



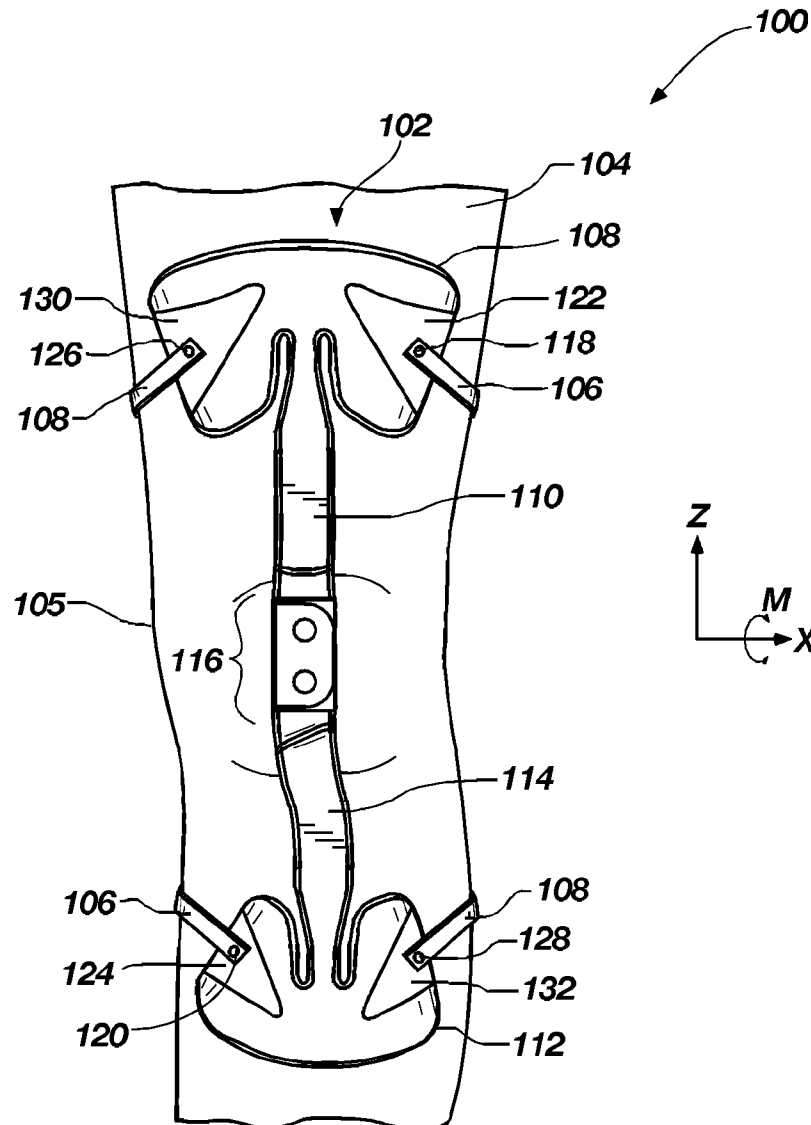
US 20120179079A1

(19) **United States**(12) **Patent Application Publication**
Sterling et al.(10) **Pub. No.: US 2012/0179079 A1**(43) **Pub. Date: Jul. 12, 2012**(54) **ORTHOTIC APPARATUS****Publication Classification**(75) Inventors: **Shane Sterling**, Seattle, WA (US);
Jay Bubnitz, Shoreline, WA (US)(51) **Int. Cl.**
A61F 5/00 (2006.01)(52) **U.S. Cl.** 602/16(73) Assignee: **BELLACURE INC.**, Seattle, WA
(US)(57) **ABSTRACT**(21) Appl. No.: **13/425,233**(22) Filed: **Mar. 20, 2012**

In one embodiment of the invention, an orthotic apparatus includes a frame structure having an upper frame portion moveable relative to a lower frame portion. The orthotic apparatus further includes at least one strap attached to the upper frame portion and the lower frame portion of the frame structure. The at least one strap and the frame structure, together, are configured to apply a therapeutic moment to a joint of a limb responsive to positioning the limb within a limb-receiving space formed between the at least one strap and the frame structure.

Related U.S. Application Data

(63) Continuation of application No. 11/975,542, filed on Oct. 19, 2007, now Pat. No. 8,167,829.



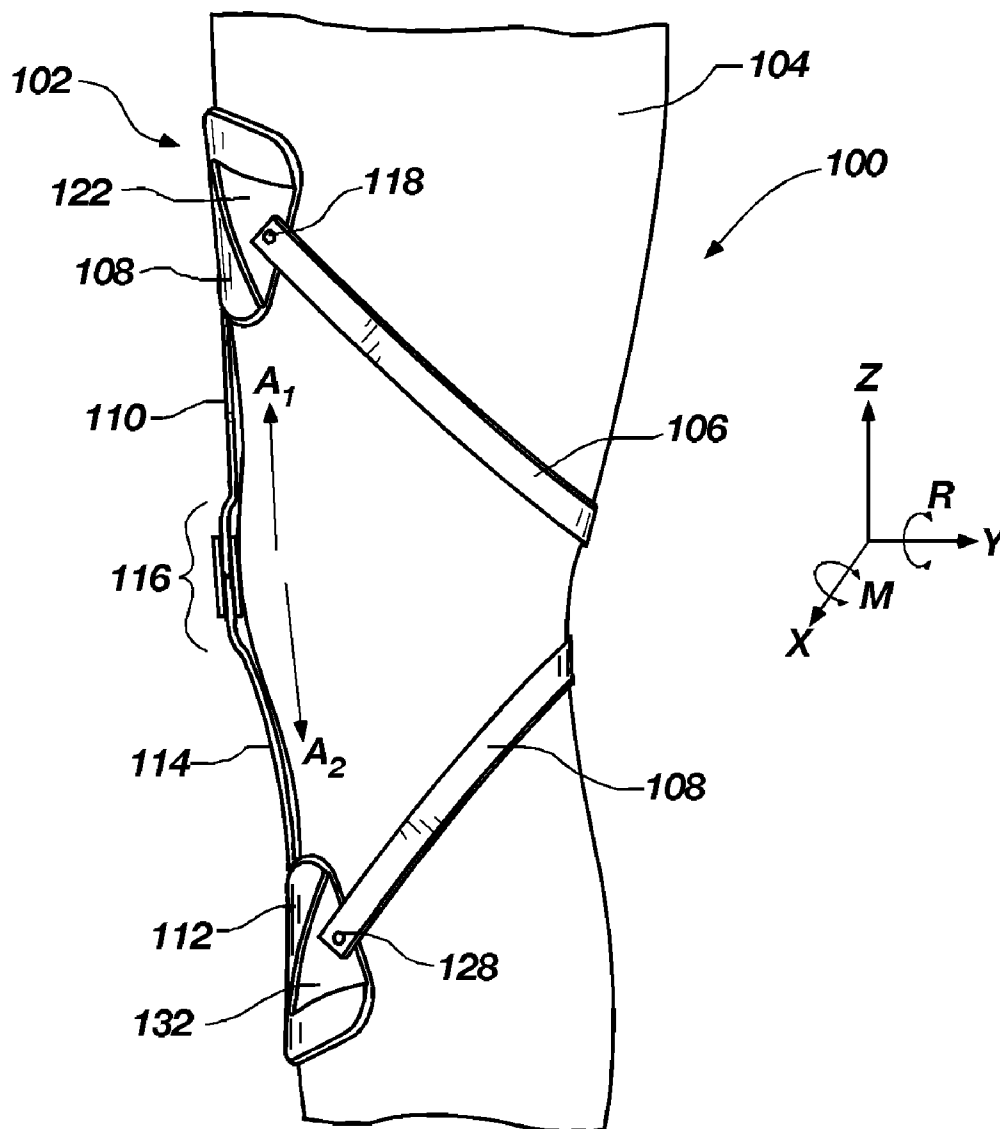


FIG. 1A

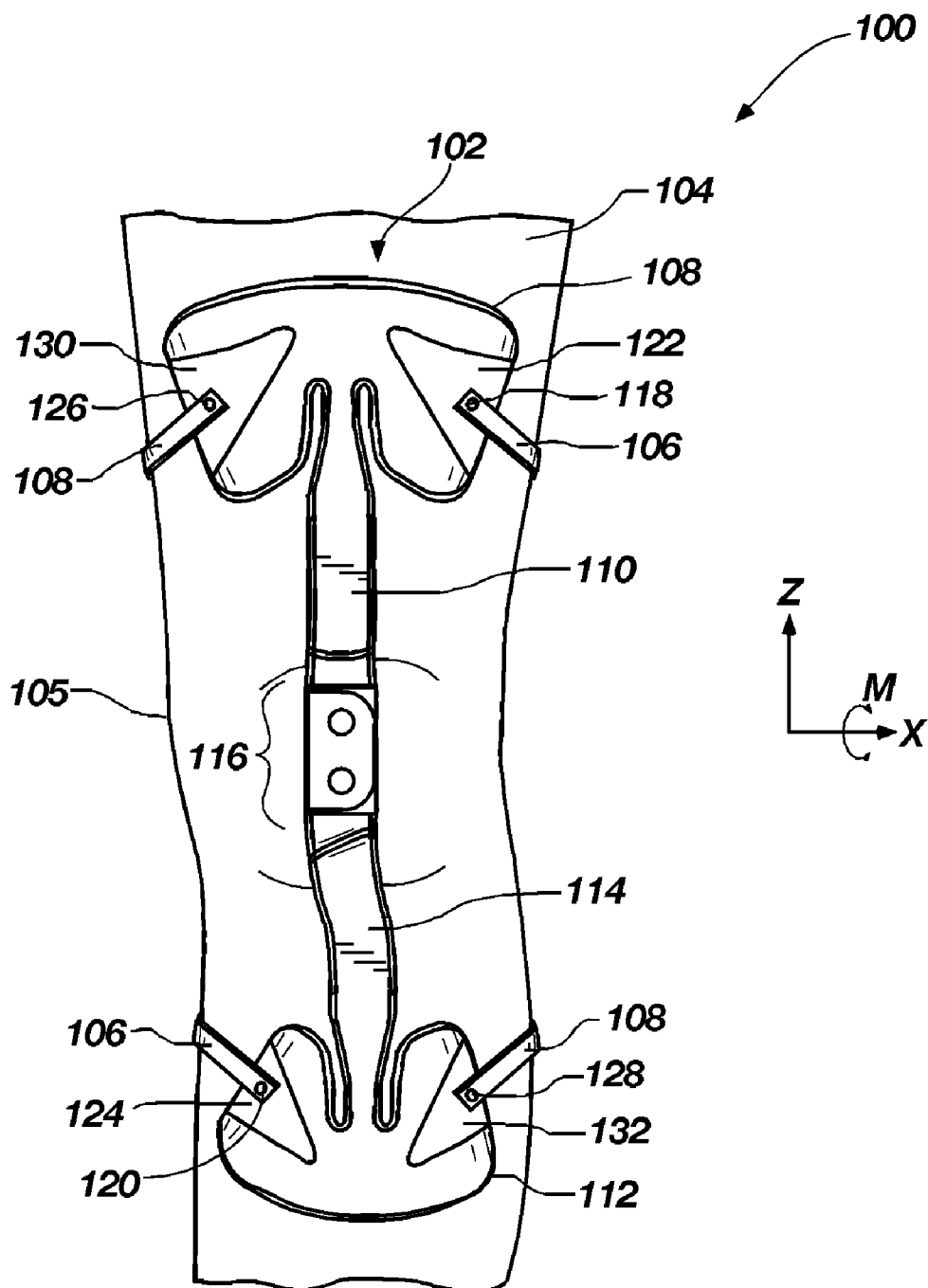


FIG. 1B

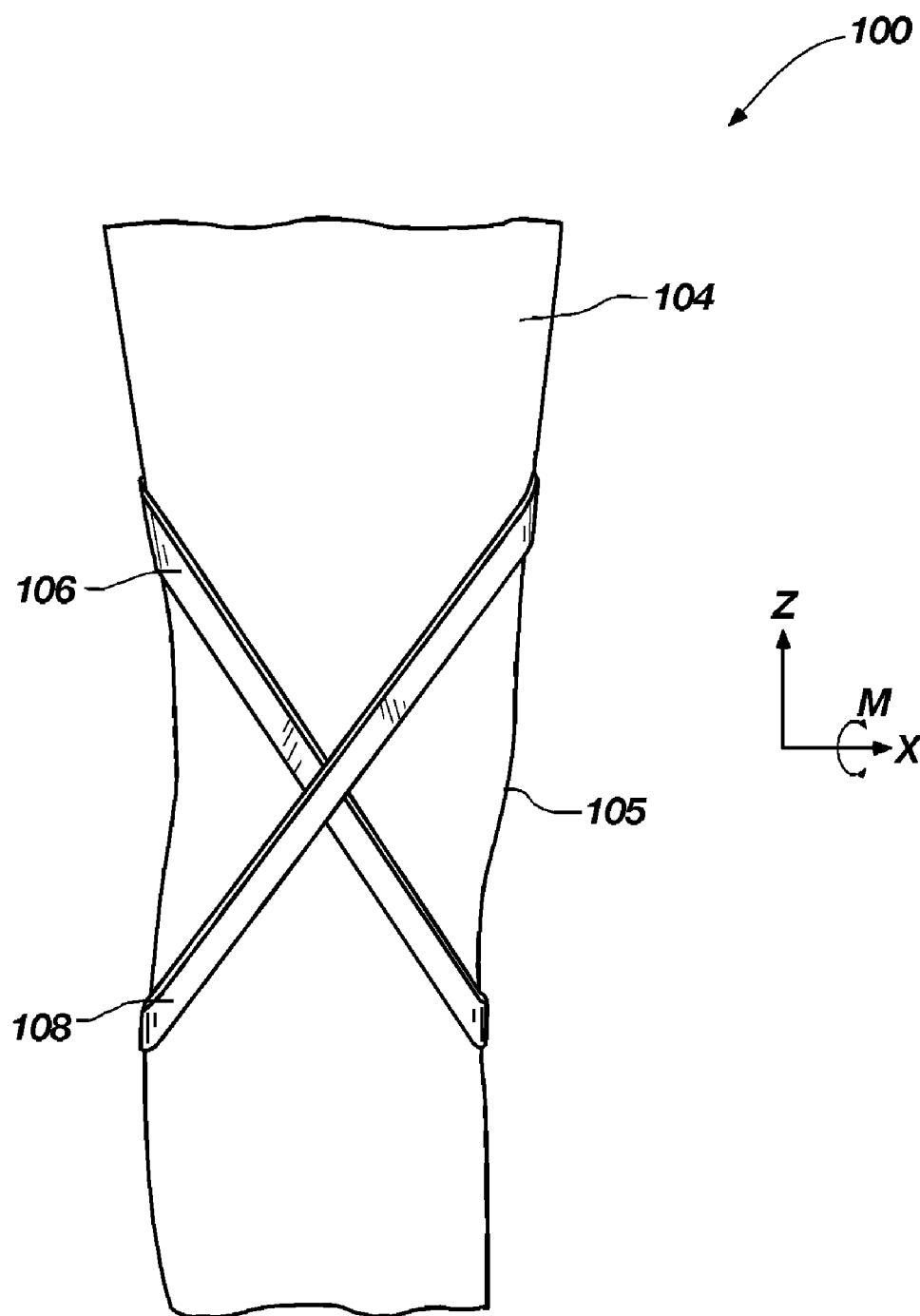


FIG. 1C

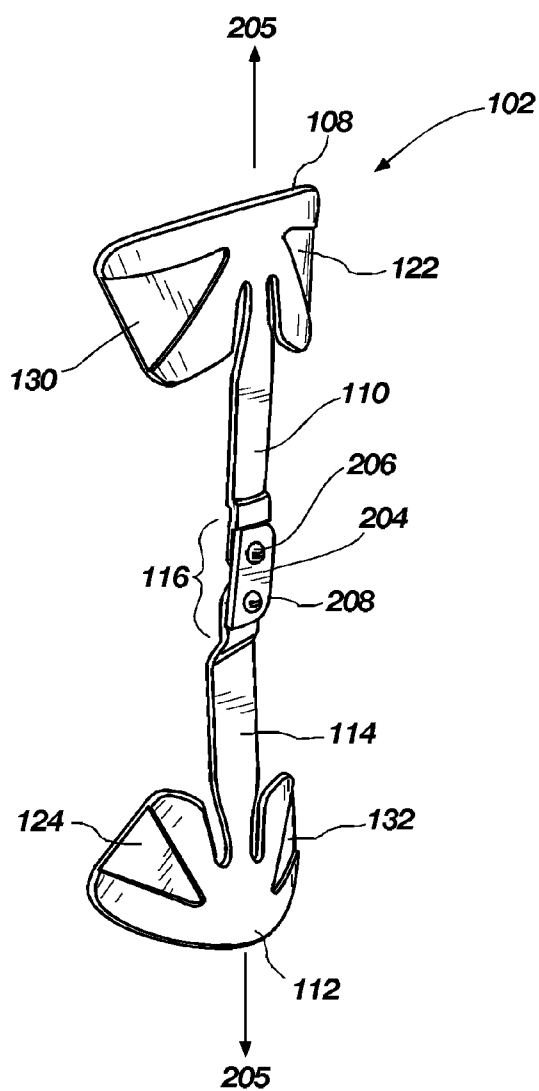


FIG. 2A

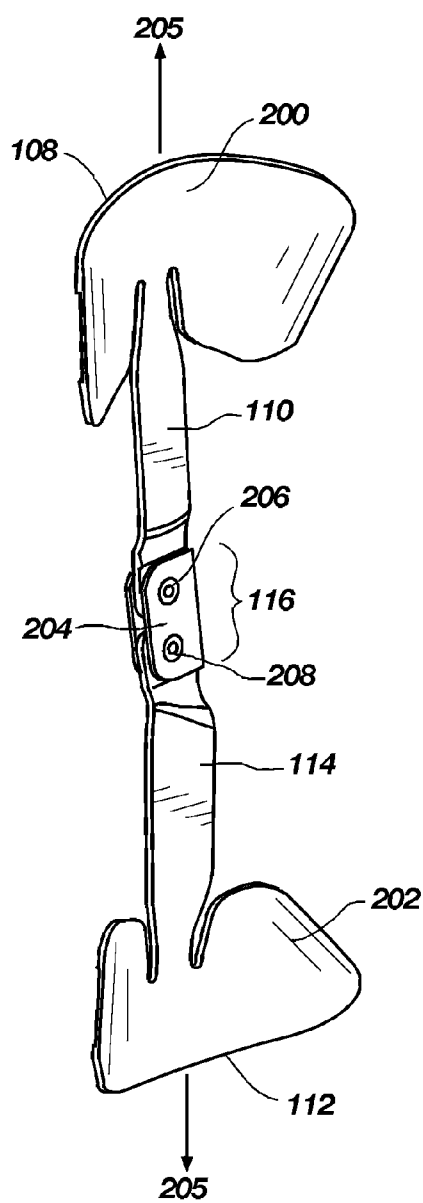


FIG. 2B

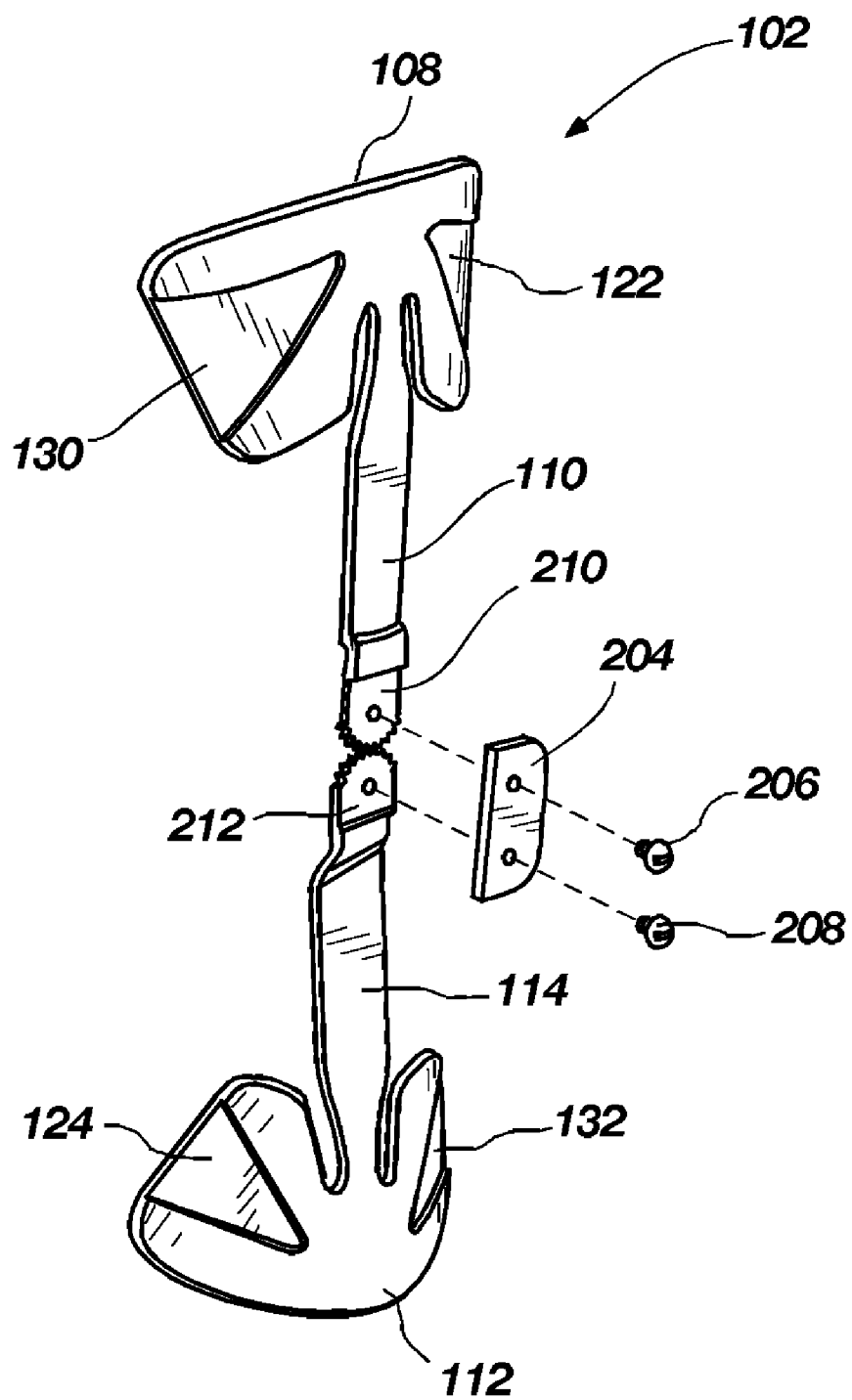
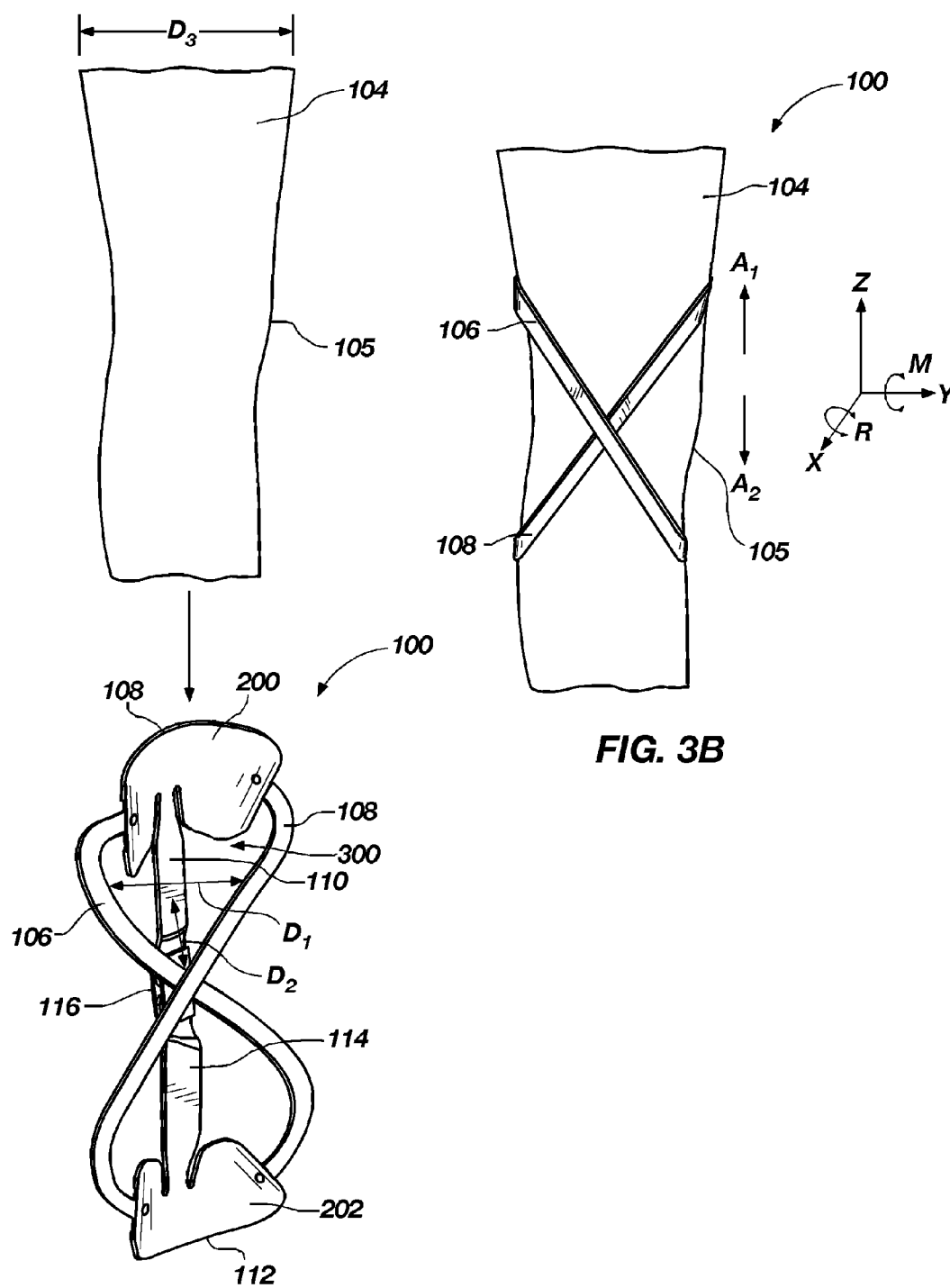


FIG. 2C



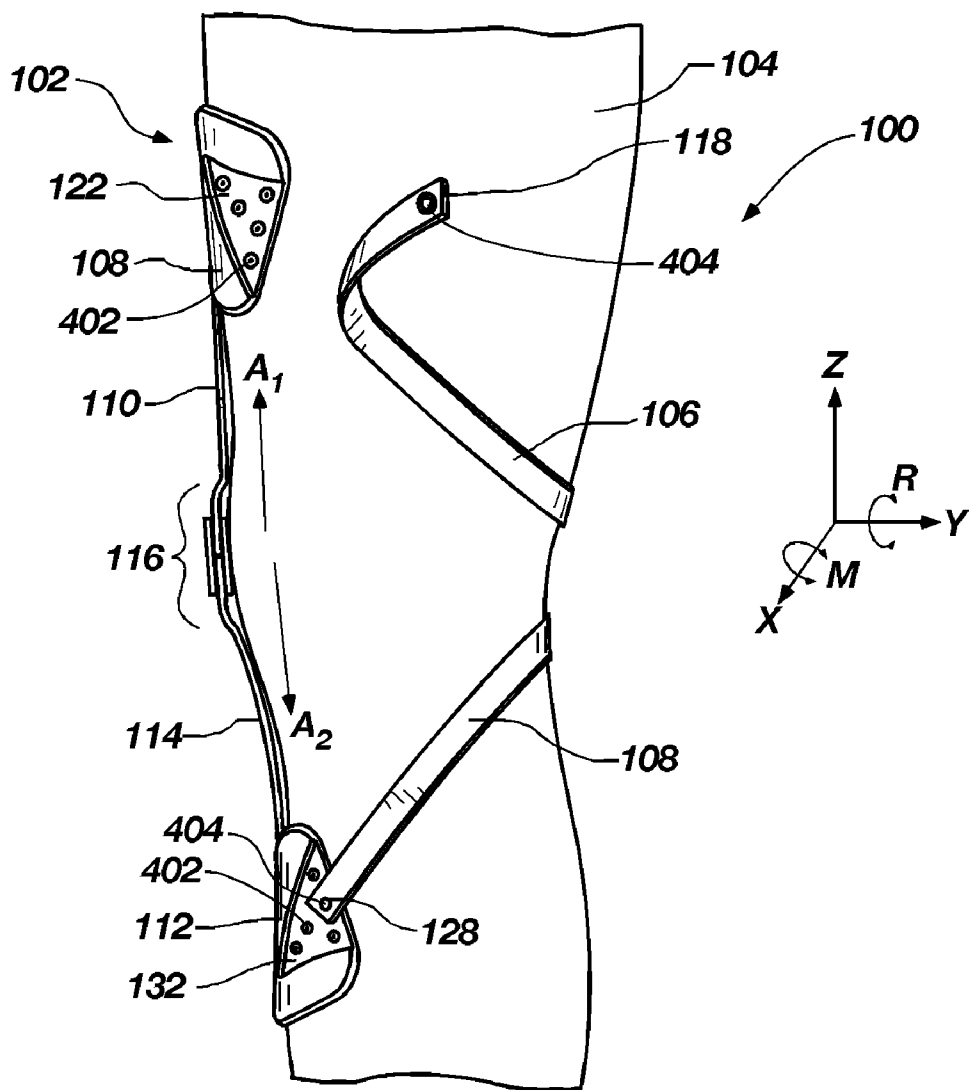


FIG. 4

ORTHOTIC APPARATUS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 11/975,542 filed on 19 Oct. 2007, the disclosure of which is incorporated herein, in its entirety, by this reference.

BACKGROUND

[0002] A variety of knee braces are currently available for treating different knee problems. Knee braces may be designed to impart forces on limbs surrounding the knee to relieve compressive forces in a portion of the knee. Additionally, knee braces are often employed to support the knee after a knee injury, such as a sprain, or to assist with rehabilitation of the knee after a traumatic event, such as knee surgery.

[0003] The human knee is a joint held together by small, powerful ligaments. The femur (i.e., the thighbone) meets the tibia (i.e., the large shin bone) to form the main knee joint called the femoro-tibial joint. The kneecap (i.e., the patella) joins the femur to form a second joint called the femoro-patellar joint. The patella protects the front of the knee. The knee is surrounded by a joint capsule with collateral ligaments strapping the inside and outside of the joint and cruciate ligaments crossing within the joint. The collateral ligaments run along the sides of the knee and limit the sideways motion of the knee. The anterior cruciate ligament ("ACL") connects the tibia to the femur at the center of the knee and functions to limit rotation and forward motion of the tibia. The ACL divides the knee into an inner (medial) and an outer (lateral) compartment. The posterior cruciate ligament ("PCL") is located aft of the ACL and limits backward motion of the tibia. The knee also includes a thickened cartilage pad known as a meniscus attached to the tibia and an articular cartridge attached to the femur. The meniscus and articular cartridge function as smooth bearing surfaces that allow for pain-free relative rotation of the femur and tibia.

[0004] Despite the knee being held together by powerful ligaments, the knee is still a relatively weak joint that can be easily damaged. For example, the knee may be damaged by participating in sporting events, overloading due to obesity, aging, or misalignment of the knee. Most knee problems are a result of damage of the cartilage of the knee and strain of the ligaments of the knee.

[0005] One important knee problem is unicompartmental osteoarthritis in which either the medial (inward) or the lateral (outward) compartment of the knee joint is deteriorated. In a proper functioning knee, both compartments are loaded generally uniformly. A knee joint that suffers from unicompartmental osteoarthritis is characterized by an uneven distribution of pressure in either the medial or lateral compartment of the knee. Such uneven distribution of pressure can wear away the smooth cartilage lining the inside of the knee, which may, consequently, lead to painful, direct contact between the femur and the tibia.

[0006] Unicompartmental osteoarthritis may be treated by using a knee brace that is configured to urge the femur and tibia apart in the affected compartment of the knee to reduce or eliminate the painful bone-to-bone contact between the femur and the tibia. However, many conventional knee braces employ complicated mechanisms for applying a load that urges the femur and tibia apart. Despite the availability of

such conventional knee braces to treat unicompartmental osteoarthritis, there is still a need for an improved knee brace to treat unicompartmental arthritis in a knee or other joint.

SUMMARY

[0007] Embodiments of the invention relate to an orthotic apparatus. In one embodiment of the invention, an orthotic apparatus includes a frame structure having an upper frame portion moveable relative to a lower frame portion. The orthotic apparatus further includes at least one strap attached to the upper frame portion and the lower frame portion of the frame structure. The at least one strap and the frame structure, together, are configured to apply a therapeutic moment to a joint of a limb responsive to positioning the limb within a limb-receiving space formed between the at least one strap and the frame structure.

[0008] According to another embodiment of the invention, in use, a limb may be positioned within a limb-receiving space formed between a frame structure and at least one strap attached thereto of an orthotic apparatus. The limb may be engaged with the frame structure and the at least one strap to tension the at least one strap and apply a therapeutic moment to a joint of the limb.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The drawings illustrate several embodiments of the invention, wherein like reference numerals refer to like or similar elements in different views or embodiments shown in the drawings.

[0010] FIG. 1A is a perspective view taken from a back side of a user's leg illustrating an orthotic apparatus having a frame structure positioned on a medial side of a knee and straps configured to apply a therapeutic load to the knee according to one embodiment of the invention.

[0011] FIG. 1B is a perspective view of the orthotic apparatus shown in FIG. 1A taken from the medial side of the knee.

[0012] FIG. 1C is a perspective view of the orthotic apparatus shown in FIG. 1A taken from a lateral side of the knee.

[0013] FIG. 2A is a front perspective view of the frame structure shown in FIGS. 1A-1C according to one embodiment of the invention.

[0014] FIG. 2B is a rear perspective view of the frame structure shown in FIG. 2A.

[0015] FIG. 2C is an exploded perspective view of the frame structure shown in FIGS. 2A and 2B that illustrates the hinge assembly of the frame structure in more detail.

[0016] FIG. 3A is a perspective view of the orthotic apparatus shown in FIGS. 1A-1C illustrating a leg of a user being inserted into a limb-receiving space of the orthotic apparatus.

[0017] FIG. 3B is a perspective view of the orthotic apparatus shown in FIG. 1A taken from a lateral side of the knee after insertion of the leg of the user into the limb-receiving space.

[0018] FIG. 4 is a perspective view of an orthotic apparatus configured to allow for the location that the straps attach to the frame structure to be slightly adjusted according to another embodiment of the invention.

DETAILED DESCRIPTION

[0019] Embodiments of the invention relate to an orthotic apparatus including a frame structure having at least one strap attached thereto, with the frame structure and the at least one

strap configured to apply a therapeutic moment to a joint of a user's limb responsive to the user donning the orthotic apparatus. The disclosed orthotic apparatus embodiments are configured to apply a therapeutic moment to, for example, a user's knee for alleviating pressure in a lateral or medial compartment of the knee for treating osteoarthritis of the knee, for alleviating other knee infirmities, or for generally supporting the knee.

[0020] FIGS. 1A-1C are perspective views of an orthotic apparatus **100** taken from a back side, a medial side, and a lateral side, respectively of a user's leg according to one embodiment of the invention. The orthotic apparatus **100** includes a frame structure **102** extending along a length of a leg **104** of the user, with the frame structure **102** positioned adjacent to a medial side of the user's knee **105**. As will be discussed in more detail below, straps **106** and **108** are connected to the frame structure **102**, and the straps **106** and **108** in conjunction with the frame structure **102** are configured to apply a therapeutic moment **M** to the knee **105** of the user's leg **104** upon the user donning the straps **106** and **108** and the frame structure **102**. Thus, the therapeutic moment **M** is not applied to the knee **105** using a complicated, costly, and possibly defect prone device (e.g., a ratchet mechanism) configured to tension the straps **106** and **108** or by the user manually tensioning the straps **106** and **108**.

[0021] The frame structure **102** includes an upper shell **108** that may be configured to generally conform to the user's leg **104** and an elongated support arm **110** extending from the upper shell **108**. The frame structure **102** further includes a lower shell **112** that may also be configured to generally conform to the user's leg **104** and an elongated support arm **114** extending toward the elongated support arm **108**. The elongated support arms **110** and **114** are hingedly connected to each other via a hinge assembly **116** to enable rotation relative to each other in a direction **R** when the user bends the knee **105**.

[0022] The elongated support arms **110** and **114** and the shells **108** and **112** may be formed from a number of different materials, such as engineering plastics, metallic materials, polymer-matrix composites, or another suitable material. In the illustrated embodiment, the elongated support arms **110** and **114** are integrally formed with the corresponding upper shell **108** and lower shell **112**. However, in other embodiments of the invention, the elongated support arms **110** and **114** and the shells **108** and **112** may be separate pieces, with the upper shell **108** attached to the elongated support arm **110** and the lower shell **112** attached to the elongated support arm **114** using fasteners or another suitable technique.

[0023] FIGS. 2A-2C are front, rear, and exploded perspective views of the frame structure **102** and hinge assembly **116** that shows the configuration thereof in more detail. As previously noted, the upper shell **108** and the lower shell **112** may be configured to conform to the user's leg **104**. As best shown in FIG. 2B, the upper shell **108** has a surface **200** and the lower shell **112** has a surface **202**, each of which may be suitably concavely curved to enable conforming to the user's leg **104**. As best shown in FIG. 2C, the hinge assembly **116** includes a coupling member **204** that may partially enclose a gear **210** located at a distal end of the elongated support arm **110**, and a gear **212** located at a distal end of the elongated support arm **114**. The coupling member **204** is secured to the elongated support arms **110** and **114** using fasteners **206** and **208** that are secured to the gears **210** and **212** and the coupling member **204**. When assembled, the gears **210** and **212** mesh with each other. As previously discussed, the hinge assembly **116**

enables the elongated support arms **110** and **114** to be relatively rotated in the direction **R** (See FIG. 1A) about an axis generally perpendicular to a longitudinal axis **205** of the frame structure **102**. The elongated support arm **110** rotates about an axis (not shown) that passes through the fastener **206** and the elongated support arm **114** rotates about an axis (not shown) that passes through the fastener **208**.

[0024] It is noted that the frame structure **102** merely represents one embodiment of a suitable frame structure for the orthotic apparatus **100**. Any suitable frame structure that is configured to rotate or bend with rotation of the user's knee **105** when the frame structure is secured to the user's leg **104** may be used. For example, the gears **210** and **212** may be omitted and the elongated support arms **108** and **112** may be pivotally connected to each other using a fastener. Additionally, in a further embodiment of the invention, the gears **210** and **212** and the hinge assembly **116** may be omitted. In such an embodiment, the frame structure **102** may be a unitary piece that is configured to flex or bend with a selected stiffness as the user bends their knee **105**. Thus, in such an embodiment, the upper shell **108** and elongated support arm **110** may move relative to the lower shell **112** and elongated support arm **114** when the user bends their knee **105**. Furthermore, in any of the embodiments of the invention disclosed herein, a fabric compression sleeve (not shown) may be provided that conceals the frame structure **102** and/or is attached to the frame structure **102**, for example, using Velcro® straps or another suitable securing structure. The fabric compression sleeve may help properly position and maintain the position of, during use, the frame structure **102** on the leg **104** of the user and further provide a therapeutic benefit of compressing muscles surrounding the knee **105**.

[0025] Turning again to FIGS. 1A-1C, the straps **106** and **108** of the orthotic apparatus **100** are each attached to the upper shell **108** and the lower shell **112** so that they cross each other to form an X-type pattern as best shown in FIG. 1C. The strap **106** includes a proximal end **118** and a distal end **120**, with the proximal end **118** attached to side portion **122** of the upper shell **108** and the distal end **120** attached to side portion **124** (FIG. 1B) of the lower shell **112**. The strap **108** includes a proximal end **126** and a distal end **128**, with the proximal end **126** attached to side portion **130** of the upper shell **108** and the distal end **128** attached to side portion **132** (FIG. 1B) of the lower shell **112**. For example, each strap **106** and **108** may be attached to the upper shell **108** and lower shell **112** using screws, rivets, buttons, or another suitable fastening mechanism. It is noted that while two straps **106** and **108** are employed in the illustrated embodiment, in other embodiments of the invention, a single strap may be coiled in figure-eight type of pattern so that the single strap crosses over itself in a manner similar to the X-type pattern shown in FIG. 1C.

[0026] Each strap **106** and **108** may be made from an elastic material. For example, the elastic material may have an elastic limit of about 1 percent to about 40 percent. Suitable elastic materials include, but are not limited to, polymeric materials (e.g., elastomeric polymers, nylon, or rubber) and elastic fabrics (e.g., Lycra®, braided elastic materials, woven elastic materials, knitted elastic materials, or corded elastic materials). As will be discussed in more detail below, by selecting the elastic stiffness of each strap **106** and **108**, the stiffness of the frame structure **102**, and the amount of physical interference between the user's leg **104** when the user inserts their leg

104 into the orthotic apparatus **100**, the magnitude of the therapeutic moment **M** applied to the knee **105** may be tailored.

[0027] The manner in which the orthotic apparatus **100** applies the therapeutic moment **M** to the knee **105** of the leg **104** is best understood with reference to FIGS. 3A and 3B. In use, the user dons the orthotic apparatus **100** by inserting their leg **104** into a limb-receiving space **300** defined between the frame structure **102** and the straps **106** and **108**. The limb-receiving space **300** may be defined by one or more lateral dimensions. For example, in the illustrated embodiment shown in FIG. 3A, the limb-receiving space **300** is defined by a first lateral dimension D_1 extending between the straps **106** and **108** and a second lateral dimension D_2 extending between the frame structure **102** and the strap **104**. Depending upon the manner in which the straps **106** and **108** are configured and attached to the frame structure **102**, the first and second lateral dimensions D_1 and D_2 may be approximately equal to each other and, in other embodiments, may be different. The leg **104** of the user exhibits a lateral dimension or diameter D_3 that is greater than the first lateral dimensions D_1 , second lateral dimension D_2 , or both. Due to the lateral dimension or diameter D_3 of the leg **104** being greater than at least one of the first and second lateral dimensions D_1 and D_2 of the limb-receiving space **300**, the leg **104** physically interferes with the frame structure **102** and the straps **106** and **108** so that the straps **106** and **108** become tensioned as the user inserts their leg **104** into the limb-receiving space **300**. Referring to FIG. 3B, tensioning the straps **106** and **108** enables the straps **106** and **108** in conjunction with the frame structure **102** (e.g., the upper shell **108** and lower shell **112** bearing against the leg **104**) to subject the knee **105** to a generally three-point bending loading that applies a moment **M** to the knee **105** of the user. The upper shell **108** and lower shell **112** function as two of the points and the point or region of the straps **106** and **108** that cross each other functions as the third point. Thus, the moment **M** is not applied to the knee **105** using a device configured to tension the straps **106** and **108** or by the user manually tensioning the straps **106** and **108**. Instead, the act of the user donning the orthotic apparatus **100** results in the moment **M** being applied to the knee **105** of the user.

[0028] The moment **M** illustrated in FIGS. 1A-1C and 3B is a valgus moment that urges the femur and tibia apart generally in directions A_1 and A_2 , respectively, to unload the affected medial compartment of the knee **105**. Of course, the orthotic apparatus **100** may be positioned with the frame structure **102** on a lateral side of the user's knee **105**. In such a case, donning the orthotic apparatus **100** applies a varus moment to the user's knee **105** and urges the femur and tibia apart on the affected lateral compartment of the knee **105** of the user.

[0029] In FIGS. 1A-3B, the straps **106** and **108** are illustrated as being non-adjustable, with the distal ends **118**, **126** and proximal ends **120**, **128** thereof attached to the frame structure **102**. In other words, the locations that the straps **106** and **108** attach to the frame structure **102** are fixed. However, in other embodiments of the invention, the frame structure **102** and the straps **106** and **108** may be configured to allow the location that the distal ends **118**, **126** and proximal ends **120**, **128** of the thereof attach to the frame structure **102**. Such embodiments enable slightly changing the volume of a limb-receiving space (e.g., the limb-receiving space **300** of the orthotic apparatus **100**) so that a range of user limb sizes can be accommodated and, further enable tailoring a magnitude of a moment applied to a user's knee upon donning the

orthotic apparatus. For example, for a given user leg size and strap configurations, reducing the volume of the limb-receiving space will increase the magnitude of the moment applied to the user's knee.

[0030] FIG. 4 is a perspective view of an orthotic apparatus **400** that allows the location that the straps **106** and **108** attach to the frame structure **102** to be slightly adjusted according to another embodiment of the invention. The orthotic apparatus **400** is structurally similar to the orthotic apparatus **100** shown in FIGS. 1A-1C. Therefore, in the interest of brevity, components in both orthotic apparatuses **100** and **400** that are identical to each other have been provided with the same reference numerals, and an explanation of their structure and function will not be repeated unless the components function differently in the substrate holders **100** and **400**. The frame structure **102** further includes a plurality of spaced buttons **402** (or other attachment member) mounted to upper shell **108** on the side portions **122** and **130** (not shown) thereof and to the lower shell **112** on the side portions **124** and **132** (not shown) thereof. The proximal and distal ends **118**, **120** of the strap **106** may each include at least one button **404** (or other attachment member) configured to releasably attach (e.g., snap fit) to each of the buttons **402**, and proximal and distal ends **126**, **128** of the strap **108** may each include at least one button **404** (or other attachment member) also configured to releasably attach to each of the buttons **402**. Thus, as desired or needed for a particular user's leg size, the position that the straps **106** and **108** attach to the frame structure **102** may be adjusted by selecting, for example, which one of the buttons **402** mounted to the side portion **122** that the button **404** of the proximal end **118** of the strap **106** snap fits with.

[0031] In other embodiments of the invention, only one of the straps **106** and **108** may be configured to releasably attach to the frame structure **102**. In further embodiments of the invention, at least one end of at least one of the straps **106** and **108** may include more than one of the buttons **404**. For example, the proximal end **118** and distal end **120** of the strap **106** may each include more than one of the buttons **404** and the side portions **122** and the side portions **124** may each include only one of the buttons **402**.

[0032] Although the invention has been disclosed and described by way of some embodiments, it is apparent to those skilled in the art that several modifications to the described embodiments, as well as other embodiments of the invention are possible without departing from the spirit and scope of the invention.

1. An orthotic apparatus, comprising:

- a frame structure including an upper frame portion moveable relative to a lower frame portion;
- at least one strap attached to the upper frame portion and the lower frame portion of the frame structure; and
- the at least one strap and the frame structure, together, are configured to apply a therapeutic moment to a joint of a limb responsive to positioning the limb within a limb-receiving space formed between the at least one strap and the frame structure.

2. The orthotic apparatus of claim 1 wherein a device operable to tension the at least one strap is not included.

3. The orthotic apparatus of claim 1 wherein the at least one strap is configured to increase in length responsive to insertion of the limb into the limb-receiving space so that the limb-receiving space can accommodate a range of limb sizes.

4. The orthotic apparatus of claim 1 wherein the at least one strap and the frame structure are configured so that a position that the at least one strap attaches to the frame structure is relatively adjustable.

5. The orthotic apparatus of claim 1 wherein the at least one strap and the frame structure are configured so that a position that the at least one strap attaches to the frame structure is non-adjustable.

6. The orthotic apparatus of claim 1 wherein the at least one strap exhibits an elastic limit of about 1 percent to about 40 percent.

7. The orthotic apparatus of claim 1 wherein the at least one strap comprises an elastomeric material.

8. The orthotic apparatus of claim 1 wherein the at least one strap comprises an elastic fabric.

9. The orthotic apparatus of claim 1 wherein the at least one strap comprises only one strap.

10. The orthotic apparatus of claim 1 wherein:

the upper frame portion comprises an upper shell having a first elongated support arm extending therefrom;

the lower frame portion comprises a lower shell having a second elongated support arm extending therefrom that is hingedly connected to the first elongated support arm; and

the at least one strap comprises first and second straps each of which is attached to the upper shell and the lower shell in a manner so that the first strap and the second strap cross each other.

11. The orthotic apparatus of claim 1 wherein the upper frame portion and the lower frame portion are rotatable relative to each other.

12. A method, comprising:

positioning a limb within a limb-receiving space formed between a frame structure and at least one strap attached thereto of an orthotic apparatus; and

engaging the limb with the frame structure and the at least one strap to tension the at least one strap and apply a therapeutic moment to a joint of the limb.

13. The method of claim 12 wherein positioning a limb within a limb-receiving space formed between a frame structure and at least one strap attached thereto of an orthotic apparatus comprises:

inserting the limb within the limb-receiving space.

14. The method of claim 12 wherein positioning a limb within a limb-receiving space formed between a frame structure and at least one strap attached thereto of an orthotic apparatus comprises:

positioning a knee of a subject within a limb-receiving space.

15. The method of claim 12 wherein engaging the limb with the frame structure and the at least one strap to tension the at least one strap and apply a therapeutic moment to a joint of the limb comprises:

physically interfering the limb with the frame structure and the at least one strap as a result of at least one lateral dimension of the limb being greater than at least one lateral dimension of the limb-receiving space prior to positioning of the limb therein.

16. The method of claim 12 wherein the act of engaging the limb with the frame structure and the at least one strap tensions the at least one strap and applies the therapeutic moment substantially simultaneously.

17. The method of claim 12, further comprising:

relatively adjusting at least one position at which the at least one strap attaches to the frame structure.

18. The method of claim 12 wherein the at least one strap comprises first and second straps each of which is attached to the frame structure.

19. The method of claim 12 wherein the at least one strap comprises only one strap.

20. The method of claim 12 wherein the at least one strap comprises an elastomeric material.

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