The patella, which is a fulcrum for the quadriceps muscle does not have its normal ability to glide over the femur. In the past, strengthening has been done by extending the knee and lifting it off the bed as one would with a "straight leg raising exercise". The disadvantage of the straight leg raising exercise is that it exercises the knee at one degree of flexion only (full extension) and this is simply not very physiologic for patients who will use their knee at up to 90 degrees of flexion for all activities of daily living, even elementary ones such as climbing and descending stairs.

What is necessary is a method of exercising the knee at all degrees of knee flexion, without causing the patellar and femoral surfaces to rub against one another. Attempts have been made in the past to use isotonic
conditioning for this purpose, however, even at low degrees of resistance, this abrasion of the surfaces occurs and pain results so that very little conditioning can occur.

The use of a hinged device similar to that shown in Figures 3 and 4 would permit the following:

- The patient would engage the hinged brace to the leg and be allowed to exercise their knee only at six points of 5, 20, 35 and 50 degrees etc., up to 90 degrees. The patient would lock at each of these measurements and perform a series of quadriceps contraction. This would be far more comfortable than the conventional method of exercising against a moving resistance, in that no motion would be allowed between the two painful surfaces. It would be far more efficient than simply straight leg raising because it allows the muscles to work at various lengths (at various degrees of motion). The result is that some strength is gained at each of the points of flexion, and this can be translated to activities of daily living.

VIII. STIFFNESS FOLLOWING TOTAL KNEE REPLACEMENT

The person who has undergone total knee replacement commonly will have difficulty with stiffness of the knee. The orthopedist will usually send the patient to a physical therapist almost immediately following surgery for instruction and coaching in the use of the knee. This is to forestall stiffness. This has the disadvantage of course, that the patient will have coaching, reinforcement, and control only in the physical therapy setting, and many patients will simply not do the exercises as forcibly and vigorously as they would if they had support, supervision, monitoring and reinforcement.

The patient who has stiffness in their knee following a total knee replacement could be placed in the
electromechanical hinge device in the following way. The brace would support the thigh and the calf and the hinged portion would be at the level of the knee and would provide the patient with the following information:

- The device would tell them immediately at what degree of flexion their knee is at the beginning of the exercise. Active level of comfort for stiff knee is usually around 35 degrees. For the purposes of this illustration, we will use the figure of 35 degrees. The patient is to understand that they will attempt to extend their knee. Following total knee replacement, there is generally no danger limit to either full extension or full flexion, so they will attempt to fully extend their knee. As they do this, the digital readout will tell them that they have reached 30 degrees, 25 degrees, 20 degrees, 15 degrees reaching 14 perhaps 13 degrees. But with this additional feedback they are encouraged to continue reaching for the last possible degree, perhaps reaching 14 or 13 degrees with sustained effort. The patient will then attempt to flex the knee, and it will come easily back to the 30 degree starting point and with effort the patient will be able to flex their knee to perhaps 40 to 60 degrees before pain, stiffness or other limitation may hold them back. With sustained effort and reinforcement coming from the device in the form of direct digital feedback, sounds, bells, etc., the patient may be able to get an extra few degrees of flexion.

This is very much the same type of training and reinforcement which the patient gets at the physical therapists' office and after a period of several days of such active exercise, a person can be expected to maximize their motion, so they will be able to get to 10 degrees or
5 degrees (near full extension) after several days of using such a device, and perhaps flex to 90 or 100 degrees in the opposite direction (as they attempt to flex their knee maximally).

A person who uses such a device would benefit from it in the following ways:

1. They are saved the expense and inconvenience of having to be seen by a physical therapist as much, since direct feedback and encouragement and documentation of their progress will occur within the device. This could be related to a therapist or a physician over the phone.

2. They are able to participate more actively, more aggressively in their own therapy since they have a direct feedback, and more progress can be expected.

3. Since the patient will get more direct feedback and support than they would get through the therapist (if only on the basis of convenience alone) they will be able to do their exercises more frequently with greater net overall effect.

4. Since the number of repetitions will be monitored and available within the device (as one proposed method of development), it would be fairly evident whether or not the patient is complying with instructions, and whether or not some insurmountable plateau is being reached (which may help the physician with any decisions towards manipulation or other forms of therapy).

IX. RHEUMATOID KNEE STATUS POST SYNOVECTOMY

The person undergoing synovectomy for rheumatoid arthritis is a great risk for stiffness. The synovium, once removed, leaves the underlying surfaces which can form scar tissue. These surfaces can heal to one another, causing mechanical blockage or obstruction of the knee, or they can simply heal with thickened scar which creates a
resistance to what should ordinarily be smooth gliding movements.

The person who has had a synovectomy of the knee would be encouraged to move the knee as frequently as possible. This is often difficult because of pain, and a person oftentimes requires the encouragement, support and reinforcement of a therapist who can tell them how the knee is moving, help them by controlling the situation and documenting their progress.

The electromechanical hinge device would be supplied to the patient and once instructed, they could apply it to themselves, so that during the course of the day, they would perform repetitively attempts at full extension and full flexion.

As with other types of knee difficulties, the knee will want to rest in a comfortable degree of flexion. This is oftentimes at approximately 35 degrees. A person with the electromechanical hinge device in place would attempt to extend the knee as much as possible and the device would read back to them how extension of the knee is progressing, whether it is reaching 15, 12, or 10 degrees, as they attempt to regain extension, or whether they are able to reach 90, 100, 120 degrees as they attempt to flex the knee. The patient would receive direct measured feedback through the devices readout of how their motion is progressing. The device would also control the extremity for them. It would give them the encouragement and feedback that they need to get that last degree or two. This type of encouragement does tend to result in more cooperation of the patient and more strenuous effort, and ultimately, more success with such therapy. Over a course of several days, a few degrees extra each day would result in continued improvement, whereas, without the device the patient is more likely not only to not gain the extra few degrees but to lose degrees as the knee, rested inappropriately, gets stiff.
In summary, the patient who has used the electromechanical hinge will have a safe, effective method of supervision, reinforcement, and documentation as they pursue motion for stiffness following synovectomy for rheumatoid arthritis.

X. ANTERIOR CRUCIATE LIGAMENT REPAIR WITH A PRE-DETERMINED SAFE ARC OR MOTION WITH A SEPARATE SAFE ARC OF STRENGTHENING

A person who has undergone an anterior cruciate repair is allowed to move their knee within a prescribed range of motion. Usually this is between 45 and 90 degrees of flexion. A person is kept out of more flexion or more extension (by active muscle contraction), because this will strain or pull against the repair.

The electromechanical hinge could be applied to such a person's knee with benefit for two main reasons:

(1) It would monitor their motion within the prescribed flexion arc so that they would not actively attempt to extend the knee outside that arc. The hinge could be set to prevent this motion.

(2) It could monitor the quadriceps and hamstring muscle contractions to determine whether or not an unacceptable degree of force is being transmitted across the knee (which could harm the repair).

The electromechanical hinge would be applied to the knee in the following way. The hinged device would be applied to the knee with the knee at some resting degree of flexion, perhaps at 35 degrees. This is considered to be a safe and comfortable resting point following such a surgery.

The patient when reminded by the device, could release the locking device, place their knee in the
prescribed free range, between 45 and 90 degrees, and attempt to exercise it. They could attempt to exercise the knee (if this was considered safe by the surgeon) against infinite resistance at 45 degrees and at 90 degrees or at other points on the star hinge. The hinge could be locked by a time release mechanism. If difficulty is encountered moving the knee in this flexion arc, the device would monitor the improvement in flexion (by reinforcing them with a direct digital readout) until endpoint (and infinite) resistance is reached. At that endpoint, the isometric contraction would begin and the patient's strengthening will be monitored much as it would be for an instrumented cast.

The person using such a device would benefit from it in the following ways:

(1) The knee could be protected in the prescribed flexion arc and they would be allowed in a supervised way (supervised by the machine) to exercise it. This should obviate some of the need for direct physical therapy intervention.

(2) The patient would benefit from strengthening the muscles in isometric contraction at the two or more points allowed by the locking hinge. In this example, there would be an isometric contraction at 45 and 90 degrees but the star hinge concept may allow them to do resistance at not only 45 and 90 degrees, but also 60 and 70 degrees. The person therefore coming out of such a device once it is safe to move the knee in a greater degree of flexion would have more strength and be more easily able to do so.

(3) A person using the device would be more likely to get the surgeon's desired degree of mobility earlier, since it would be in a controlled and managed fashion.

(4) This brace could be their post-operative brace instrumented in such a way that it could be
applied by the surgeon for direct control immediately.

Preferably, some type of device to monitor translation of the tibia could be incorporated so that, if the repair is stressed, this device could alarm the patient.

AUGMENTING DEVICES

PROPOSED METHODS OF USE

FIVE-YEAR-OLD WITH LONG OBLIQUE FRACTURE OF DISTAL TIBIA, WEIGHT BEARING DISALLOWED

A child with a long oblique fracture of the distal tibia is a special problem since the child will not or cannot obey a medical instruction to protect the tibia against unwanted weight bearing. Shortening or deformity can result. Such a fracture is ordinarily treated in a long leg cast but cannot prevent the child from placing unwanted weight on the extremity.

A weight bearing alarm mechanism comprising a standard commercial load cell interconnected with a control unit including an alarm device is incorporated into the restraining device with the load cell located on the bottom of the cast or perhaps across the ankle so that a child bearing weight on the cast would be personally notified by some type of audible or palpable signal. Additionally, digital memory in the control unit records the number of infractions which occur for later feedback to the physician. This may be useful information in determining methods of treatment (altering the cast or the child's mobility), degree of healing and relative stability (an undisplaced fracture after multiple infractions and, in fact, be proven to be stable).

The physician and the patient would benefit from the use of an alarm mechanism to monitor a cast in a
child with a long oblique fracture of the tibia in the following way:

- The compliance of the individual is monitored and direct evidence is available to the physician as to whether or not further changes in the treatment program are necessary and whether or not compliance with the plan is present.

**TIME RELEASE MECHANISM FOR RANGE OF MOTION CONTROL**

A person who has undergone anterior cruciate reconstruction or other types of ligament surgery about the knee is allowed only a certain degree of movement immediately after the surgery. The amount of movement allowed at the knee is gradually increased until the patient is approaching near full extension and near full flexion at 6-12 weeks post surgery.

There has always been some confusion as to exactly how fast the patient may progress. There is not a lot of literature data to support exactly what degree of freedom will protect the repair. Most orthopedists doing this type of surgery do believe that active extension against resistance near full extension may disrupt the repair, so most surgeons do not allow this initially.

The proposed augmentation of the electromechanical hinge device includes a time release mechanism such that a computer control unit interconnected with the electromechanical hinge would, with its internal clock, allow 45-90° of flexion, let’s say, at one week; 35-90° at two weeks; 25-90° of flexion at three weeks; and so on until the patient gradually reaches full extension.

At the present time the patient with such a hinge must report to the doctor's office to have the hinges adjusted, and sometimes this results in rather marked limitation in a patient’s ability to move the knee. For example, a patient may go from an allowable flexion arc of
45-90° to an allowable flexion arc of 15-90° at two or three weeks. This sudden release of the knee from such constraints is uncomfortable and the patient is pushing against more stiffness than if the knee had been allowed to release gradually. This results in a certain degree of discomfort.

A person with a time release hinge would be benefited in the following ways:

(1) An electromechanically hinged brace would be applied to the knee following ligament reconstruction surgery, with the physician's desired protocol for motion programmed into the control unit of the brace.

(2) The brace would allow the patient to move the knee in the desired flexion arc immediately after surgery. Alternately or preferably, the brace may be locked by the time mechanism initially so that the patient may have comfort during the early post-operative period when pain is most acute.

(3) The patient would be discharged from the hospital and the knee motion would be gradually regained at the expected rate by the surgeon's instructions as it is programmed into the brace. The patient may then be able to maintain contact with the physician over the phone, discussing how the motion is progressing within the brace, having direct digital readout and feedback through the computerized device.

(4) The patient would have, at the end of the period of immobilization, a more limber knee, a more efficient period of immobilization.

(5) The patient would probably have less discomfort since the allowable motion is returned to the knee gradually.
During the course of immobilization in the incrementally adjustable hinge, whether or not controlled by the timing mechanism, the patient may be able to lock their knee at various degrees of flexion, perhaps at 15 degree intervals, so that they can perform isometric contraction, gaining strength within the allowable flexion arc. This would be an application of the incrementally adjustable hinge concept within the electromechanical hinge concept. A combination of the incrementally adjustable hinge concept, the electromechanical hinge concept and the timing mechanism concept would be greatly advantageous to such a patient. Their pursuit of strength and motion would be optimized within the constraints of the needed immobilization and protection.

It is to be understood that even though numerous characteristics and advantages of various embodiments of the present invention have been set forth in the foregoing description, together with details of the structure and function of various embodiments of the invention, this disclosure is illustrative only, and changes may be made in detail, especially in matters of shape, size and arrangement of parts within the principles of the present invention to the full extent indicated by the broad general meaning of the terms in which the appended claims are expressed.
WHAT IS CLAIMED IS:

1. A personal orthopedic restraining device for use to restrain flexibly connected body portions of an individual, said personal orthopedic restraining device comprising:

   (a) an ambulatory housing including first and second distal end portions, said respective end portions being configured to receive respective flexibly connected body portions of the individual, said housing further including restraining means for restraining movement of said first and second distal end portions relative to one another, whereby movement of respective body portions relative to one another can be restrained by said housing;

   (b) stress sensing means for sensing stress on said restraining means and for providing outputs representative of the sensed stress, said stress sensing means being attached to said restraining means; and

   (c) control means for indicating sensed stress based upon outputs from said stress sensing means, said control means being interconnected with said stress sensing means for receiving outputs from said stress sensing means, said control means further including programmed processing means for processing outputs from said stress sensing means in a previously prescribed manner and memory means for retaining processed data respecting outputs from said stress sensing means, said programmed processing means being interconnected with said stress sensing means for receiving outputs from said stress sensing means and said memory means being interconnected with said programmed processing means for receiving data from said programmed processing means respecting outputs from said stress sensing means, said
programmed processing means having the capability of retrieving said retained data for further processing subsequent to receipt and retention by said memory means, wherein said personal orthopedic restraining device is an ambulatory appliance which can be worn by the individual to prevent specific movements of respective body portions restrained thereby relative to one another, and wherein stress on said restraining means can be monitored with said indicating means.

2. The personal orthopedic restraining device of claim 1 wherein said restraining means include an elongated restraining bar having first and second distal end sections, wherein said first and second distal end sections are fixedly secured to said first and second distal end portions of the housing, respectively; wherein said elongated restraining bar includes an adjustable hinge interconnecting said distal end sections, wherein the angular position of the respective distal end sections relative to one another can be adjusted; wherein said adjustable hinge includes position sensing means for sensing the relative angular position of said first and second distal end sections and for providing an output or outputs representative of the sensed position, said control means being interconnected with said positioning sensing means for receiving outputs therefrom.

3. The personal orthopedic restraining device of claim 2 wherein said incrementally adjustable hinge is an electromechanical hinge.

4. The personal orthopedic restraining device of claim 3 wherein said control means further include recording means for recording outputs from said stress sensing means and said position sensing means; wherein said stress sensing
means include a plurality of strain gauges, said plurality of strain gauges being attached to said elongated restraining bar.

5. The personal orthopedic restraining device of claim 4 wherein said stress sensing means include four strain gauges attached to said elongated restraining bar, said strain gauges being interconnected with one another in a wheatstone bridge circuit arrangement.

6. The personal orthopedic restraining device of claim 4 wherein said restraining means includes a second elongated restraining bar wherein each of the elongated restraining bars have first and second distal end sections disposed on opposite sides of respective flexibly connected body portions, said stress sensing means including a plurality of strain gauges attached to each of said elongated restraining bars, wherein said first and second distal end sections of each of said restraining bars are fixedly secured to said first and second distal end portions of the housing, respectively; each of said elongated restraining bars including an incrementally adjustable hinge interconnecting said respective distal end sections, wherein the angular position of the respective distal end sections of each elongated restraining bar can be adjusted; wherein said incrementally adjustable hinge is an electromechanical hinge, said electromechanical hinge including position sensing means for sensing the relative angular position of the respective first and second distal end sections of the respective elongated restraining bar and for providing outputs representative of the sensed position, said control means further including recording means for recording outputs from said stress sensing means and said position sensing means, and program means for processing outputs from said stress sensing means and said position sensing means, said control means being interconnected with said stress sensing means and from
said position sensing means for receiving outputs therefrom; wherein said electromechanical hinge further includes an electromechanical clutch mechanism.

7. The personal orthopedic restraining device of claim 1 wherein said control means include statistical display means for displaying statistical information from outputs representative of said sensed stress; said programmed processing means having a first idle state and a second operational state, wherein said control means require less power in the idle state as compared to the operational state; and wherein said operational state includes an exercise mode of operation which senses outputs from said stress sensing means and processes said outputs.

8. A personal orthopedic restraining device for use to restrain flexibly connected body portions of an individual, said personal orthopedic restraining device comprising:

(a) an ambulatory housing including first and second distal end portions, said respective end portions being configured to receive respective flexibly connected body portions of the individual, said housing further including restraining means for restraining movement of said first and second distal end portions relative to one another, said restraining means including at least one elongated restraining bar having first and second distal end sections, wherein said first and second distal end sections of each elongated restraining bar are fixedly secured to said first and second distal end portions of the housing, respectively, whereby movement of respective body portions relative to one another can be restrained by said housing;

(b) an incrementally adjustable hinge interconnecting the respective distal end sections of said
elongated restraining bar, wherein the angular position of the respective distal end sections can be adjusted relative to one another; wherein the incrementally adjustable hinge is an electromechanical hinge including position sensing means for sensing the relative angular position of said first and second distal end sections interconnected therewith and for providing outputs representative of the sensed position, said control means being interconnected with said position sensing means for receiving outputs therefrom, the electromechanical hinge further including a brake mechanism for preventing incremental adjustment of the incrementally adjustable hinge when the brake is activated;

(c) stress sensing means for sensing stress on said personal orthopedic restraining means and for providing an output or outputs representative of the sensed stress, said stress sensing means including a plurality of strain gauges attached to each elongated restraining bar; and

(d) control means including indicating means for indicating sensed stress based upon the output or outputs from said stress sensing means, recording means for recording the output or outputs from said stress sensing means, and program means for processing outputs from said stress sensing means, said control means being interconnected with said stress sensing means for receiving outputs therefrom, wherein said restraining device is an ambulatory appliance which can be worn by the individual to present specific movements of respective body portions restrained thereby relative to one another, and wherein stress on said restraining means can be monitored with said indicating means.
9. The personal orthopedic restraining device of claim 8 wherein said restraining means includes a second elongated restraining bar, wherein the respective elongated restraining bars are disposed on opposite sides of said flexibly connected body portions when engaged therewith; wherein each of said elongated restraining bars includes an electromechanical, incrementally adjustable hinge interconnecting said respective distal end sections, wherein the angular position of the respective distal end sections of each elongated restraining bar can be adjusted relative to one another; wherein at least one of said electromechanical hinges including position sensing means for sensing the relative angular position of said first and second distal end sections interconnected therewith and for providing outputs representative of the sensed position, said control means being interconnected with said position sensing means for receiving outputs therefrom.

10. A method of rehabilitating or conditioning flexibly connected body portions, said method comprising the steps of:

(a) engaging flexibly connected body portions in an orthopedic restraining device, said restraining device including an ambulatory housing having first and second distal end portions, said respective distal end portions being configured to receive respective flexibly connected body portions, said housing further including restraining means for restraining movement of said first and second distal end portions relative to one another, whereby movement of respective body portions relative to one another can be restrained by said housing, said orthopedic restraining device further including stress sensing means for sensing stress on said
restraining means and for providing outputs representative of the sensed stress, and control means for indicating sensed stress based upon outputs from said stress sensing means, said stress sensing means being attached to said restraining means, and said control means being interconnected with said stress sensing means for receiving outputs therefrom, wherein said restraining means include at least one elongated restraining bar, each restraining bar having first and second distal end sections, wherein each first and second distal end section is secured to said first and second distal end portions of the housing, respectively, said stress sensing means including a plurality of strain gauges attached to each elongated restraining bar, each elongated restraining bar including an incrementally adjustable hinge pivotally interconnecting said respective first and second distal end sections;

(b) exercising said flexibly connected body portions by applying measurable isometric force against said restraining means;

(c) monitoring stress placed upon said restraining means by said exercising; said monitoring step including monitoring sensed stress indicated by said control means by monitoring said control means; and

(d) adjusting said incrementally adjustable hinge so that the respective distal end sections pivot about the incrementally adjustable hinge in relation to one another so that an angular position of the respective distal end sections relative to one another is changed prior to repeating steps (b) and (c).
11. The method of rehabilitating or conditioning flexibly connected body portions according to claim 10 wherein said incrementally adjustable hinge is an electromechanical hinge including brake means for preventing pivotal movement of the respective distal end sections about the incrementally adjustable hinge when said brake means is activated, and wherein said step of adjusting said incrementally adjustable hinge is followed by a subsequent step of activating said brake means prior to a further step of repeating steps (b) and (c).

12. The method of rehabilitating or conditioning flexibly connected body portions according to claim 11 wherein said exercising step includes applying measurable isometric force against said restraining means in a series of repetitive isometric exercise events; and wherein said exercising step and said monitoring step are repeated following a series of repetitions of said adjusting step.

13. A method of monitoring an individual's exercise routine, said method including the steps of:
   (a) engaging first and second flexibly connected body portions of the individual in an orthopedic restraining device, said orthopedic restraining device including: an ambulatory housing including restraining means which can restrain movement of said first and second flexibly connected body portions relative to one another when engaged in said orthopedic restraining device; stress sensing means for sensing stress on said restraining means and for providing outputs representative of said sensed stress; and stress recording means for recording outputs from said stress sensing means; said stress sensing means being attached to said restraining means; and said stress recording means being interconnected with said stress sensing means for receiving outputs therefrom;
(b) requesting the individual to exert measurable isometric force against said restraining means in a repetitive series of isometric exercise events; and
(c) monitoring outputs representative of stress sensed during and in response to said series of isometric exercise events by accessing said recorded outputs with monitoring means for monitoring outputs recorded by said recording means, said monitoring means being interconnected with said recording means for accessing outputs recorded therein.

14. The method of claim 13 wherein said monitoring step includes retrieving said recording means from said individual subsequent to said step of requesting; and interconnecting said monitoring means with said recording means to access said recorded outputs subsequent to the occurrence of an exercise event for which outputs are recorded; and wherein said step of requesting the individual to exert measurable isometric force against said restraining means includes requesting the individual to exert measurable isometric force against said restraining means in a series of repetitive isometric events.

15. The method of claim 14 wherein said restraining device includes a housing having first and second distal end portions, said respective end distal portions being configured to receive respective first and second flexibly connected body portions of the individual, said restraining means including an elongated restraining bar having first and second distal end sections, said first and second distal end sections being fixedly secured to said first and second distal end portions respectively, said elongated restraining bar including an incrementally adjustable hinge interconnecting said first and second distal end sections, wherein the angular position of the respective distal end sections relative to one another can
be adjusted, said incrementally adjustable hinge including position sensing means for sensing the relative angular position of said first and second distal end sections and for providing outputs representative of said senses position, said recording means being interconnected with said position sensing means for receiving outputs from said position sensing means, said step of requesting the individual to exert measurable isometric force against said restraining means in a series of isometric exercise events including requesting the individual to adjust the relative angular position of said first and second distal end sections to different relative angular positions and to exert measurable isometric force against said restraining means in a series of repetitive isometric exercise events following each adjustment; wherein the incrementally adjustable hinge is an electromechanical hinge, said restraining device further including control means, said control means including said recording means, stress indicating means for indicating sensed stress based upon outputs from said stress sensing means, and program means for processing outputs from said stress sensing means and said position sensing means, said control means being interconnected with said stress sensing means and said position sensing means for receiving outputs therefrom, said program means being interconnected with said indicating means for directing outputs thereto, said program means including visual display means for providing exercise commands for the individual in response to a set of program guidelines and in response to outputs from said stress sensing means and from said position sensing means, said step of requesting the individual to exert measurable isometric force against said restraining means in a repetitive series of isometric exercise events including requesting the individual to respond to a series of exercise commands prescribed by said program means in response to outputs from said stress sensing means.
16. A personal orthopedic restraining device for use to restrain flexibly connected body portions of an individual, said person orthopedic restraining device comprising:

(a) an ambulatory housing including first and second distal end portions, said respective end portions being configured to receive respective flexibly connected body portions of the individual, said housing further including restraining means including an electromechanical hinge having brake means for restraining pivotal movement of said first and second distal end portions relative to one another, wherein the electromechanical hinge pivotally interconnects the respective first and second end portions, whereby movement of respective body portions relative to one another can be restrained by said housing;

(b) stress sensing means for sensing stress on said restraining means and for providing an output or outputs representative of the sensed stress, said stress sensing means including at least one stress sensing device attached to said housing; and

(c) control means for indicating sensed stress based upon outputs from said stress sensing means, said control means being interconnected with said stress sensing means for receiving outputs from said stress sensing means, wherein said personal orthopedic restraining device is an ambulatory appliance which can be worn by the individual to prevent specific movements of respective body portions restrained thereby relative to one another, and wherein stress on said restraining means can be monitored with said indicating means.
FIG. 16B

1. POWER UP & INITIALIZE HARDWARE
   START

2. DISPLAY MAIN MENU SELECTION

3. HAS ONE MINUTE ELAPSED W/O USER SELECTION
   102
   YES
   TURN UNIT OFF

4. RETURN TO IDLE

5. HELP CHOSEN?
   108
   YES
   DISPLAY HELP SCREENS ONE AT A TIME

6. RETURN TO IDLE

7. SETUP CHOSEN?
   112
   YES
   SELECT NUMBER OF REPETITIONS
   SELECT TORQUE

8. EXERCISE CHOSEN?
   118
   YES
   EXERCISE

9. STATISTICS CHOSEN?
   122
   YES
   DISPLAY STATISTICS

10. OFF CHOSEN?
    123
    YES
    TURN UNIT OFF

11. RETURN TO IDLE
FIG. 16C

10/10

EXERCISE 126

INITIALIZE EXERCISE DISPLAY 128

NO REP INITIATED YET? 130

YES

TAKE 8 A/D READINGS AND AVERAGE THEM 132

DISPLAY A/D READING AS BAR GRAPH AND A HISTOGRAM 134

SOUND TONE AT FREQUENCY CORRESPONDING TO PERCENT OF TARGET, OR A PURE TONE IF 100% 136

NO FINISHED THE REP? 138

YES INCREMENT THE COUNTER AND CONTINUE 142

FINISHED COUNT REPS? 140

RETURN TO MAIN 149
# INTERNATIONAL SEARCH REPORT

**International Application No:** PCT/US91/01212

## I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all)

According to International Patent Classification (IPC) or to both National Classification and IPC:

**IPC (5):** A61H 1/02  U.S. CL: 128/25R

## II. FIELDS SEARCHED

<table>
<thead>
<tr>
<th>Classification System</th>
<th>Classification Symbols</th>
</tr>
</thead>
</table>

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched:

## III. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of Document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to Claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A, P</td>
<td>US, A, 4, 905, 560 (SUZUKI ET AL) 06 MARCH 1990, SEE FIGURES 1-7.</td>
<td>1-16</td>
</tr>
<tr>
<td>A</td>
<td>US, A, 4, 306, 571 (McLEOD, JR.) 22 DECEMBER 1981, SEE FIGURES 1, 2, 10A-11B.</td>
<td>1-3, 8, 10, 11</td>
</tr>
<tr>
<td>A</td>
<td>US, A, 4, 586, 495 (PETROFSKY) 06 MAY 1986, SEE FIGURE 4.</td>
<td>1, 2, 8, 10, 11</td>
</tr>
<tr>
<td>A</td>
<td>US, A, 4, 848, 152 (PRATT, JR.) 18 JULY 1989, SEE FIGURES 1, 3, 5, 6.</td>
<td>1-3, 8, 10, 11</td>
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</tbody>
</table>

* Special categories of cited documents:
  - "A" document defining the general state of the art which is not considered to be of particular relevance
  - "E" earlier document but published on or after the international filing date
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  - "O" document referring to an oral disclosure, use, exhibition or other means
  - "P" document published prior to the international filing date but later than the priority date claimed
  - "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
  - "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
  - "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
  - "Z" document member of the same patent family

## IV. CERTIFICATION

- **Date of the Actual Completion of the International Search:** 22 APRIL 1991
- **Date of Mailing of this International Search Report:** 05 JUN 1991

**International Searching Authority:** ISA/US

Signature of Authorized Officer: JOE H. CHENG