

have a gradual roller shape that begins just distal to a heel, which may have a cushion. In one or more embodiment, a portion of the heel, for example a posterior heel base, may comprise a SACH heel (solid ankle cushion heel).

**[0043]** During heel strike, the heel decreases impact on the limb and allows the patient to easily bring the forefoot to a floor. A cushioned heel may allow a gradually increasing load to the posterior strut as the tibia moves forward, while the plantarflexed foot position increases the degree of deflection and amount of energy storage from midstance through terminal stance. Energy storage and return is evident during agility drills, running, and sprinting activities, which are primarily performed while up on the forefoot. A distal third of the plantar surface may have a dorsiflexion radius design that maintains solid metatarsal contact to the ground for increased proprioception and control.

**[0044]** In a specific embodiment, the alignment of the orthosis can be adjusted on average up to about 7° of dorsiflexion, plantarflexion, and external or internal rotation and about 5° of inversion or eversion.

#### E. Versions of the Exoskeletal Orthosis

**[0045]** In a specific embodiment, the orthosis **100** may comprise cushioned foam attached to a proximal sole on a bottom portion the ankle section/footplate. The cushioned foam may be an entirely different and separate component from the orthosis, as the foam may require fabrication by a specially trained orthotist (preferably prosthetist-orthotist) and orthotic technician.

**[0046]** In embodiments, there orthosis may be made from modular components or fixed components. A modular version may be used during initial fittings and may be modified as patients progress during their rehabilitation, for example, progressing from a softer strut to a stiffer strut as they become stronger. The modular version may also include an external fixator (e.g., fastener and mounting plates).

**[0047]** In a specific embodiment, the modular version may comprise a flat bar (e.g., TRULIFE Littig) posterior strut. The posteriorly mounted 'run plate' may be utilized in a posterior-mounted running prosthesis. The alignment of the ankle section/footplate may also be modifiable. The angle of the footplate may be adjusted within 6 different planes, similar to adjustments for a prosthesis, in relation to a patient's foot and leg. In specific embodiments, the modular version may have a posterior strut that is attached to the proximal cuff proximally via an ÖSSUR posterior mounted run plate with two bolts, plus a second ÖSSUR posterior mounted run plate with two bolts at the distal end of the posterior strut (FIGS. 1-2).

**[0048]** In a specific embodiment, a fixed version may comprise a dual bar strut (e.g., MEDI CLEVER BONE™) for an overall lighter weight of the brace, use for higher loading and impact activities (greater durability), and the capacity for twisting motions of the lower leg. The fixed version allows for use inside boots and tighter clothing about the legs. The dual bar strut may be permanently attached (bonded) to the proximal cuff proximally and the foot/ankle component distally (as shown in FIG. 3). The fixed version may allow an inherent torsional component and accommodates twisting motions more than the modular version. The fixed version has subjectively shown an increased energy return and improved high intensity performance associated with its springlike effect,

per verbal accounts from patients. However, it is may be possible to use a dual posterior strut configuration in a modular version.

#### F. Partial Foot Embodiment

**[0049]** With reference now to FIGS. 6a-b, a partial foot orthosis **200** may be applied to individuals with amputation of part of the foot. The partial foot exoskeletal orthosis **200** may have a similar construction to the orthosis **100** discussed above. The partial foot orthosis **200** has a circumferential configuration of the footplate **205** (extending around the area of the foot that was amputated).

#### G. Other Aspects of the Exoskeletal Orthosis

**[0050]** With reference now to FIG. 7, another embodiment of the orthosis **100** is shown in which at least one of the proximal cuff **110** or ankle section/footplate **140** comprise a laminate material.

**[0051]** With reference now to FIGS. 8-9, an embodiment of the present invention directed to a knee ankle foot orthosis **300** is shown. In one or more embodiments, the knee ankle foot orthosis may comprise a modular removable fabricated version that allows a patient to attach or detach a knee orthosis section **305** to a custom standard ankle foot orthosis (AFO) section **310** depending on desired activity and limb stability needs.

**[0052]** In one or more embodiments, the knee ankle orthosis may comprise a fixed version comprising Tm5 or original TOWNSEND knee hinges **315** with a upper anterior carbon knee orthosis cuff fused to the lower monolithic exoskeletal orthosis section. The knee ankle foot orthosis may be either modular or monolithic, and may be used for varying weaknesses, nerve injuries, ligamentous injuries, proximal knee or femoral fx's histories to allow a patient to walk, run, or perform some level of high impact activity with greater function and increased safety.

**[0053]** Knee ankle foot orthosis versions, both modular and monolithic, may also be used for dynamic exoskeletal orthosis cases deploying and participating in fast rope helicopter jumps, static line parachuting, or standard parachuting maneuvers to prevent potential knee injuries while using the dynamic exoskeletal orthosis for prior injury of the ankle, nerve, and the like.

**[0054]** The exoskeletal orthosis is a viable alternative to amputation despite severe impairment of the leg. In addition, the exoskeletal orthosis may allow at least one of: 1) a more normal walking or running pattern for those with severe injury to the leg, ankle, and/or foot that results in decreased ankle range of motion or increased pain; 2) those with an isolated peroneal neuropathy to run; 3) those with tibial neuropathy to walk and run; or 4) increased agility (stepping forward, backward, side-to-side) despite stated physical impairments. The orthosis also promotes use and subsequent strengthening of the quadriceps muscle during everyday activities. The orthosis may also be used for spinal cord injuries in which there is weakness at the ankle and at least 4 out of 5 strength in the knee.

**[0055]** The exoskeletal orthosis of the present invention may be modified to allow safer and more normalized gait pattern during the early postoperative period after leg/foot/ankle surgery instead of the CAM boot (a 'walking boot') The orthosis may also be used as a pediatric device for those with