

fuse small particles of plastic, metal (direct metal laser sintering), ceramic, or glass powders into a mass that has a desired 3-dimensional shape.

### C. Mounting Plates

**[0050]** The exoskeletal orthosis **100** may comprise at least one mounting plate, for example, two mounting plates: a first mounting plate **150** for attaching one end of the at least one posterior strut **130** to the proximal cuff and a second mounting plate **160** for attaching an opposite end of the at least one posterior strut **130** to the ankle section/footplate **140** (as shown in FIGS. **1** and **4**). In one or more embodiments, the at least one mounting plate may comprise an ÖSSUR® posterior mounting plate (designed for transtibial prostheses).

**[0051]** The mounting plates **150**, **160** may include a fastener including, but not limited to, at least one of a screw, bolt, nail, nut, adhesive, combination thereof, or any other effective fastener.

**[0052]** The attachment of the at least one posterior strut **130** to an ankle section/footplate **140** may be slightly more proximal than traditional orthoses. This helps offset motion within the ankle, which is often painful or severely limited in these patients, to the at least one posterior strut without compromising comfort.

### D. Ankle Section/Footplate

**[0053]** The exoskeletal orthosis **100** comprises an ankle section/footplate **140**. The ankle section/footplate comprises a supramalleolar ankle section **170** and footplate section **180** (e.g., FIG. **1**). The ankle section/footplate **140** may be a single piece comprising a reinforced carbon fiber composition. In one or more embodiments, the ankle section **170** comprises a lateral wing **190** for mediolateral stability and for fitting better in shoes or boots (FIG. **5**). In one or more embodiments, the ankle section may also have a medial wing.

**[0054]** In one or more embodiments, the footplate section **180** has a “rollover” shape (e.g., FIG. **1** and FIG. **3**). The shape of the footplate section **180** positions an individual’s toes in slight extension and extends to his or her toetips. A forefoot (end of the footplate) is set in slight plantarflexion compared to a midfoot. In one or more embodiments, the ankle section/footplate **140** may be stiff due to the layering of materials and carbon fiber. The footplate section **180** may have an arch (instead of being completely flat) and have extension at the metatarsophalangeal joints, which enables the metatarsal heads to remain in contact with the ground for a longer duration during ambulation.

**[0055]** The plantar surface of the footplate allows optimal function of the at least one posterior strut and long-term durability of the orthosis. As noted, the footplate section may have a gradual roller shape that begins just distal to a heel, which may have a cushion. In one or more embodiments, a portion of the heel, for example a posterior heel base, may comprise a SACH heel (solid ankle cushion heel).

**[0056]** 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.

**[0057]** 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

**[0058]** In a specific embodiment, the orthosis 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. Thickness and density of the foam are specific to a patient’s relative ankle position, injury, weight, height, and activity level.

**[0059]** In embodiments, the 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).

**[0060]** In a specific embodiment, a 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**).

**[0061]** 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 may be possible to use a dual posterior strut configuration in a modular version.

### F. Partial Foot Embodiment

**[0062]** 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).