

[0023] FIG. 6a is a side view of a partial dynamic exoskeletal orthosis according to an embodiment of the present invention.

[0024] FIG. 6b is a top view of the partial dynamic exoskeletal orthosis of FIG. 6a.

[0025] FIG. 7 is a side view of a dynamic exoskeletal orthosis according to another embodiment of the present invention.

[0026] FIG. 8 is a side view of a dynamic knee ankle foot exoskeletal orthosis according to an embodiment of the present invention.

[0027] FIG. 9 is a rear view of a dynamic knee ankle foot exoskeletal orthosis according to an embodiment of the present invention.

[0028] FIG. 10 is a side view of a dynamic exoskeletal orthosis according to another embodiment of the present invention.

[0029] FIG. 11 is a rear view of a dynamic exoskeletal orthosis of FIG. 10.

[0030] FIG. 12 is a side view of a knee ankle foot exoskeletal orthosis according to another embodiment of the present invention.

[0031] FIG. 13 is a side rear perspective view of the knee ankle foot exoskeletal orthosis according to FIG. 12 in use.

[0032] FIG. 14 is a rear view of a knee ankle foot exoskeletal orthosis according to FIG. 13 in use.

[0033] FIG. 15 is a side view of a knee ankle foot exoskeletal orthosis according to FIG. 13 while a user is seated.

[0034] FIG. 16a is a side view of a bolt mechanism for an alignable configuration of an exoskeletal orthosis according to an embodiment of the present invention.

[0035] FIG. 16b is a top view of the bolt mechanism of FIG. 16a.

[0036] FIG. 17 shows dual posterior struts and mounting plates for a non-alignable configuration of an exoskeletal orthosis according to an embodiment of the present invention.

[0037] Given the following enabling description of the drawings, the methods and apparatus should become evident to a person of ordinary skill in the art.

DETAILED DESCRIPTION OF INVENTION

[0038] The orthosis of the present invention is designed to allow walking and running for individuals or patients with severe injury to the lower limb that causes reduced ankle range of motion, weakness, and pain. The orthosis allows for a range of activities including, but not limited to, at least one of early ambulation during an early post-injury phase, agility and impact activities, running, sprinting, or deploying with a military unit.

[0039] The orthosis of the present invention is designed to compensate for weakness, pain, and/or decreased range of motion (either alone or in combination) at the ankle that result from a variety of potential diagnoses including, but not limited to, at least one of ankle fusion, talus or calcaneus fractures, tibial nerve injuries, peroneal nerve injuries, partial foot amputation (which results in ankle plantarflexion weakness), soft tissue loss in the leg (resulting in inherent weakness), or pain in the ankle during weight bearing activities.

[0040] Current research suggests that the orthosis of the present invention not only compensates for weakness, but also generates forces about the ankle that more closely approaches the normal gait than other currently available orthoses. The article Patzowski et al., *Comparative Effect of Orthosis Design on Functional Performance*, J. Bone Joint Surg. Ab., 2012; 94:507-15, is incorporated by reference

herein in its entirety. The article Patzowski et al., *Can an Ankle-Foot Orthosis Change Hearts and Minds?*, J. Surgical Orthopaedic Advances, 20(1):8-18, 2011, is also incorporated by reference herein in its entirety.

[0041] In specific embodiments, the orthosis of the present invention may be applied to the leg below the knee. The orthosis (also referred to as the Intrepid Dynamic Exoskeletal Orthosis or IDEO) may comprise the following components (description from an upper/proximal aspect to a lower/distal aspect).

A. Proximal Cuff

[0042] With reference now to FIG. 1, the exoskeletal orthosis **100** according to the present invention comprises a proximal cuff **110**. The proximal cuff may comprise at least one of a carbon material, reinforced carbon fiber composition, or resin material. The cuff may have a bivalve or a monolithic configuration.

[0043] A monolithic, one-piece, solid configuration comprises a solid cuff and is designed for a patient who has a stable size of the upper leg (calf and shin) and does not have limited ankle plantarflexion.

[0044] In specific embodiments, the proximal cuff may comprise a two piece or bivalve cuff having a hinge **115** (as shown in FIGS. 2-3) along an upper edge or aspect, thereby allowing the proximal cuff **110** to have a wider opening distally when donning the brace. This configuration may be utilized for patients who are not able to plantarflex the ankle enough to fit through a monolithic (solid) configuration and also allows for volume fluctuation of the upper leg. The hinge **115** allows the proximal cuff **110** to open upward due to a proximal fixed axis point (see FIG. 2).

[0045] In one or more embodiments, the proximal cuff **100** may have a strap **120** to help hold it in place while in use.

B. Posterior Strut

[0046] The exoskeletal orthosis **100** comprises at least one posterior strut **130** for connecting the proximal cuff **110** to an ankle/footplate section **140**. The at least one posterior strut **130** may comprise a single bar (e.g., FIG. 1) or dual bars (e.g., FIG. 3), which may be bonded together. The at least one posterior strut may be of any shape for example, a flat bar, a cylindrical or tubular shape, or having a circular or semi-circular cross section. In one or more embodiments, the at least one posterior strut **130** may have a length of about 5 inches to about 13 inches (12.7 cm to 33 cm).

[0047] In specific embodiments, the at least one posterior strut **130** may comprise an alignable dynamic carbon strut, for example, a TRULIFE Littig strut or a MEDI CLEVER BONE™ strut. The Littig strut was originally designed for use in the upper portion of hip disarticulation prostheses. The MEDI CLEVER BONE™ strut (bone system) may be designed for use as a dynamic pylon for transtibial prostheses.

[0048] The at least one posterior strut **130** may comprise at least one of a carbon material, reinforced carbon fiber composition, or resin material. In a specific embodiment, the at least one posterior strut may have an Aerolon core.

[0049] In one or more embodiments, the at least one posterior strut may comprise an SLS material. Selective laser sintering (SLS) is an additive manufacturing technique that uses a high power laser (for example, a carbon dioxide laser) to