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[US/US]; 355 East Erie Street, Chicago, Illinois 60611 (US). **KUIKEN, Todd** [US/US]; 355 East Erie Street, Chicago, Illinois 60611 (US).

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(74) Agent: **PAHNKE, Chad A.**; McAndrews, Held & Malloy Ltd., 500 West Madison Street, 34th Floor, Chicago, Illinois 60661 (US).

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(71) Applicant: **REHABILITATION INSTITUTE OF CHICAGO D/B/A SHIRLEY RYAN ABILITYLAB** [US/US]; 355 East Superior Street, Chicago, Illinois 60611 (US).

(72) Inventors; and

(71) Applicants: **LENZI, Tommaso** [US/US]; 355 East Erie Street, Chicago, Illinois 60611 (US). **CEMPINI, Marco**

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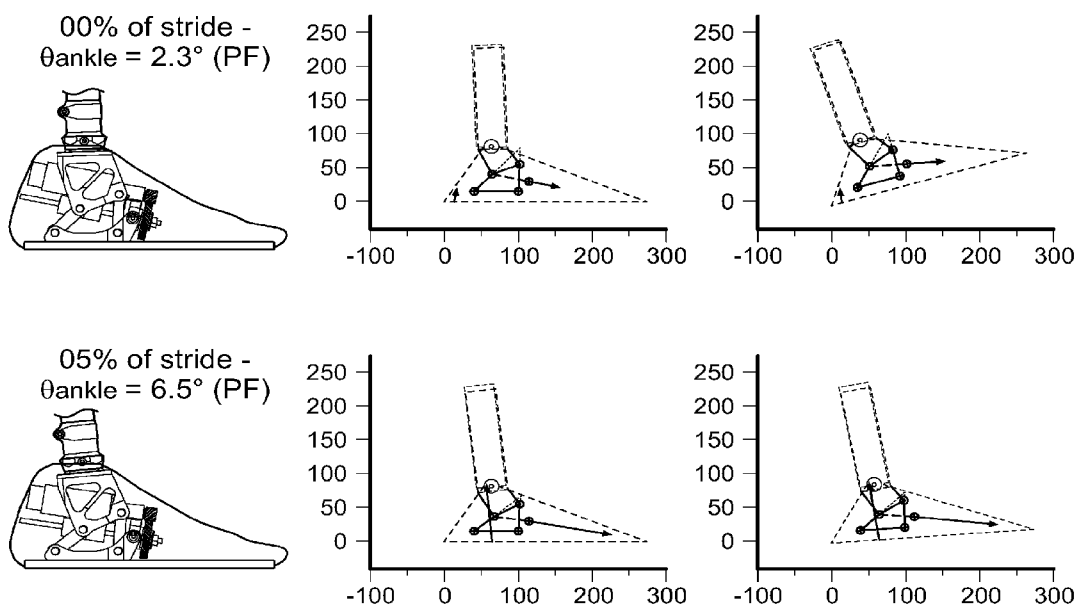


FIG. 1A

(57) Abstract: Systems and methods are disclosed for a powered ankle prosthesis. The prosthesis may comprise a polycentric mechanism having a defined path for an instantaneous center of rotation. The path of the instantaneous center of rotation may be defined by a trajectory substantially equal to an arc positioned over a joint of the polycentric mechanism.

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## **POLYCENTRIC POWERED ANKLE PROSTHESIS**

### **RELATED APPLICATIONS**

[0001] This patent claims priority to U.S. Provisional Patent Application Serial No. 62/319,430, filed on April 7, 2016, entitled “Polycentric Powered Ankle Prosthesis.” The entirety of U.S. Provisional Patent Application Serial No. 62/319,430 is incorporated herein by reference.

### **FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT**

[0001] This invention was made with government support under Award No. 90RE5014-02-00 awarded by the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR), an agency of the United States Department of Health and Human Services, and under Award No. W81XWH-14-C-0105 awarded by the United States Army. The government has certain rights in the invention.

### **CROSS REFERENCE TO RELATED APPLICATION**

[0002] This application is a non-provisional that claims benefit to U.S. Provisional Patent Application No. 62/319,430 filed on April 7, 2016, which is herein incorporated by reference in its entirety.

### **BACKGROUND**

[0003] Prosthetic ankle devices are frequently used as replacement after the loss of lower limb following amputation. Prostheses can fulfill both the aesthetic and the functional role of the lower leg, such as running, sports, or other exercise; climbing or descending stairs; ascending or

descending slopes; level walking; other movement; and restoration of the appearance of the missing limb.

**[0004]** A sound human ankle helps a person walk during gait. The phase of gait where the foot touches the ground is known as the stance phase of gait. In the initial part of stance phase (from heel-strike to mid-stance), the ankle stores elastic energy in the elongation of its tendons. In late-stance (from mid-stance to toe-off), the energy stored in the tendons is returned, along with the addition of an active muscle-powered component. This energy propels a person forward while walking. Such behavior cannot be replicated by passive or quasi-passive prosthesis that require the user to supply this missing energy, such as by pushing forward the user's body center of mass on toe-off; through an increased torque in the remaining lower-limb joints (mainly the hip); or by altering the symmetry of the gait between the two limbs.

**[0005]** Some prostheses are fully powered. Powered ankle prostheses have the potential to provide substantial benefits for amputees and provide further opportunities for clinical research. However, powered ankle prostheses known in the art have drawbacks in technology and implementation. Achieving one or more of the design goals of appropriate battery duration, structural strength, high range of motion and lightness are difficult to meet while also enclosing the design of the ankle prosthesis into an anatomical shape, such as a shape that would fit within the user's shoe. Moreover, interchangeability and modularity (such as interfacing with the stump's socket, or pylon or torsion-elements) can be a problem due to the prosthesis dimensions and built-height, especially for transtibial amputees.

### **BRIEF SUMMARY**

**[0006]** In various embodiments, a powered ankle prosthesis is disclosed. The prosthesis may comprise a polycentric mechanism having a defined path for an instantaneous center of

rotation; wherein the path of the instantaneous center of rotation is defined by a trajectory substantially equal to an arc positioned over a joint of the polycentric mechanism. The path of the instantaneous center of rotation may be further defined such that during late stance, the instantaneous center of rotation is positioned to provide a shortened moment arm in relation to a ground reaction force.

[0007] The polycentric mechanism may comprise a first member and a second member. The first member may define the path for the instantaneous center of rotation. The first member may comprise a base element connected to a foot component, a first crank pivotally coupled to the first member, and a second crank pivotally coupled to the first member. The first crank and the second crank each may be pivotally coupled to a bottom portion of the second member. The first crank and the second crank each may be aligned to define the path for the instantaneous center of rotation. A top portion of the second member may be angled for attachment to a shank component connection.

[0008] In various embodiments, the prosthesis may further comprise an actuator for moving the polycentric mechanism. The actuator may be at least partially housed within an opening of the polycentric mechanism. The actuator may be configured to adjust the distance between a hinge of the first member and a hinge of the driven member. The actuator may comprise a motor, a transmission, and a screw. The screw may be, for example, a leadscrew, a ballscrew, or a rollerscrew.

[0009] The polycentric mechanism of the prosthesis may fit within the contour of an anatomical foot profile.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Reference is further made to the following description taken with the accompanying drawings.

[0011] **FIGS. 1A-1D** displays side views of an embodiment of an ankle prosthesis at positions ranging from 0% of stride to 60% of stride, and kinematic diagrams corresponding to each position.

[0012] **FIG. 2A** displays a front three-quarter view of an embodiment of an ankle prosthesis. **FIG. 2B** displays a rear three-quarter view of an embodiment of an ankle prosthesis.

[0013] **FIG. 3A** displays a side view of an embodiment of an ankle prosthesis. **FIG. 3B** displays a kinematic representation of an embodiment of an ankle prosthesis.

[0014] **FIG. 4A** displays a side view of a plantar-flexed ankle prosthesis embodiment and a kinematic representation of a plantar-flexed ankle prosthesis embodiment, in either stance or swing phase.

[0015] **FIG. 4B** displays a side view of a neutral ankle prosthesis embodiment and a kinematic representation of a neutral ankle prosthesis embodiment, in either stance or swing phase.

[0016] **FIG. 4C** displays a side view of a dorsi-flexed ankle prosthesis embodiment and a kinematic representation of a plantar-flexed ankle prosthesis embodiment, in either stance or swing phase.

[0017] **FIG. 5** displays a rear view of a prosthesis embodiment.

[0018] **FIG. 6** displays various views of structural analysis of an embodiment.

## DETAILED DESCRIPTION

[0019] In certain embodiments, a powered ankle prosthesis is disclosed that employs a polycentric mechanism. A polycentric mechanism is one where the center of rotation of at least a portion of the mechanism changes in response to the position of at least a portion of the mechanism. The center of rotation of a polycentric mechanism is known as an “instantaneous center of rotation” or “ICR”. It is referred to as “instantaneous” because it is the center of rotation of at least a portion of the polycentric mechanism, at the particular instant at which the mechanism is at a particular position.

[0020] In an embodiment, a polycentric mechanism may comprise a first member and a second member. The first member and the second member may be connected by a joint structure. For example, the joint structure may comprise a plurality of joints that connect the first member and the second member.

[0021] Each member may comprise a one or more members to form a linkage. The polycentric mechanism may preserve one “degree of freedom,” meaning that only one parameter is needed to describe the posture of the polycentric mechanism. The motion of the polycentric mechanism may be shared among multiple joints within the mechanism which move simultaneously. The resultant motion may be a combination of both translational and rotational motion. The nature of this motion can be characterized by the position of the instantaneous center of rotation as the polycentric mechanism moves from one position to another. For example, the polycentric mechanism may be integrated into a powered ankle-foot prosthesis that can be worn by a person, and which helps the person walk. When the person begins the gait phase of stance, he or she brings the heel of the prosthesis to the ground (“heel strike”). When the person ends the gait phase of stance, he or she lifts the toe of the prosthesis from the ground

(“toe off”). The nature of the motion of the polycentric mechanism can be characterized by the position of the instantaneous center of rotation as the polycentric mechanism moves from the heel strike position to the toe off position.

**[0022]** Using a polycentric mechanism can provide certain benefits to a battery powered foot-ankle prosthesis, such as a powered foot-ankle prosthesis that employs a battery-powered actuator to move, or actuate, the polycentric mechanism. For example, using a polycentric mechanism allows for the instantaneous center of rotation to extend outside of the profile of the polycentric mechanism, as shown, for example, in certain of the figures herein. As a result, the amount of torque the actuator must produce to provide in certain phases of gait (such as late stance, when the ankle needs to provide more torque in order to push off from the ground) may be reduced. This allows for a prosthesis that employs a smaller actuator, a smaller battery, and/or an actuator that can operate for a longer period of time before the battery runs out of energy.

**[0023]** In one embodiment, the polycentric mechanism may comprise a four-bar linkage, where two members of the linkage are connected by two distinct cranks, hinged to both members: the relative motion between the members is a rotation around the ICR, which can be detected by the intersection of the direction of the two cranks.

**[0024]** There are several features for a powered ankle prosthesis which can be optimized through a proper sizing of an actuated four-bar linkages. For example, the ICR progression may be optimized so as to minimize the work-load for a motor that provides power to the prosthesis. As another example, the range of motion of the prosthesis may be adjusted to be comparable with the natural range of motion of a human ankle. As yet another example, the translational portion of motion may be optimized as to be less evident, for an intended use of the prosthesis.

[0025] Another feature of certain embodiments described herein is a translational movement of the ankle prosthesis, instead of angular movement, with respect to the residual limb, as to minimize the shear stresses transmitted through the cuff to the residual leg stump.

[0026] Another feature of certain embodiments described herein is that the actuator may be enclosed within an opening in the polycentric mechanism. Another feature of certain embodiments is that the structural strength of the ankle-foot prosthesis is shared among more connecting members that carry both the user's weight and the powered loads, which can reduce the overall weight of the prosthesis.

[0027] In certain embodiments, a powered ankle prosthesis may comprise a polycentric mechanism that provides a swiveling motion between a first member and a second member. The first member may be referred to as the "reference" member and second member may be referred to as the "driven" member. The swiveling motion between the reference member and the driven member can result in the driven member rotating with respect to the reference member. Either member may be linked to a foot prosthetic component, or element, and the other member may be linked to a shank prosthetic component, or element. The foot component and the shank component may be made of materials used in the art, such as plastics and/or metals.

[0028] An ankle prosthesis may further comprise an actuator that drives the motion of the polycentric mechanism, and therefore drives the motion of the prosthesis, for instance as the prosthesis moves from heel strike to toe off. The actuator may be a linear actuator. The actuator may drive the motion of the polycentric mechanism by adjusting the distance between one point of the driven member and one point of the reference member. For example, the linear actuation system may adjust the distance between one point of the driven member, such as a hinge of the driven member, and one point of the reference member.

[0029] An ankle prosthesis embodiment may further exploit the kinematic property of the polycentric mechanism, such as the progression of the ICR position, and the position of the driven member's hinges in order to realize a fully powered motion of the ankle articulation. In various embodiments, the prosthesis may be sized as to support the ground reaction force ("GRF") profile over gait-time, which is elicited from the floor as the user walks, together with the angular range of motion of the ankle joint.

[0030] In certain embodiments, the linkages in the polycentric mechanism may be proportioned in order to provide the mechanism with an angular range of motion that mimics the angular range of motion of a natural, human ankle. For example, for an ankle prosthesis, an ankle range of motion for minimal mobility covers from 15° in plantar-flexion to 10° in dorsi-flexion. (Plantar-flexion is the position of a foot with the toe pointed downwards. Dorsi-flexion is the position of the foot with the toes pulled up towards the shin.) In various embodiments described herein, the ankle range of motion covers from at least 29° in plantar-flexion to at least 27° in dorsi-flexion. Additionally, certain linkages may be proportioned in order to provide a prospected displacement of the instantaneous center of rotation ("ICR"). For instance, the prospected displacement of the ICR becomes more advanced as the power requirements become higher. Placement of a linear actuator motorized axis can achieve a long enough lever-arm with respect to the ICR, so as to exert the torque that would otherwise be provided by a natural ankle. Identifying a proper mounting angle of the foot component and/or of the shank component with respect to the driven member and reference member respectively, can help center the polycentric mechanism's range of motion and the ICR trajectory in an appropriate position for covering anatomical gait requirements. For example, the mounting angle may be 19.5°.

**[0031] FIGS. 1A-1D** display side views of an embodiment of an ankle prosthesis at positions ranging from 0% of stride to 60% of stride. Each position is accompanied by three images in the figures. The left-hand image is a side view of an embodiment of a powered ankle-foot prosthesis, in a reference frame in which the foot is fixed, and in a posture corresponding to the stride percentage. The middle image is a side view kinematic representation of the same posture, with the GRF and active force represented in arrows. The GRF is represented in each image by the arrow that starts at the sole of the foot. In an embodiment, values associated with the GRF may be taken from information that is well known and documented in the art, and which, for instance, has been collected from studies involving GRF on human feet and ankles. Such values include the amount of the GRF, its orientation, and the position of the center of pressure (in other words, the position at the sole of the foot where the gray arrow originates).

**[0032]** The active force that the actuator is required to provide is represented in each image by the gray arrow that initiates at a point in the middle of the foot. Each middle image also traces a monocentric joint case, for comparison between the ICR position and the fixed joint. The position of the ICR is determined by the intersection of two lines, each congruent to each of the opposite sides of the quadrilateral figure of the reference member. The line segments resulting in the intersection are displayed as dashed lines.

**[0033]** Each right-hand image shows the same image as in the middle panel, but represented in a reference frame oriented according to the floor (x-axis is horizontal and y-axis is vertical), so that the transition of the prosthesis from 0% of stride to 60% of stride can be seen. Labels along x and y are distances in mm with respect to the heel location. Forces vector are scaled.

[0034] Briefly, the progression of the GRF with respect to the foot-ankle system during the stance phase of walking is depicted in **FIGS. 1A-1D**. For comparison, the middle images in each of **FIGS. 1A-1D** depict both the ICR and the monocentric center of rotation. The monocentric center of rotation is indicated in each figure as a circle with dot at its center, placed in between the foot component and the shank component. As the user walks, the center of pressure of recorded GRF from sound limb data progresses from the heel to the toe. In order to elicit the GRF being placed in a certain position under the foot, the ankle is expected to provide a certain torque. During gait, the most demanding phase for the ankle is in late stance, particularly during push off. During this period, the center of rotation is at a greater distance from the ankle, and the horizontal and total GRF are each greater than at other phases of stance. By moving the ICR outside the profile of the polycentric mechanism, the ICR is placed in an advantageous position during late stance, resulting in the GRF having a smaller lever arm than it would in a mono-centric system. For example, when the ankle is at about 45% of stride, as shown in **FIG. 1C**, the moment arm of the GRF to the monocentric center of rotation is substantially longer than the shortened moment arm of the GRF to the ICR. As a result, the amount of torque the GRF provides is lower, which means that the actuator may provide a lower amount of torque than it would need to in other systems, such as a mono-centric system. Other moment arms also are involved in the torque profile of the ankle prosthesis, as shown in the figures.

[0035] In the embodiment shown in **FIGS. 1A-1D**, the ICR trajectory is outside the profile of the polycentric mechanism, while the profile of the polycentric mechanism remains confined within the foot profile. Keeping the profile of the polycentric mechanism in the foot profile means that the artificial prosthesis has an aesthetically acceptable shape. It can, for

instance, be inserted into an ordinary shoe, or otherwise sized so that it is not apparent to a casual observer that a person is using an artificial ankle or ankle-foot prosthesis.

[0036] Additionally, during an initial phase of stance, the actuator can function as a “brake” rather than an actuator, since the direction of active force and related equivalent ankle torque are opposite to the direction of the motion progression. In an embodiment, rather than the battery exerting energy during this phase, the actuator provides energy back to the battery, as the “braking” effect is given by the weight-acceptance back-driving the motor. For instance, if a backdrivable roller screw is used in the actuator, the “braking” effect may return energy to the battery. Backdrivable rollers screws are known in the art.

[0037] In a four bar polycentric mechanism, forces exchanged in between the driven and the fixed members, due to the polycentric mechanism connections, can arise but are geometrically aligned along the connecting cranks (being those connected through pivoting joints, they can only be compressed or tensed along their direction). Thus, whichever these components, they have a geometrically-null-arm with respect to the ICR (their direction are always crossing in the ICR): as a consequence, they do not change the exposed relationship between the actuated powered force and the GRF.

[0038] The actuator may comprise a rotating electrical motor, which is coupled to a linear screw-nut system. The actuator may convert rotating motion to linear motion, and vice versa. In another embodiment, a roller screw and a roller nut may be employed. The actuator may comprise a parallel-axis transmission stage, such as a pulley/belt system, or a geared system. The polycentric mechanism may provide for an opening in its interior, as shown in the various figures, such as an open space between the driven member’s brackets where a portion of the actuator can be housed. This helps provide some degree of protection for the motor and any

wiring of the actuator. As shown in the figures, the actuator can be enclosed in the foot shape, which can provide a substantial benefit to patients. In an embodiment, the actuator is so enclosed is as a result of placement of the actuator's axis, and the angled shape of the bracket **102** of the polycentric chain.

[0039] Description of the device mainly lies into the sagittal plane, while for the dimensions outside such plane, it can be seen from **FIGS. 2A-2B** how this is limited up to the size of a commercial pyramid connector **130**, thus being competitive with all other foot and/or ankle prosthetic component of such genre. One embodiment of the assistive device is shown in **FIG. 2**. The assistive device **100** interfaces with a shank-ylon (or other prosthetic components) **200**, via a modular connector **130**, and with a foot **300** via direct fastening under the element **101**.

[0040] The device **100** realizes the motion of the pylon **200** with respect to the foot **300** without co-locating the ankle joint in any physical position, but utilizing an exemplary polycentric mechanism with a resulting swiveling motion of the member **102** with respect to the member **101** on the lateral side of the device **100** and a resulting swiveling motion of the member **110** with respect to the member **101** on the medial side of the device **100**. A kinematic chain is realized by connecting the two said members on each of the lateral or medial sides, via crank elements through four total pivoting axes (**107-110**). In particular, said cranks are replicated in pairs (**103/105** and **104/106**), connecting member **101** and member **102** both on the medial and on the lateral sides. As shown in **FIG. 2A-2B**, member **101** is connected to crank **103** and crank **105** via pins along the pivoting axis **107**, and to cranks **104** and **106** via pins along the pivoting axis **108**; member **102** is connected to crank **103** and crank **105** along the pivoting axis **109**, and

to crank **104** and crank **106** along the pivoting axis **110**. Thus the same structure is provided on the medial and lateral sides of the device **100**.

[0041] The device also includes an actuator, which may be housed within the opening between the two four-bar kinematic chain instances. The actuator provides power to assist motion of the device. In particular, the actuator exerts the required torque for the ankle flexion-extension movement. The actuator can adjust the distance between certain preferential axis pairs, such as the axis **109** and an additional axis **121** located in the foot component **101** as shown in **FIG. 2B**. Actuation can be realized via a linear element, such as a linear guide, a screw or a rail, and a sliding element such as a linear bushing, a nut or a carrier. The actuator may be attached to the two four-bar kinematic chain structures so that actuation of the actuator results in movement of one of the four-bar kinematic chain structures with respect to the other. As a result, relative position of the slider with respect to the guide can determine the posture of the four-bar kinematics. The actuator may be coupled to the polycentric mechanism in various ways, for instance as shown in the figures.

[0042] In one embodiment, shown in **FIGS. 2A, 2B, and 3**, the actuator **120** is powered with a rotational motor **126**. The motor **126** may be, for example, a DC brushed or brushless electrical motor. The power of the motor **126** is transformed into linear motion by the screw/nut pair **122/125**. In this embodiment, the nut **125** is connected to the element **102** and the cranks **103** and **105** via pins along the line of axis **109**. The actuator may be interior to the element **102** as shown in **FIGS. 2A and 2B**. A transmission **124** comprising gears **124a** and **124b** transmits power from the motor **126** to the linear drive comprised by the screw **122** and the nut **125**. A pivot element **125a** (see **FIG. 2A**) may extend from the end of the motor **126** to a connection point to element **101** via a connector along the axis **121**. Allowing the actuator **120** to pivot

relative to the element **101** affixed to the foot **300** allows the actuator **120** to slightly rotate around axis **121** during gait. The slight rotation of the actuator **120** is reflected in the series of figures shown in **FIG. 1A-1D**.

[0043] It should be understood that other transmissions may be employed, such as a pulley-and-belt system or a different gearing system. The actuator **120** may employ other components known in the art of powered prostheses, such as control boards, motor controllers, microprocessors, memory, and so forth. The device **100** may provide ankle stiffness (such as physiological ankle stiffness) through, for example, software motor control. As shown by foot outline **120** in **FIG. 3A**, the device **100** can be fit within the profile of a human foot.

[0044] The device **100** can realize the ankle motion without constraining its mechanical components on a fixed hinge joint collocated on the ankle anatomical position itself, thus providing greater design freedom in mechanical and structural optimization. In particular, movement of the device **100** results in a motion between the foot component **300** and the shank component **200** which is substantially and aesthetically equivalent to a rotation around a fixed joint, but different in kinematics, shown in **FIG. 3B**. Instantaneously, the motion of the shank **200** with respect to the foot **300** corresponds to a rotation around the ICR **111**, which (as discussed above) is not fixed. The arc **112** in **FIG. 3B** represents the trace of the ICR points as the device **100** from heel strike to toe off. The combination of rotation around the ICR, and the progression of the position of the ICR itself due to the polycentric mechanism's orientation, results in the global motion of the shank **200** with respect to the foot **300**. In particular, the kinematic and kinetic characteristics (specifically, the angular range of motion and the transmission ratio from the actuator to the powered assistive torque) of the polycentric motion are completely defined by the arc **112** and ICR position **111**. The assistive device **100** can

provide the correct amount of powered torque for each angular position, properly evaluated accordingly to the kinematic of the ICR **111**.

[0045] Simultaneously, the aesthetic appearance of the motion is also dependent on the relative position between the shank component **200** and the element **102**. In one embodiment, shown in **FIGS. 2-3**, such relative position is optimized as to minimize the translational component of the swiveling motion parallel to the pylon axis itself (i.e. elevation or depression of the shank component **200** during motion).

[0046] In particular, being the physical motion of the shank component **200** depending also on the relative mounting between its interface and the member **102**, this provides additional design parameters which can be conveniently tuned in order to meet particular characteristics in the motion, e.g. having a bigger foot clearance during swing phase.

[0047] Behavior of the represented embodiment with the extremal device postures (maximum plantar-flexion and dorsi-flexion), together with the neutral one, is shown in **FIGS. 4A-4C**. In particular, the greater deviation of the trace **112** from a closed point (ideal condition for a polycentric motion perfectly corresponding to a fixed-hinged rotation) occurring in high values of the plantar-flexion, which are commonly not exploited during the level walking gait. Plantar-flexed, neutral and dorsi-flexed position of the prosthesis and corresponding kinematic scheme, with position of ICR for current configuration. The range of motion covers about 30° in both plantar-flexion (**FIG. 4A**) and dorsi-flexion (**FIG. 4C**).

[0048] The embodiments described herein are intended to be merely exemplary, and numerous variations and modifications will be apparent to those skilled in the art. All such variations and modifications are intended to be within the scope of the present invention as defined in the appended claims.

## CLAIMS

What is claimed is:

1. A powered ankle prosthesis, comprising a polycentric mechanism having a defined path for an instantaneous center of rotation; wherein the path of the instantaneous center of rotation is defined by a trajectory substantially equal to an arc positioned over a joint of the polycentric mechanism.
2. The prosthesis of claim 1, wherein the path of the instantaneous center of rotation is further defined such that during late stance, the instantaneous center of rotation is positioned to provide a shortened moment arm in relation to a ground reaction force.
3. The prosthesis of claim 2, wherein the polycentric mechanism comprises a first member and a second member.
4. The prosthesis of claim 3, wherein the first member defines the path for the instantaneous center of rotation.
5. The prosthesis of claim 4,
  - a. wherein the first member comprises a base element connected to a foot component, a first crank pivotally coupled to the first member, and a second crank pivotally coupled to the first member;
  - b. wherein the first crank and the second crank each are pivotally coupled to a bottom portion of the second member; and
  - c. wherein the first crank and the second crank are aligned to define the path for the instantaneous center of rotation.
6. The prosthesis of claim 5, wherein a top portion of the second member is angled for attachment to a shank component connection.

7. The prosthesis of claim 1, further comprising an actuator for moving the polycentric mechanism.
8. The prosthesis of claim 7, wherein the actuator is at least partially housed within an opening of the polycentric mechanism.
9. The prosthesis of claim 8, wherein the actuator is configured to adjust the distance between a hinge of the first member and a hinge of the driven member.
10. The prosthesis of claim 9, wherein the actuator comprises a motor, a transmission, and a screw.
11. The prosthesis of claim 10, wherein the screw is a lead-screw.
12. The prosthesis of claim 10, wherein the screw is a ball-screw
13. The prosthesis of claim 10, wherein the screw is a roller-screw.
14. The prosthesis of claim 1, wherein the polycentric mechanism fits within the contour of an anatomical foot profile.

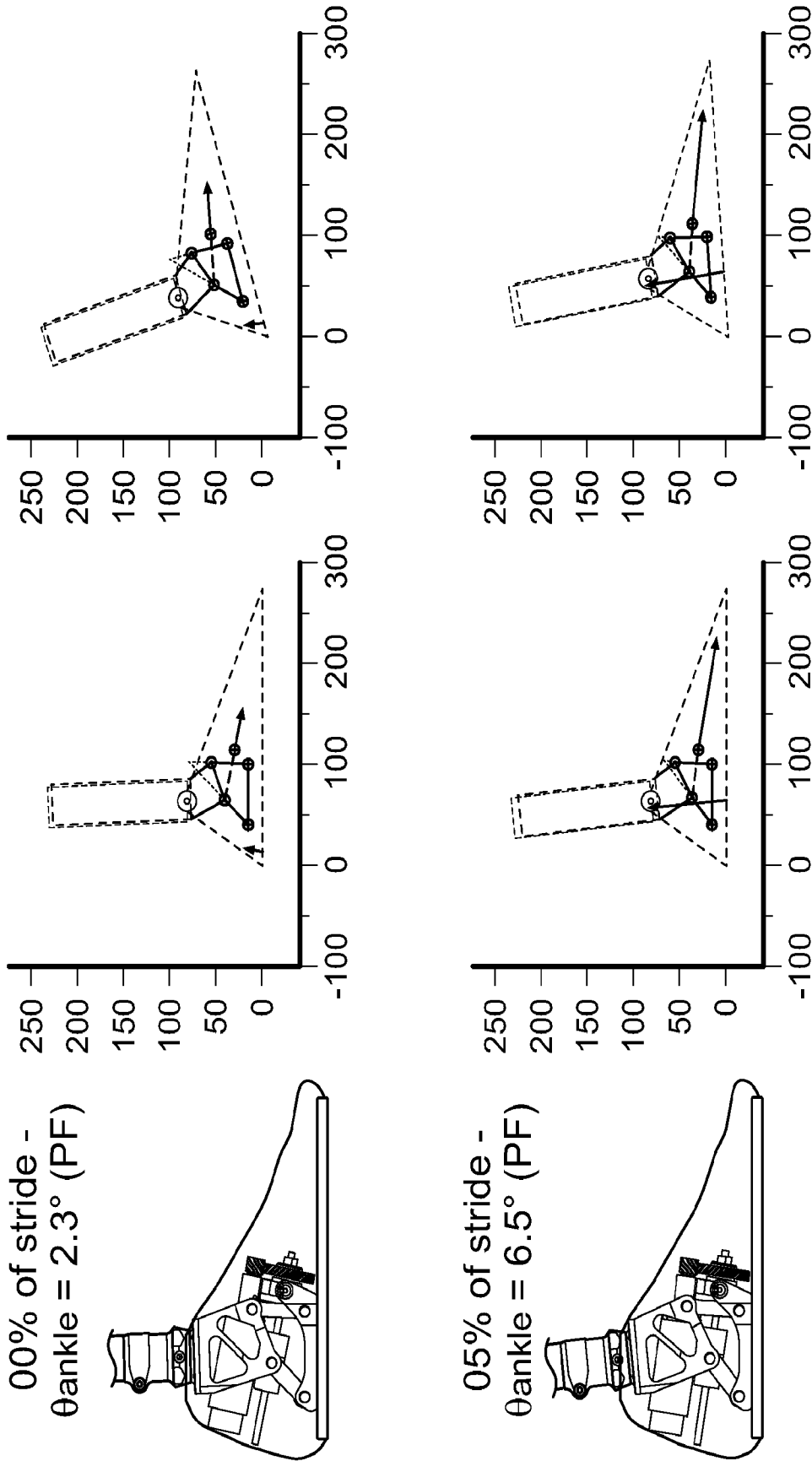


FIG. 1A

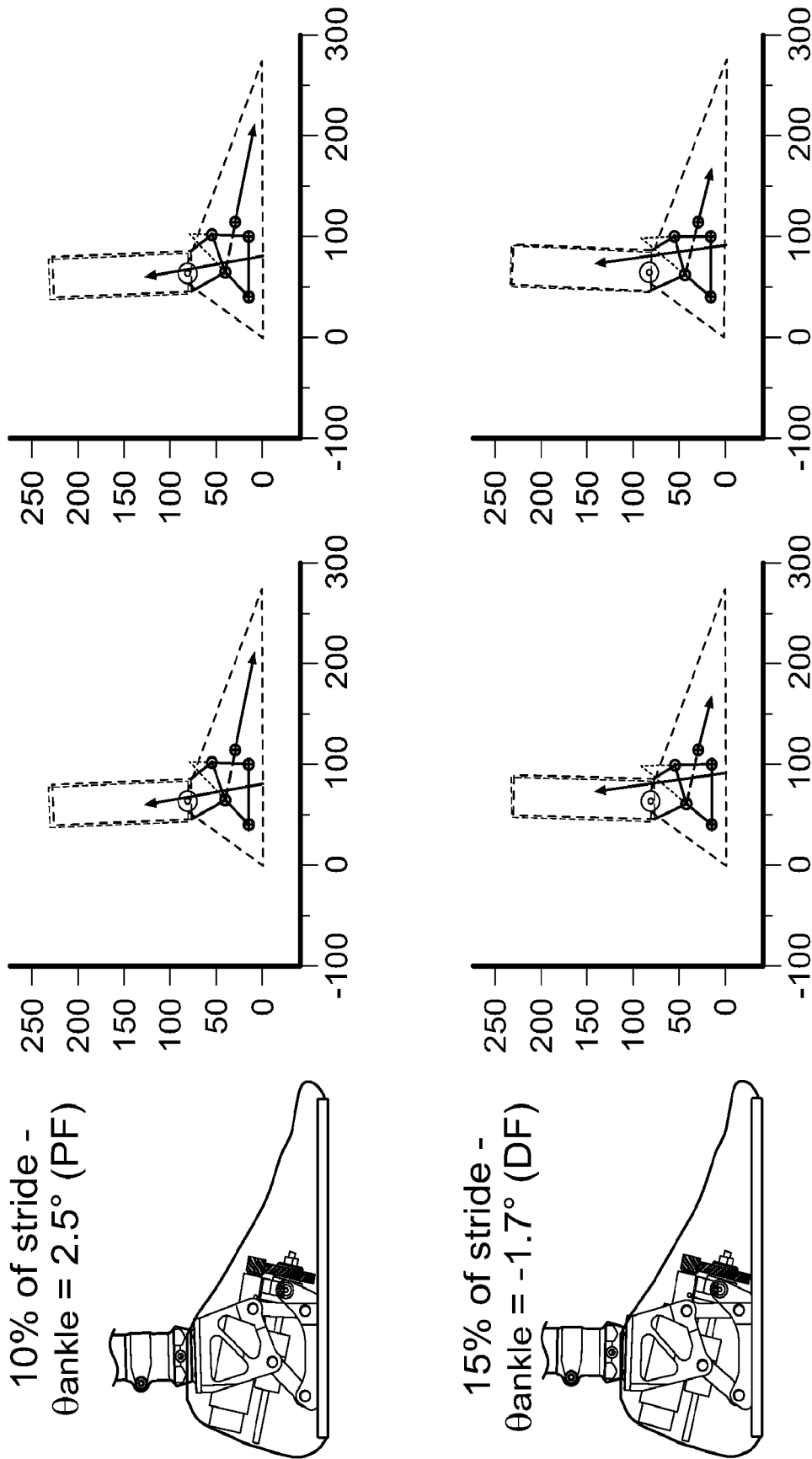


FIG. 1B

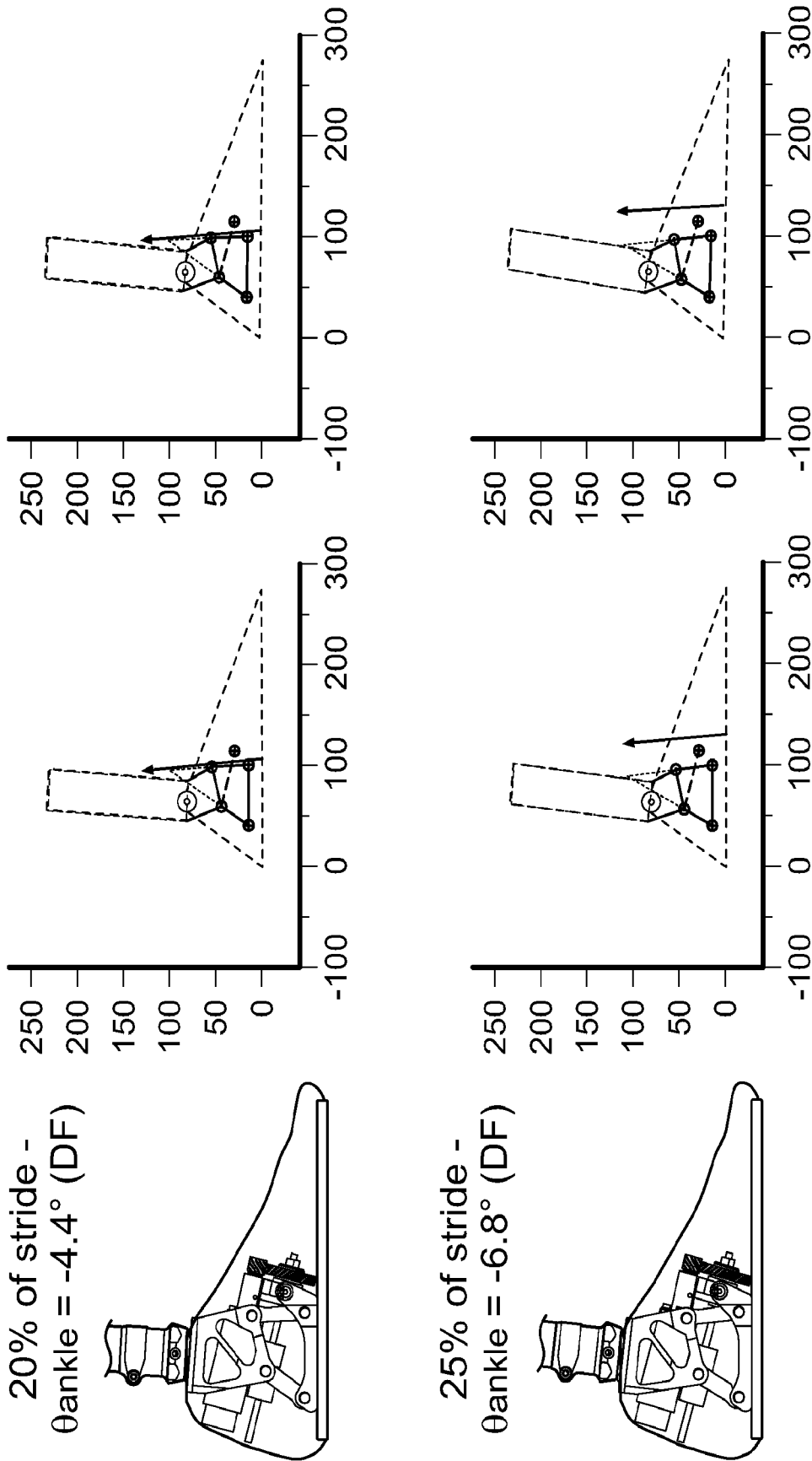


FIG. 1B (Cont.)

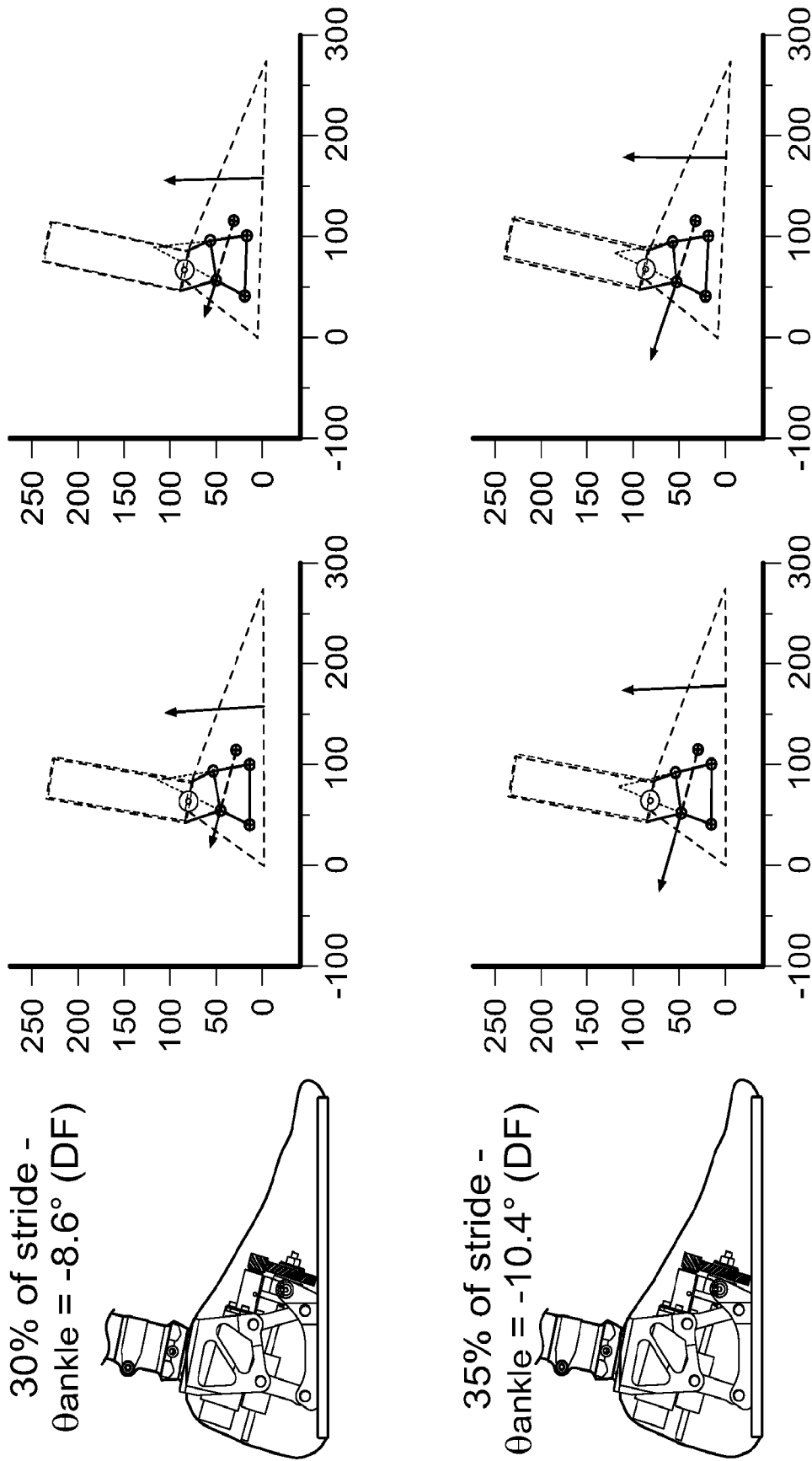


FIG. 1C

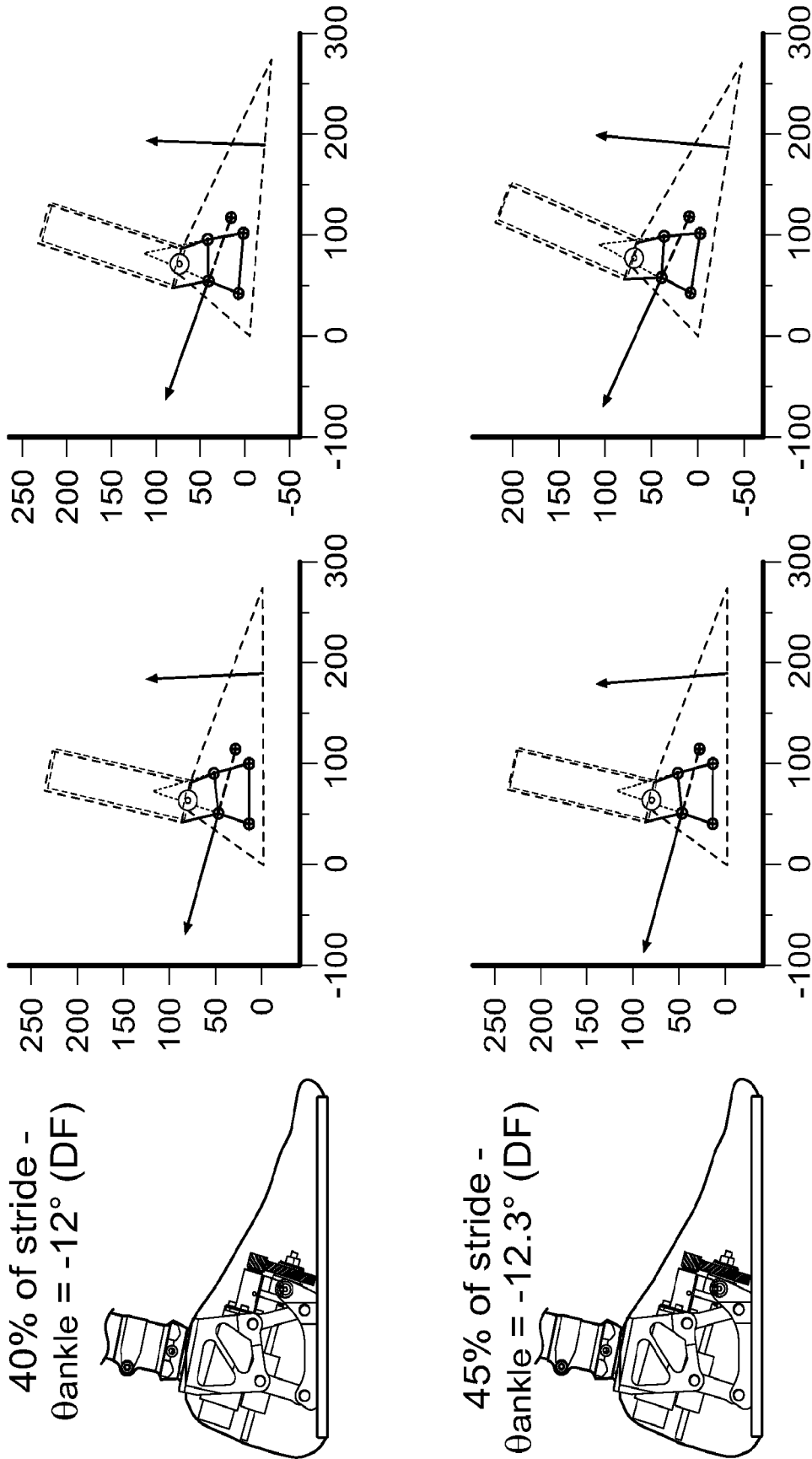


FIG. 1C (Cont.)

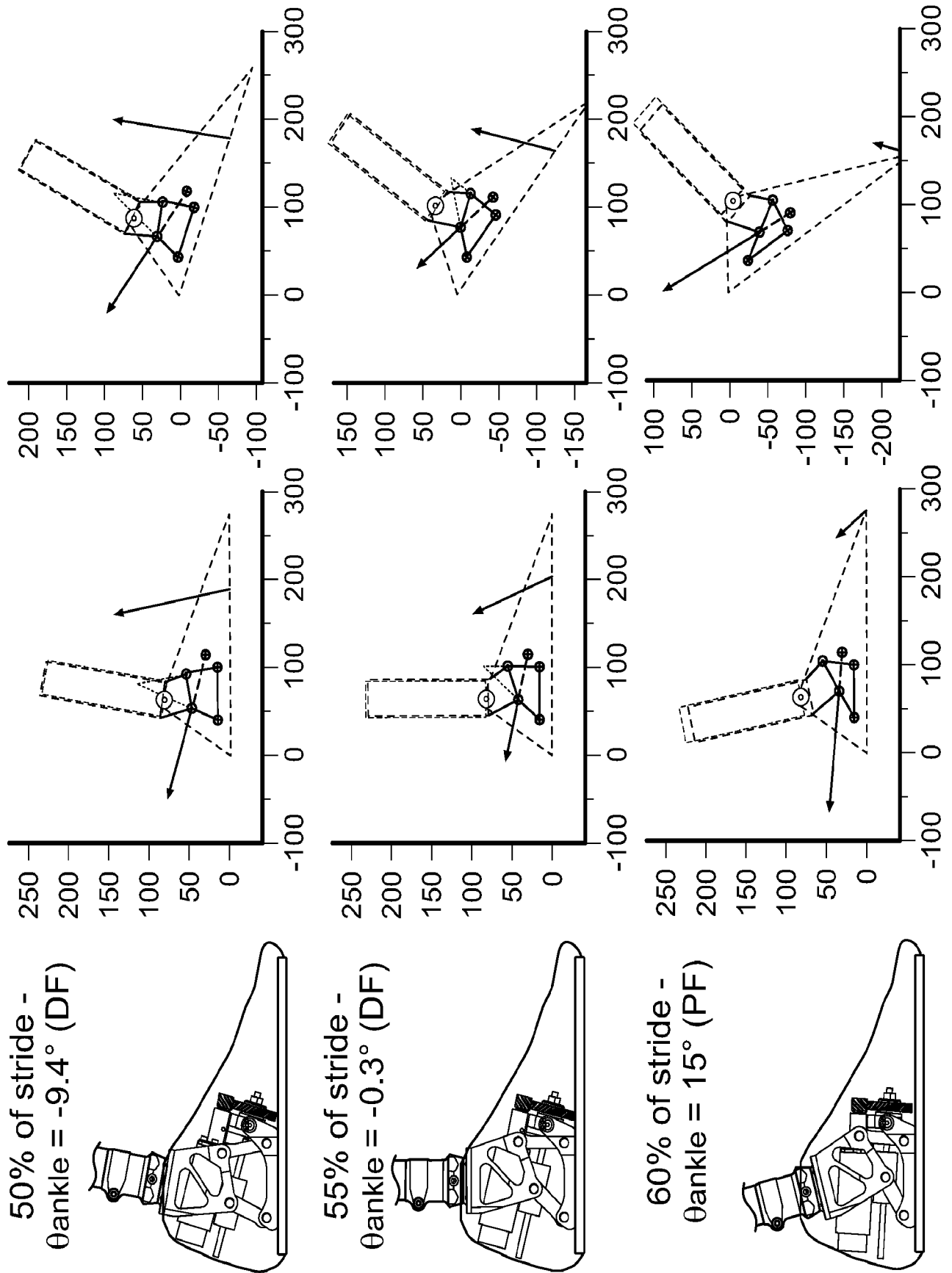


FIG. 1D

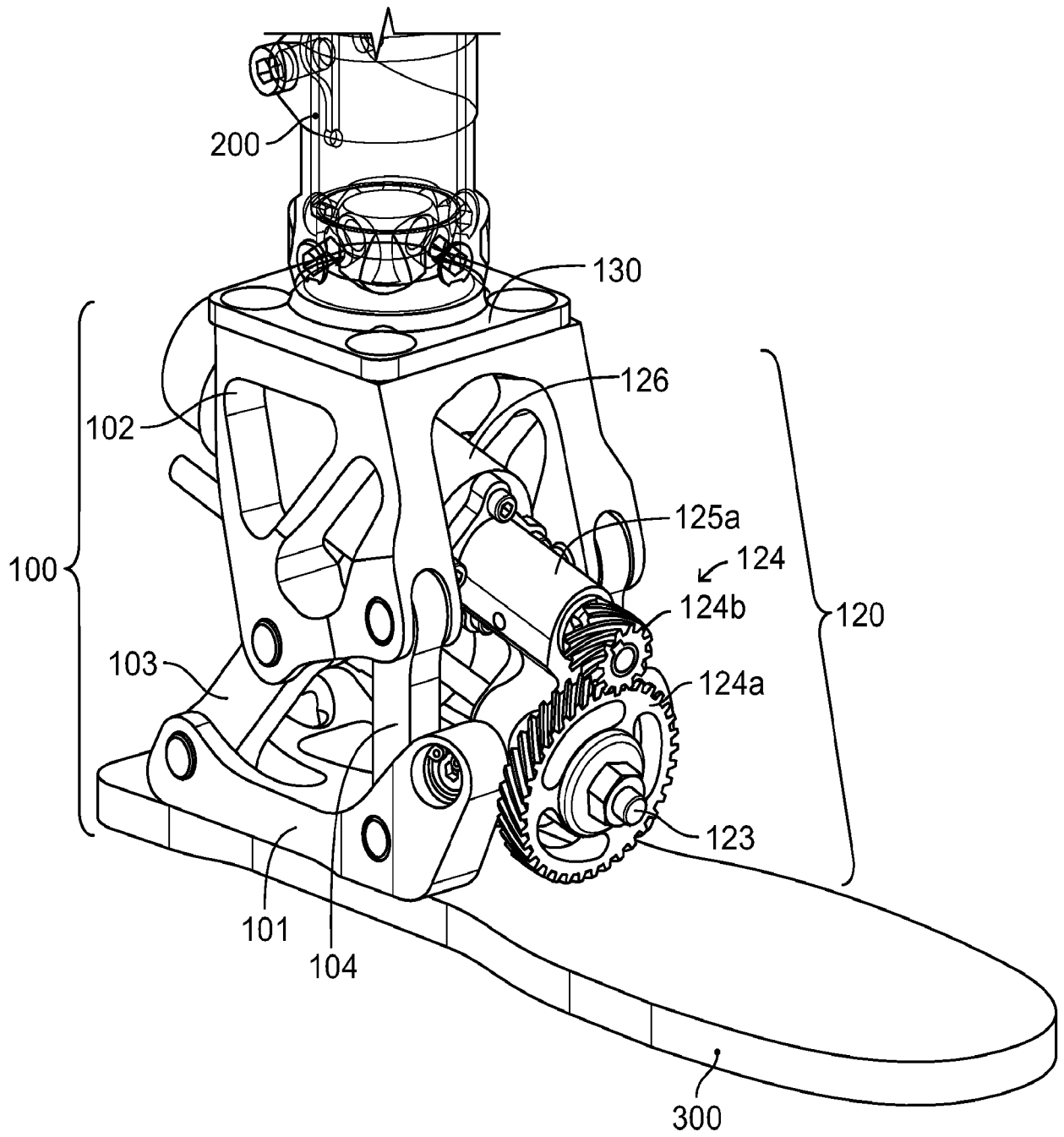


FIG. 2A

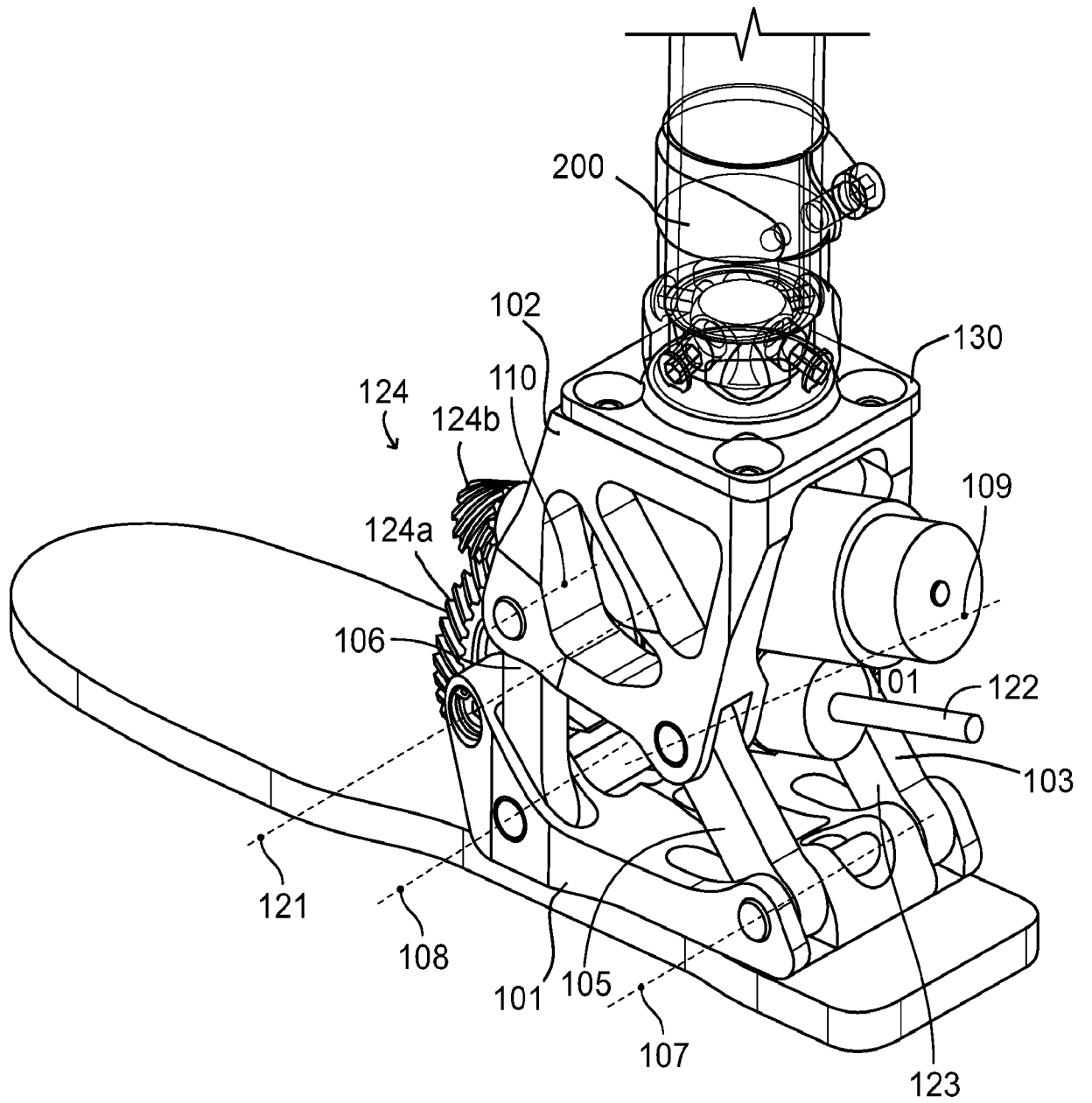


FIG. 2B

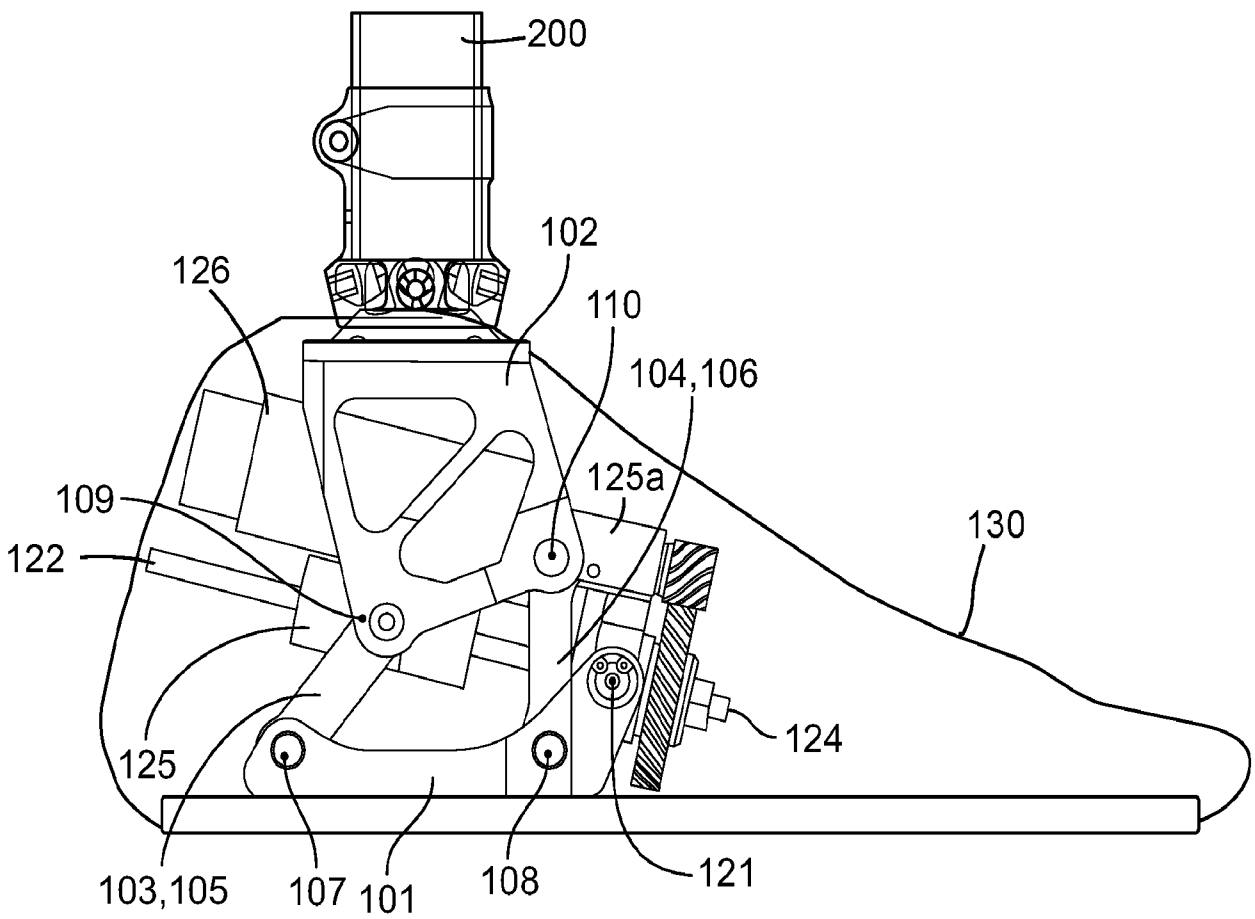


FIG. 3A



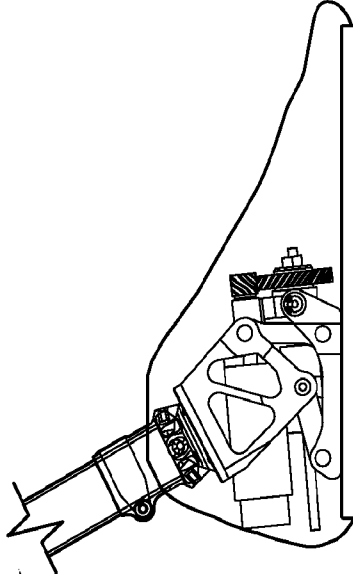
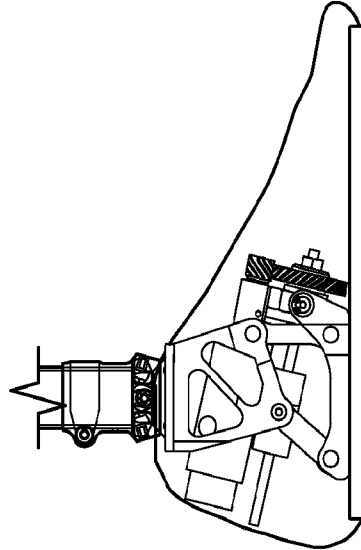
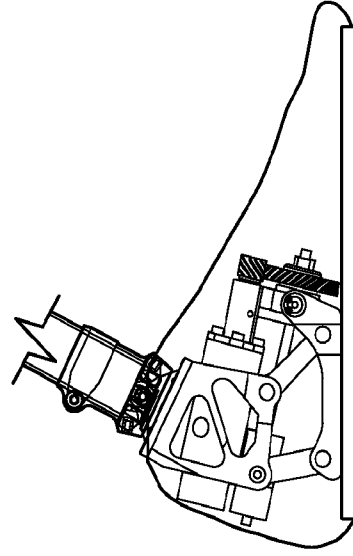
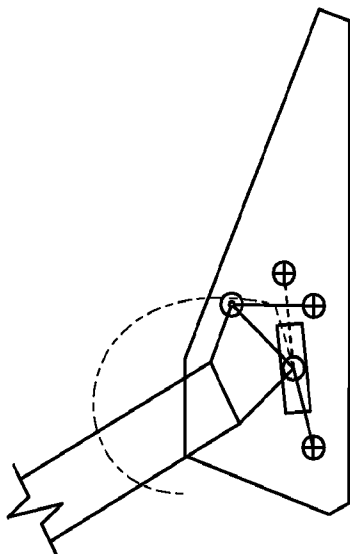
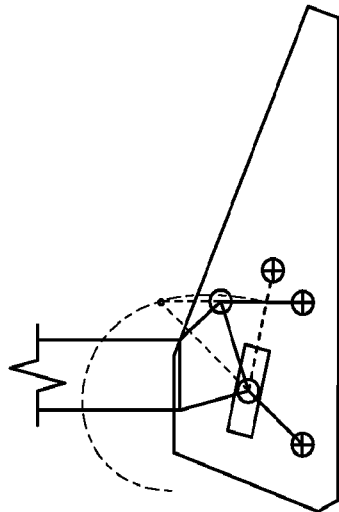
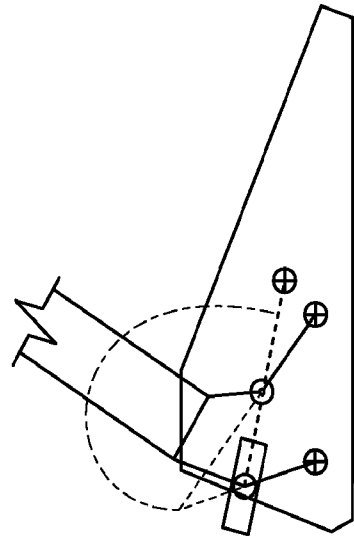
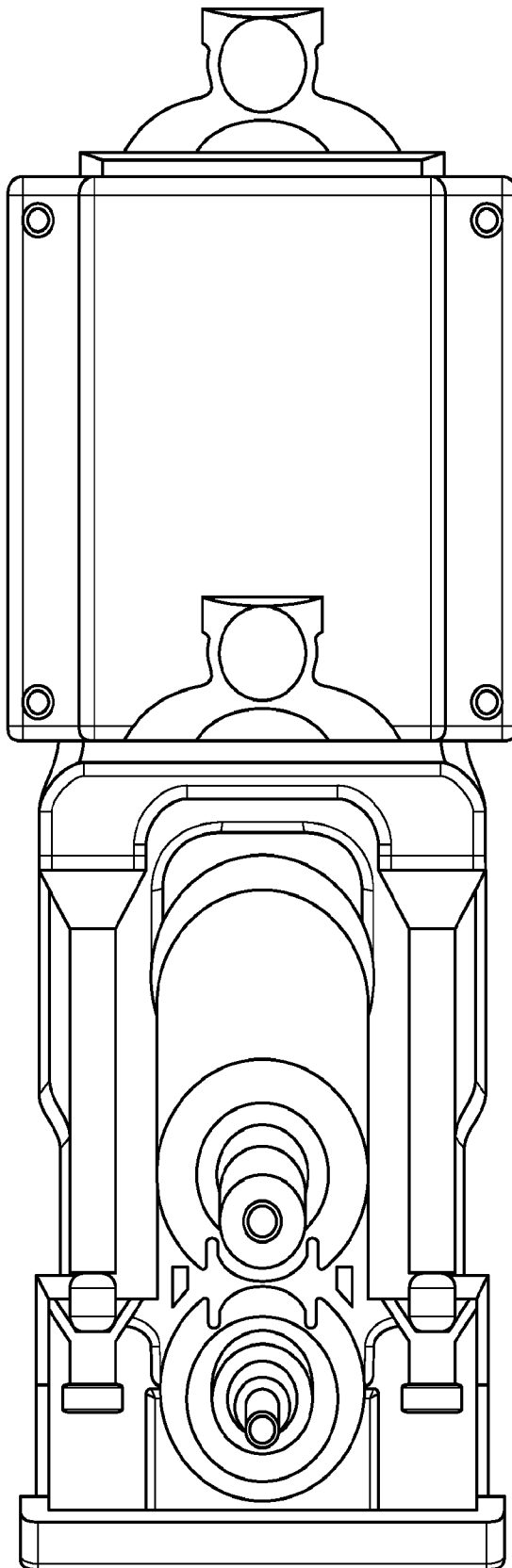


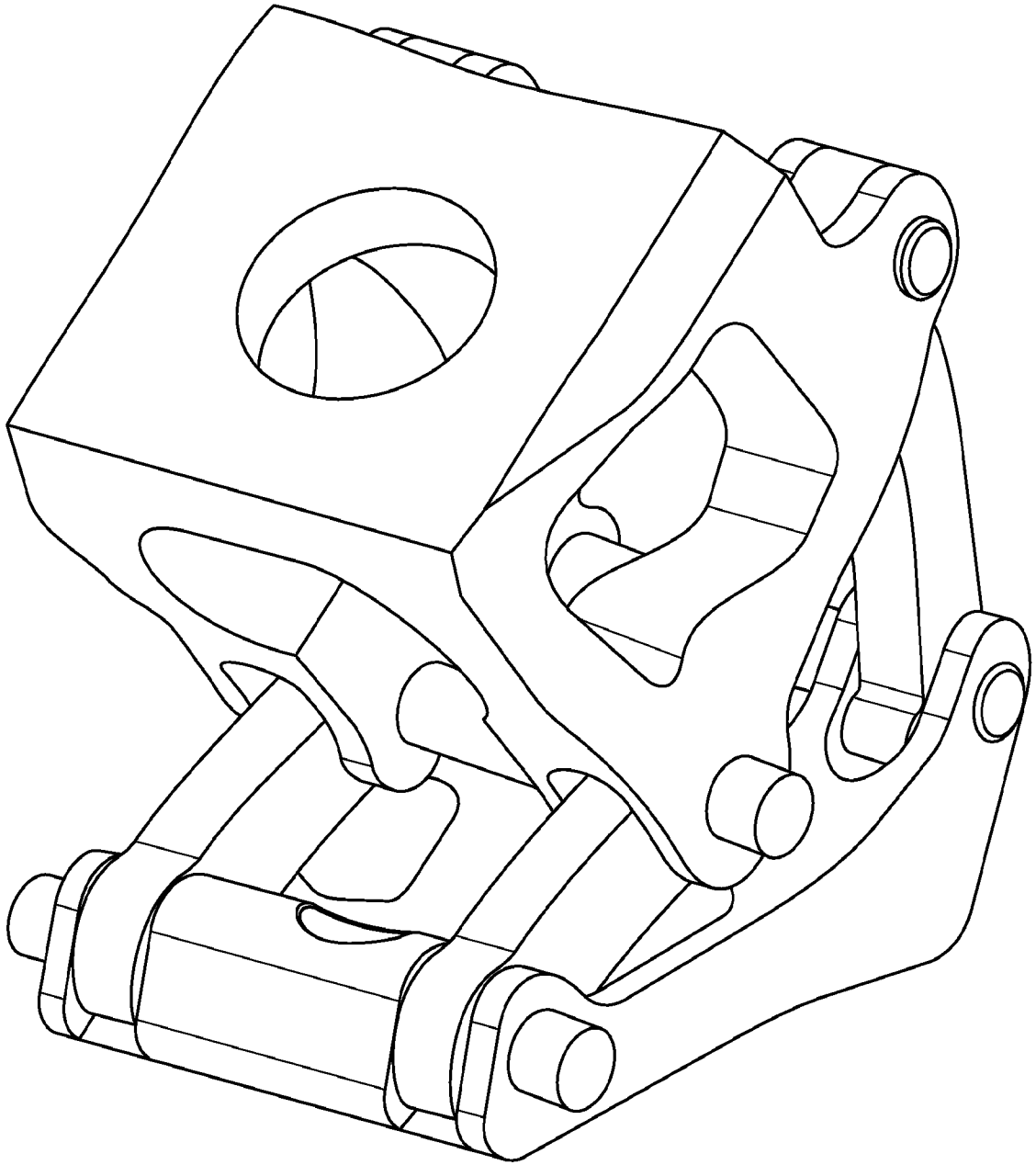
FIG. 4C

FIG. 4B

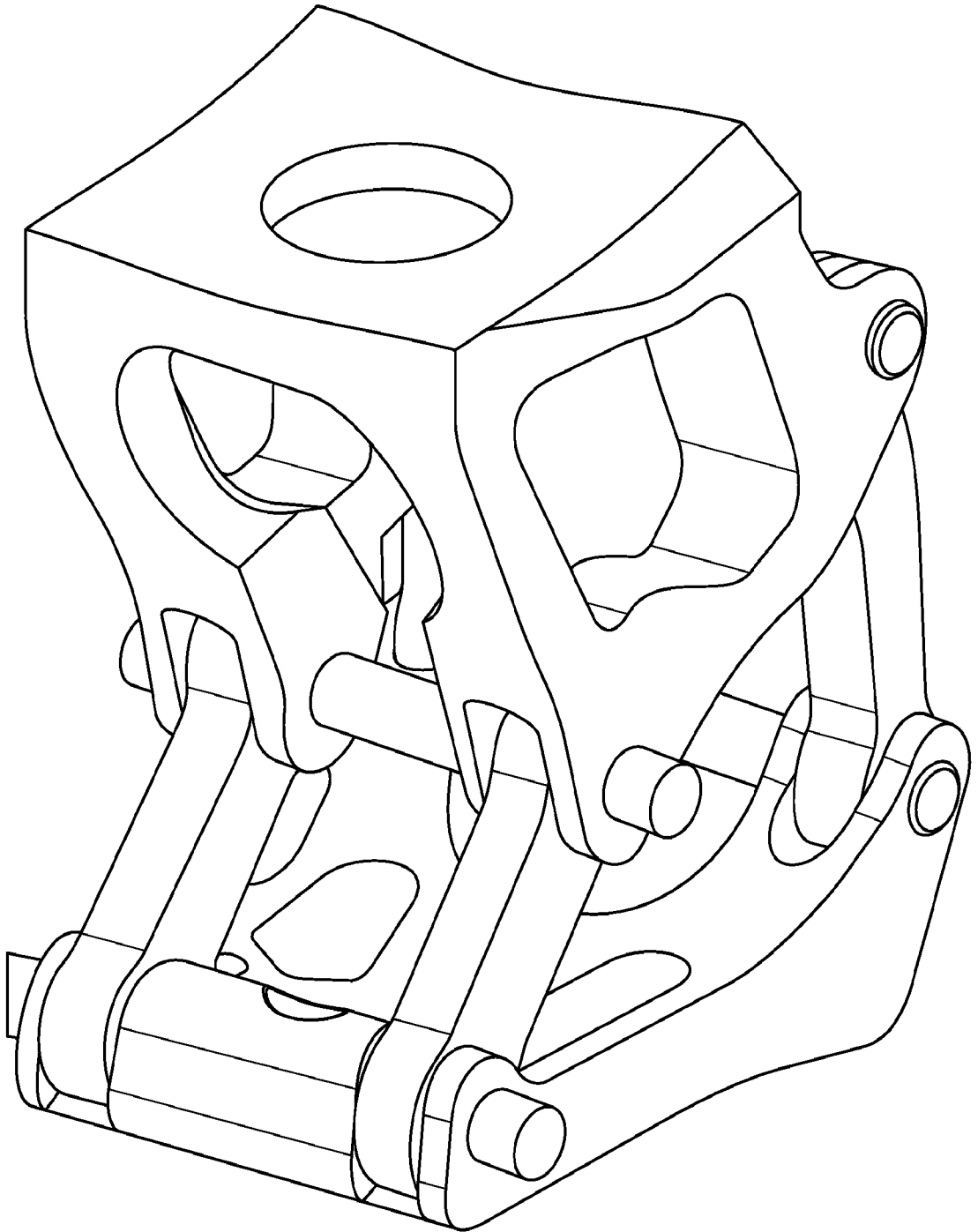
FIG. 4A



**FIG. 5**



**FIG. 6**



**FIG. 6 (Cont.)**

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 60661WO01	<b>FOR FURTHER ACTION</b>	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 17/26703	International filing date ( <i>day/month/year</i> ) 07 April 2017 (07.04.2017)	(Earliest) Priority Date ( <i>day/month/year</i> ) 07 April 2016 (07.04.2016)
Applicant REHABILITATION INSTITUTE OF CHICAGO		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- the international application in the language in which it was filed.  
 a translation of the international application into \_\_\_\_\_ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b.  This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c.  With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2.  **Certain claims were found unsearchable** (see Box No. II).

3.  **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

- the text is approved as submitted by the applicant.  
 the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- the text is approved as submitted by the applicant.  
 the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 1  
 as suggested by the applicant.  
 as selected by this Authority, because the applicant failed to suggest a figure.  
 as selected by this Authority, because this figure better characterizes the invention.
- b.  none of the figures is to be published with the abstract.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/26703

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/66, A61F 2/70, A61F 2/64, A61F 2/74 (2017.01)

CPC - A61F 2/6607, A61F 2/66, A61F 2002/6614, A61F 2002/741, A61F 2002/701

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History Document

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

See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History Document

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y -- A	US 2015/0209214 A1 (Massachusetts Institute of Technology), 30 July 2015 (30.07.2015), entire document, especially Fig. 19A-19B; para [0022], [0024], [0091] and [0110]	1, 7 and 14 ----- 2-6 and 8-13
Y -- A	ALBERTO LEARDINI ET AL. "Biomechanics of the Natural, Arthritic, and Replaced Human Ankle Joint," Journal of Foot and Ankle Research, published on February 2014 (02.2014), retrieved on 22 November 2017 (22.11.2017), accessed at <https://www.researchgate.net/publication/260116283_Biomechanics_of_the_natural_arthritic_and_replaced_human_ankle_joint>, entire document, especially Fig. 2; pg. 2, col 2, para 2-3	1, 7 and 14 ----- 2-6 and 8-13
A	US 2015/0359643 A1 (LIMBS International Inc.), 17 December 2015 (17.12.2015), entire document	1-14
A	US 2014/0039642 A1 (Ossur hf), 06 February 2014 (06.02.2014), entire document	1-14
A	GB 2283920 A (Cooper), 24 May 1995 (24.05.1995), entire document	1-14
A	US 6,443,994 A (White), 25 December 1984 (25.12.1984), entire document	1-14
A	US 2009/0171469 A1 (Thorstiensson et al.), 02 July 2009 (02.07.2009), entire document	1-14
T	US 2017/0290684 A1 (Rehabilitation Institute of Chicago d/b/a Shirley Ryan Ability Lab), 12 October 2017 (12.10.2017), entire document	1-14

 Further documents are listed in the continuation of Box C. See patent family annex.

\* 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 application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"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 when the document is taken alone

"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

"&amp;" document member of the same patent family

Date of the actual completion of the international search

22 November 2017

Date of mailing of the international search report

29 DEC 2017

Name and mailing address of the ISA/US

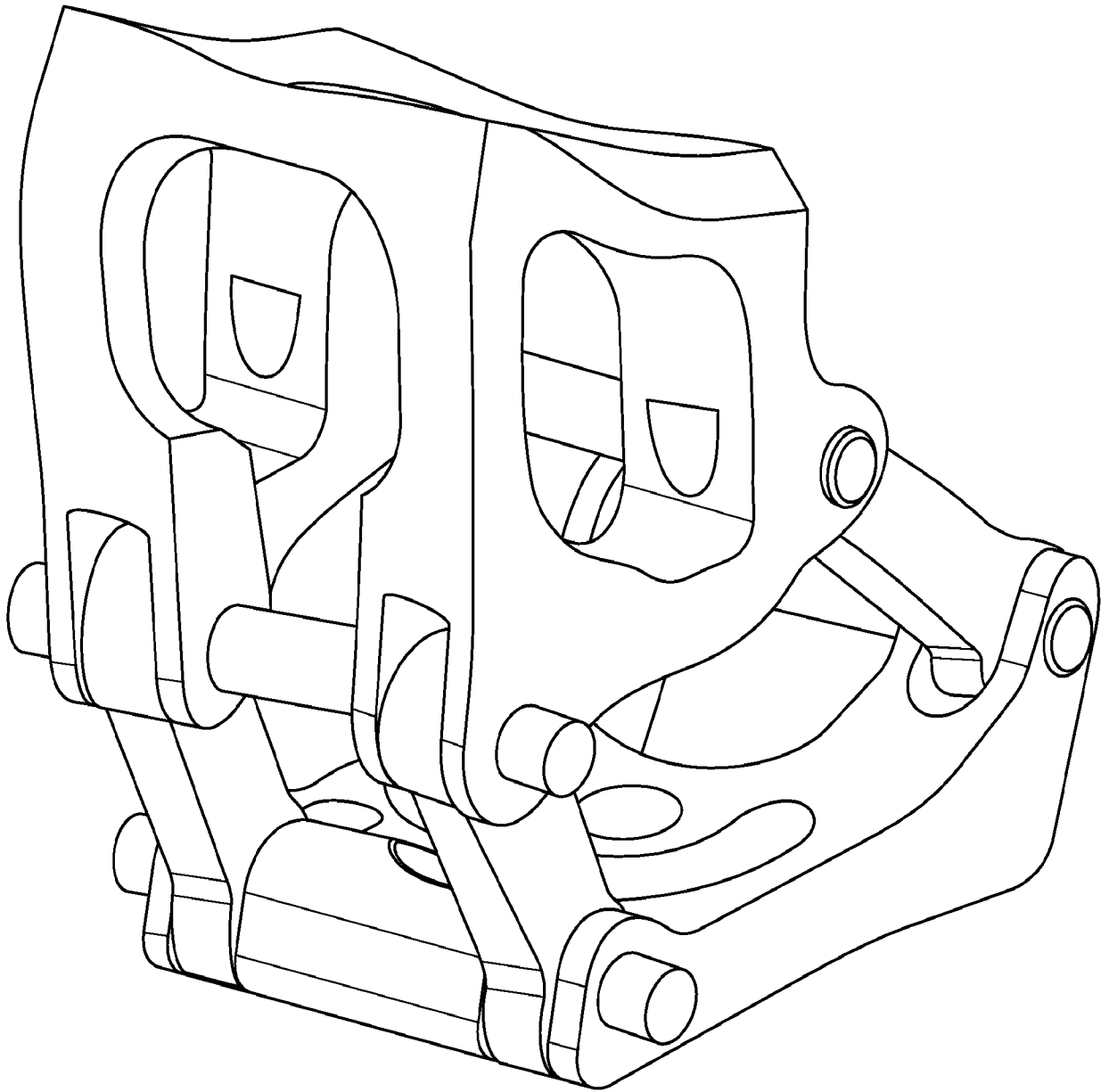
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Lee W. Young

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PCT OSP: 571-272-7774



**FIG. 6 (Cont.)**