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(54) Title: IMPROVEMENTS TO PASSIVE ANKLE-FOOT PROSTHESIS AND ORTHOSIS CAPABLE OF AUTOMATIC ADAPTATION TO SLOPED WALKING SURFACES AND METHODS OF USE

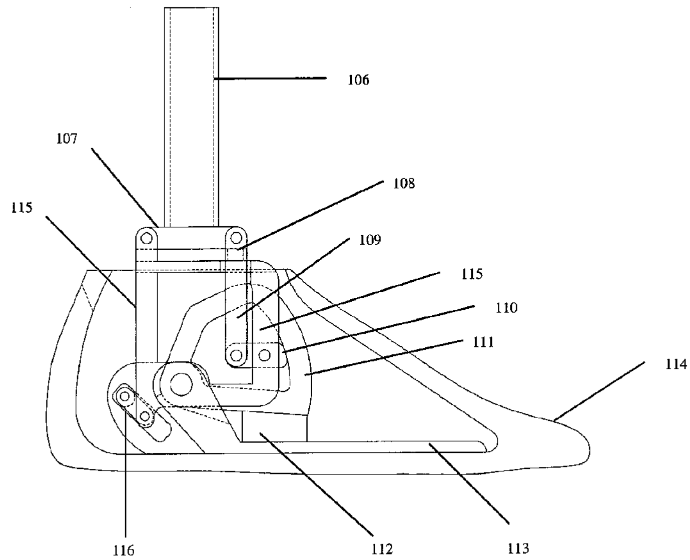


Fig 36

(57) Abstract: The present invention relates to an improved system for use in rehabilitation and/or physical therapy for the treatment of injury or disease to the lower limbs or extremities. The system can enable an amputee to proceed over any inclined or declined surface without overbalancing. The system is mechanically passive in that it does not utilize motors, force generating devices, batteries, or powered sources that may add undesirable weight or mass and that may require recharging. In particular the system is self-adapting to adjust the torque moment depending upon the motion, the extent of inclination, and the surface topography. An additional advantage of the improvement is that the system can be light and may also be simple to manufacture.

WO 2011/129892 A2

Improvements to Passive Ankle-Foot Prosthesis and Orthosis Capable of Automatic Adaptation to Sloped Walking Surfaces and Methods of Use

[01] The present application claims priority to United States Provisional Patent Application Serial Number 61/342,281 entitled "Improvements to Passive Ankle-Foot Prosthesis Capable of Automatic Adaptation to Sloped Walking Surfaces and Methods of Use", filed 12 April, 2010, which is herein incorporated by reference in its entirety for all purposes. This application is also related to International Patent Application Serial No. PCT/US2007/022208, filed 17 October, 2007, US Patent Application Serial No. 12/311,818, filed 13 April, 2009, and US Provisional patent application Serial No. 60/852,174, filed 17 October 2006.

[02] This invention was made with government support under United States Department of Veterans Affairs' grant numbers A6567R and A6565R. The United States government has certain rights in the invention.

Technical Field

[03] The inventions relate to improved ankle-foot prosthetic and orthotic systems and methods of use. In particular the prosthetic or orthotic systems comprise an ankle unit that, in combination with other mechanical elements of prosthetic or orthotic systems, enable the gait of an individual using the device to emulate the gait of able-bodied individual and that automatically adapts the gait to different terrains and slopes on each and every step.

Background Art

[04] Many currently available prosthetic and orthotic ankle-foot mechanisms do not allow ankle motion. Rigid ankle prosthetic and orthotic ankle-foot devices generally attempt to replace the actions of the biologic ankle-foot system through deformations of their materials and/or by utilizing rocker shapes on the plantar surfaces. The prosthetic and orthotic ankle-foot devices that do incorporate ankle motion usually allow rotational motion about a single point that does not change without mechanical adjustments of the prosthesis or orthosis. Some of these devices use springs and/or bumpers to store and release energy and return the device's ankle joint to one "equilibrium" point. This single and constant "equilibrium" point can result in good function on level terrain and when using shoes of one particular heel height (heel and forefoot sole differential). However, problems can arise when walking on different terrain or when using shoes of different heel height. The heel height problem can be fixed using a change in the

alignment of the prosthesis. However, this is not a simple task and one that does not happen automatically.

[05] A patent issued to Wayne Koniuk (USPN 6,443,993 B1, "Self-Adjusting Prosthetic Ankle Apparatus", issued September 3, 2002) discloses a device that will adapt to various terrains and to shoes of different heel height. However, Koniuk's design does not appear to have energy storage and release properties, utilizes more sensing devices than the proposed design, and does not appear to give plantarflexion at late stance. Koniuk's design is based on damping control of the ankle joint whereas the proposed device is based on the control of stiffness about the ankle. Damping removes energy from a system whereas stiffness can store and release energy to a system throughout a loading and unloading cycle (that is, a walking cycle).

[06] Recent research has suggested that roll-over shape, the effective rocker shape that the ankle-foot system conforms to between heel contact and opposite heel contact, is an important characteristic for walking. Hansen ((2002); "Roll-over Characteristics of Human Walking With Applications for Artificial Limbs." Ph.D. dissertation, Northwestern University, Evanston, Illinois) found that the able-bodied ankle-foot system adapts to several walking conditions to maintain a similar roll-over shape and that its roll-over shape changes predictably when walking on inclined or declined surfaces. Specifically, able-bodied ankle-foot systems are capable of automatically adapting to differences in shoe heel height and to different surface inclinations. Current prosthetic ankle-foot mechanisms cannot automatically adapt to these conditions.

[07] The prior art demonstrates that there is a current and long-felt need for an improved ankle prosthesis or ankle-foot prosthesis or orthosis that can better emulate the gait of an able-bodied individual and adapt to the terrain on the first step.

Disclosure of Invention

[08] The invention provides prosthetic and orthotic ankle-foot systems. The systems can be used by a human subject as a prosthesis or an orthosis to assist the user's gait and to prevent or reduce the likelihood of compromising the user's balance.

[09] In one embodiment the invention provides a self-adapting prosthetic system, the self-adapting prosthetic system comprising a foot shell, an improved passive adaptive ankle-foot prosthesis, and means for attachment to a leg, the ankle foot prosthesis comprising a footplate, an ankle system, the ankle system comprising a housing, a first cam, a second cam, a bracket, wherein the housing and the bracket are fixedly attached to the means for attachment to the leg, wherein the bracket is fixedly attached to the first cam, wherein the first cam is in movable contact with a part of the second cam and the first cam and second cam comprise a cam clutch system, and wherein the footplate comprises an anterior portion and a posterior portion and further comprising an essentially horizontal plantar member, a torsion means, and an essentially vertical

member, the vertical member being perpendicular to the horizontal plantar member and operatively attached to the posterior portion of the footplate, the vertical member further comprising an aperture, the aperture shaped and adapted to confine at least one neutralizing element and a spacer, the neutralizing element being operatively connected to the spacer, wherein the spacer is axially connected to the housing, wherein the housing is axially connected to the vertical member of the footplate, and wherein the second cam is axially connected to the vertical member of the footplate and wherein the torsion means is shaped and adapted for confined placement between the second cam and the horizontal plantar member, and wherein the improved passive adaptive ankle-foot prosthesis is shaped and adapted for placement within the foot shell and wherein the foot shell comprises, in part, a flexible material. In a preferred embodiment, wherein the torsion means is selected from the group consisting of a spring, a tunable spring, a clockwork spring, a piston, a damper, a bumper, and an elastomeric material. In another preferred embodiment the neutralizing element and the cam clutch are in-line. In yet another preferred embodiment, the second cam comprises an external surface and an internal surface. In a more preferred embodiment, the first cam is in movable contact with the internal surface of the second cam. In a most preferred embodiment the range of movable contact of the first cam in contact with the second cam is not greater than 95°. In another most preferred embodiment, the ankle system has a plantarflexion-dorsiflexion range of from between 80° plantarflexion to about 45° dorsiflexion. In another embodiment the ankle system allows a user to emulate normal gait. In an alternative embodiment, the ankle system allows a user to approximately emulate normal gait.

[10] In another preferred embodiment the self-adapting prosthetic system comprises a composition selected from the group consisting of stainless steel, copper, aluminum, titanium, metal matrix composite, metal alloy, NITINOL, DELRIN (acetal), acrylonitrile butadiene styrene (ABS), nylon, polypropylene, polybromate, polycarbonate, glycolised polyethylene terephthalate (PETg) copolyester, polytetrafluorethylene (PTFE), ePTFE, polypropylene, a polymer, glass fiber-resin composites, and carbon fiber resin composites. In an alternative embodiment the self-adapting prosthetic system further comprises a foot shell. In a preferred embodiment, the means for attachment to a leg are selected from the group consisting of a residual limb socket, direct skeletal attachment to the residual limb, and a leg cuff.

[11] In another embodiment the invention provides a self-adapting orthotic system, the self-adapting orthotic system comprising a footplate, an improved passive adaptive ankle system, and means for attachment to an ankle, the ankle system comprising the footplate, means for attaching to the means for attachment to an ankle, a housing, a first cam, a second cam, a bracket, wherein the housing and the bracket are fixedly attached to the means for attachment to the ankle, wherein the bracket is fixedly attached to the first cam, wherein the first cam is in movable contact with a

part of the second cam and the first cam and second cam comprise a cam clutch system, and wherein the footplate comprises an anterior portion and a posterior portion and further comprising an essentially horizontal plantar member, a torsion means, and an essentially vertical member, the vertical member being perpendicular to the horizontal plantar member and operatively attached to the posterior portion of the footplate, the vertical member further comprising an aperture, the aperture shaped and adapted to confine at least one neutralizing element and a spacer, the neutralizing element being operatively connected to the spacer, wherein the spacer is axially connected to the housing, wherein the housing is axially connected to the vertical member of the footplate, and wherein the second cam is axially connected to the vertical member of the footplate and wherein the torsion means is shaped and adapted for confined placement between the second cam and the horizontal plantar member, and wherein the improved passive adaptive ankle-foot orthosis is shaped and adapted for placement on at least one side of the biological ankle of the user or individual. In a preferred embodiment, wherein the torsion means is selected from the group consisting of a spring, a tunable spring, a clockwork spring, a piston, a damper, a bumper, and an elastomeric material. In another preferred embodiment the neutralizing element and the cam clutch are in-line. In yet another preferred embodiment, the second cam comprises an external surface and an internal surface. In a more preferred embodiment, the first cam is in movable contact with the internal surface of the second cam. In a most preferred embodiment the range of movable contact of the first cam in contact with the second cam is not greater than 95°. In another most preferred embodiment, the ankle system has a plantarflexion-dorsiflexion range of from between 80° plantarflexion to about 45° dorsiflexion. In another embodiment the ankle system allows a user to emulate normal gait. In an alternative embodiment, the ankle system allows a user to approximately emulate normal gait.

[12] In another preferred embodiment the self-adapting orthotic system comprises a composition selected from the group consisting of stainless steel, copper, aluminum, titanium, metal matrix composite, metal alloy, NITINOL, DELRIN (acetal), acrylonitrile butadiene styrene (ABS), nylon, polypropylene, polybromate, polycarbonate, glycolised polyethylene terephthalate (PETg) copolyester, polytetrafluorethylene (PTFE), ePTFE, polypropylene, a polymer, glass fiber-resin composites, and carbon fiber resin composites. In an alternative embodiment the self-adapting orthotic system further comprises a foot shell. In a preferred embodiment, the means for attachment to an ankle are selected from the group consisting of a residual limb socket, direct skeletal attachment to the residual limb, a clamshell socket, and a leg cuff.

[13] In another embodiment, the invention provides a prosthetic or orthotic system for a user to emulate normal gait, the prosthetic system comprising an ankle member, the ankle member comprising a reversible engagement means, a first torsion means, and a joint, and wherein in use, a torsion curve plot of ankle moment against ankle dorsiflexion angle of the prosthetic system

during a gait cycle comprises at least one transition point, wherein the reversible engagement means is operatively connected to the first torsion means, wherein the first torsion means is operatively connected to the joint, and wherein the joint is operatively connected to the engagement means. In an alternative embodiment, the system allows a user to approximately emulate normal gait. In a preferred embodiment the system is used by a user to proceed over a surface without compromising balance wherein the surface comprises a plurality of grades or elevations. More preferably the torsion curve plot comprises a plurality of transition points. In one alternative embodiment the transition point of the torsion curve plot is at a negative torque moment. In another alternative embodiment the transition point of the torsion curve plot is at a negative ankle dorsiflexion angle. In another alternative embodiment the transition point of the torsion curve plot is at a positive torque moment. In yet another alternative embodiment the transition point of the torsion curve plot is at a positive ankle dorsiflexion angle. In a most preferred embodiment the prosthetic system automatically adapts to different surface conditions. In an alternative embodiment the self-adapting prosthetic or orthotic system further comprises a foot shell

[14] In one embodiment the prosthetic system comprises a composition selected from the group consisting of stainless steel, copper, aluminum, titanium, metal matrix composite, metal alloy, such as NITINOL, DELRIN (acetal), acrylonitrile butadiene styrene (ABS), nylon, polypropylene, polybromate, polycarbonate, glycolised polyethylene terephthalate (PETg) copolyester, polytetrafluorethylene (PTFE), ePTFE, polypropylene, a polymer, glass fiber-resin composites, carbon fiber resin composites, and the like.

[15] In a more preferred embodiment the equilibrium point β of the torsion curve plot is calculated using the equation

$$T_{ts} = k_{ts}(\theta - \beta),$$

where T_{ts} = torque due to *triceps surae* spring(s); θ = ankle dorsiflexion angle; β = ankle angle at the trigger time; and k_{ts} is the impedance factor. In an alternative more preferred embodiment the equilibrium point ζ of the torsion curve plot is calculated using the equation

$$T_{ns} = k_{ns}(\theta - \zeta),$$

where T_{ns} = torque due to neutralizing spring(s); θ = ankle dorsiflexion angle; ζ = ankle dorsiflexion bias; and k_{ns} is the impedance factor. In another preferred embodiment the method comprises the step of wherein a toe-off and the trigger time occur in continuous and alternating order. In a more preferred embodiment the method provides automatic adaptation in the sagittal plane of the self-adapting ankle-foot device. In another more preferred embodiment the method provides the self-adapting ankle-foot device that adapts to three-dimensional changes in terrain. In a most preferred embodiment the three-dimensional changes in terrain is selected from the group consisting of side slopes, and combinations of side and upward sloping surfaces.

[16] The ankle-foot devices automatically adapt to various walking surfaces using stiffness-based control and few sensing devices. This mode of control may be preferable to damping-based control (Koniuk, 2002) because it allows for return of stored energy. In theory, equilibrium-point prosthetic ankle-foot devices of the invention are designed to store and return energy with a high degree of efficiency.

Brief Description of the Figures

[17] Figure 1 illustrates an exemplary embodiment of the invention.

[18] Figure 2 illustrates a linear braking mechanism exemplifying the invention.

[19] Figure 3 illustrates an exemplary loading phase of a device of the invention.

[20] Figure 4 illustrates an exemplary torsion curve of a pair of neutralizing springs (NS; prior art) showing ζ, the point of intersection of the curve at $T = 0$ (the equilibrium point).

[21] Figure 5 illustrates an exemplary torsion curve of a "triceps surae" spring (TS; part of the instant invention) showing β, the point of intersection of the curve at $T = 0$ (the equilibrium point).

[22] Figure 6 illustrates an exemplary torsion curve of the invention showing that the torsion curve has at least two equilibrium points. Figures 6A and 6B exemplify the invention in use up a gradient (slope). Figures 6C and 6D exemplify the invention in use on a level surface. Figures 6E and 6F exemplify the invention in use down a gradient (slope or incline/decline). Figures 6B, 6D, and 6F illustrate the predicted curve of the invention in use showing the transition point (intersection of the NS curve with the TS curve.

[23] Figure 7 illustrates average ankle moment plotted against dorsiflexion angle of twenty-four able-bodied subjects.

[24] Figure 8 illustrates an equilibrium-point ankle-foot orthosis (AFO).

[25] Figure 9 an exemplary device of the invention.

[26] Figure 10 illustrates an exemplary device of the inventors' prior art invention in use.

[27] Figure 11 illustrates two stages during operation of the prosthetic ankle-foot system (inventors' prior art invention) showing, in part, the relative positions of the internal gear and external gear in use. Figure 11A shows the device in a loaded state. Figure 11B shows the device in an unloaded state.

[28] Figure 12 illustrates an exploded illustration of an exemplary device of the inventors' prior art invention as well as an exemplary illustration of the device in use.

[29] Figure 13 illustrates two stages during operation of the prosthetic ankle-foot system (inventors' prior art invention) showing, in part, the relative positions of the base and the cam during active motion of the use. Figure 13A shows the device in a loaded state. Figure 13B shows the device in an unloaded state.

[30] Figure 14 through 20 illustrate a sequence of images of the invention showing how the invention works on inclines and declines.

[31] Figures 21 through 31 illustrates a sequence of images of the invention showing how the invention works and discloses plots of ankle dorsiflexion/plantarflexion against time.

[32] Figure 32 illustrates a series of experimental data obtained during testing of a device of the invention on inclined, level, and declined surfaces.

[33] Figure 33 illustrates a theoretical plot of ankle dorsiflexion/plantarflexion against time for the system or device showing the time at when a first minimum dorsiflexion angle is reached (1) where the brake, lock, or clutch engages and would remain engaged until a second minimum dorsiflexion angle is reached (2).

[34] Figure 34 illustrates three phases of ambulatory motion, (A) plantarflexion, (B) neutral, and (C) dorsiflexion, showing how each of the elements interact with one another.

[35] Figure 35 illustrates an exemplary embodiment of the invention shown wherein the hinge bar and hinge spring are substituted with an actuator (**117**).

[36] Figure 36 illustrates an exemplary embodiment of the invention shown when ts = 0 and ns = 0.

[37] Figures 37A-O illustrate exemplary sequences of gait cycles at different NS and TS angle values. Figures 37A-37C: Cam engaged at 10° NS plantarflexion. 0-10 ° TS range shown; Figures 37D-37F: Cam engaged at 5° NS plantarflexion. 0-10 ° TS range shown; Figures 37G-37I: Cam engaged at 0° NS plantarflexion. 0-10 ° TS range shown; Figures 37J-37L: Cam engaged at 5° NS dorsiflexion. 0-10 ° TS range shown; Figures 37M-37O: Cam engaged at 10° NS dorsiflexion. 0-10 ° TS range shown.

[38] Figures 38A-E illustrate an exemplary gait cycle with 0° TS dorsiflexion and between 10° NS plantarflexion through 10° NS dorsiflexion. Figure 38A: NS: 10° plantarflexion, TS: 0°; Figure 38B: NS: 5° plantarflexion, TS: 0°; Figure 38C: NS: 0°, TS: 0°; Figure 38D: NS: 5° dorsiflexion, TS: 0°; Figure 38E: NS: 10° dorsiflexion, TS: 0°.

[39] Figures 39A-E illustrate an exemplary gait cycle with 5° TS dorsiflexion and between 10° NS plantarflexion through 10° NS dorsiflexion. Figure 39A: NS: 10° plantarflexion, TS: 5° dorsiflexion; Figure 39B: NS: 5° plantarflexion, TS: 5° dorsiflexion; Figure 39C: NS: 0°, TS: 5° dorsiflexion; Figure 39D: NS: 5° dorsiflexion, TS: 5° dorsiflexion; Figure 39E: NS: 10° dorsiflexion, TS: 5° dorsiflexion.

[40] Figures 40A-E illustrate an exemplary gait cycle with 10° TS dorsiflexion and between 10° NS plantarflexion through 10° NS dorsiflexion. Figure 40A: NS: 10° plantarflexion, TS: 10° dorsiflexion; Figure 40B: NS: 5° plantarflexion, TS: 10° dorsiflexion; Figure 40C: NS: 0°, TS: 10° dorsiflexion; Figure 40D: NS: 5° dorsiflexion, TS: 10° dorsiflexion; Figure 40E: NS: 10° dorsiflexion, TS: 10° dorsiflexion.

Best Mode for Carrying out the Invention

[41] The system described herein provides at least three improvements to the inventors' prior art invention. The inventors were under obligation at the time all the inventors were made to assign the rights to the same entities.

[42] (1) A simpler weight activation element: In the improvement, the prior art four-bolt telescoping system (see, for example, Figures 10 through 13, that illustrate inventors' prior art invention) is substituted by a simple hinge (see Figures 9, and 34 through 40. The resulting system comprising the simple hinge therefore takes up much less space, is lighter in weight, and is more robust that the prior art.

[43] (2) Improved cam assembly: In the improvement, the cam assembly is greatly reduced in size by moving the drive cam inside the main cam. In addition, the knurls have been omitted that results in quieter operation and a more durable system.

[44] (3) In-line clutch and neutralizing elements: The neutralizing elements and the cam clutch system (comprising the drive cam and the main cam) are positioned in a fore-aft arrangement that allows a much thinner outer housing and having a reduced overall ankle size and ankle thickness. All of these improvements are of benefit to a user.

[45] The equilibrium point prosthetic and orthotic ankle-foot devices work by utilizing a natural movement of the ankle during early stance phase to adjust the resting length, also known as the equilibrium point, of a spring mechanism (see, for example, Williams, et al. (2009) J. Biomechan. Engin. 131: DOI: 10.1115/1.3005335; and PCT/US2007/022208). The devices are named after Feldman's equilibrium point hypothesis ((1986) "Once more on the equilibrium-point hypothesis (lambda model) for motor control" J. Motor Behav. 18: 17-54) regarding the control of human movements. As used herein, the term "equilibrium point" is the angular position of the ankle system when the net external torques (not including those applied by components within the system or in the absence of external forces and moments) are equal to zero.

[46] The premise of the design is the use of two sets of elastic elements, such as a spring or the like, wherein one set dominates the response of the system when an engaging/disengaging mechanism, such as brake or the like, is engaged and another set that dominates the response when the engaging/disengaging mechanism is released. Allowing the foot to "find" the walking

surface during early stance and then applying the engaging/disengaging mechanism will allow the device to inherently and automatically adapt to a variety of terrain and/or shoe heel heights. Refer to Figures 1-9, 14-30, 32, 34, 35, 36, 37, 38, 39, and 40, for drawings illustrating the embodiment of the invention.

[47] The device comprises two sets of springs: A set of "neutralizing springs" (NS) and a larger and stiffer "*triceps surae*" spring (TS spring) that is in series with a braking or locking component. The "neutralizing" springs are configured such that their equilibrium point (point of zero ankle moment) is at a point where the ankle is neutral or slightly dorsiflexed (see figure 4, at ζ, below). The "*triceps surae*" spring may be located where the corresponding muscle group (*gastrocnemius* and *soleus* muscles) would be (that is, in or proximal to the calf region). This larger and considerably stiffer spring is in series with an engagement means (for example, a braking or locking component) as stated earlier. Preferably, the TS spring and the engagement/disengagement (braking or locking) mechanism, are in series. In the alternative, the TS spring/ engagement combination and the NS spring(s) are in parallel. In one embodiment, the engagement mechanism may be considered to be a variable damper that switches between near-zero damping to extremely high damping values.

[48] At all times, the neutralizing springs (ns) are acting according to the following equation (k_{ns}, impedance factor; could be a function of θ, the ankle dorsiflexion angle in degrees). This is also an example of the prior art (Figure 4):

$$T_{ns} = k_{ns}(\theta - \zeta),$$
$$where$$
$$T_{ns} = torque\ due\ to\ neutralizing\ springs$$
$$\theta = ankle\ dorsiflexion$$
$$\zeta = ankle\ dorsiflexion\ bias$$

[49] Between the "trigger (engagement) time" to toe-off (the beginning of swing phase), the *triceps surae* spring (ts) is also engaged according to the following equation (k_{ts}, impedance factor, could be a function of θ, the ankle dorsiflexion angle in degrees). This is also an example used to illustrate the instant invention (see, for example, Figure 5):

$$T_{ts} = k_{ts}(\theta - \beta),$$
$$where$$
$$T_{ts} = torque\ due\ to\ triceps\ surae\ spring$$
$$\theta = ankle\ dorsiflexion$$
$$\beta = ankle\ angle\ at\ the\ trigger\ time$$

[50] The ankle angle at the trigger time (β) changes for different terrain: β increases for uphill terrain causing the curve to shift to the right; β decreases for downhill terrain, causing the curve to shift to the left.

[51] For the preferred embodiment, the trigger time is the time of foot flat (in early stance phase). It is conceivable that other trigger times could be used, though, including a time at which the pylon reaches a particular orientation in stance phase (for example, near vertical). So the overall torque at the ankle (T) can be described as follows:

$$T = \begin{cases} T_{ns}; & t_{toe-off} < t < t_{trigger} \\ T_{ns} + T_{ts}; & t_{trigger} < t < t_{toe-off} \end{cases}$$

[52] Note that the act of walking is cyclic so the toe-off and trigger times occur in continuous and alternating order. In addition to this, the invention provides not only automatic adaptation in the sagittal plane, but also envisions devices that can adapt to three-dimensional changes in terrain, for example, side slopes, and combinations of side and upward sloping surfaces.

[53] At the transition point, the system engages and sets the equilibrium point of at least one torsional element. This transition switches the system between a low impedance state to a high impedance state. Because the transition point can be tied to a gait event, such as foot flat, the equilibrium point of at least one torsional means can be adjusted in the device, leading to a change in the system's equilibrium point. This adaptability allows for automatic adjustment to different walking surface inclinations.

[54] As shown in Figures 6A through 6F, at initial contact of the heel with the walking surface, the brake is unlocked allowing free movement. The neutralizing springs are compressed (and/or stretched) as the ankle moves into a plantarflexed position (that is, as the forefoot comes down to make contact with the floor). During this time, the *triceps surae* spring remains at its resting length while the braking mechanism changes its length or angle (depending on linear or rotational realization of the device). At the time when the ankle stops moving in the direction of plantarflexion and begins to move into dorsiflexion (that is, at the point of maximum plantarflexion), the braking mechanism locks. This locking action sets the equilibrium point of the *triceps surae* spring at the point of maximum plantarflexion. As the person rolls forward (during Perry's second rocker (1992) Gait Analysis: Normal and Pathological Function, Thorofare, SLACK Inc.), the *triceps surae* spring is stretched creating an appropriate ankle

moment for walking or the like. After opposite heel contact, the load is removed from the device and the *triceps surae* spring returns stored energy to the leg by plantarflexing the ankle. When the load is almost fully removed, the ankle will be close to the resting length of the *triceps surae* spring and the ankle will be at an angle of plantarflexion that is close to that at which the braking mechanism was locked. When the ankle plantarflexion angle comes within a threshold value of the amount that it acquired in early stance, the braking mechanism is released. As the foot leaves the floor in early swing, the neutralizing springs bring the ankle into a neutral or slightly dorsiflexed position (back to position at ζ) to allow for better clearance between the toe and the floor in swing phase. In the alternative, the braking mechanism can be released when a load, such as the weight of the user, is released from being applied to the device.

Improvements of the Invention Over Existing Technologies

[55] The improvements over existing technologies include the ability to adapt to various shoe heel heights and walking inclinations and the provision for plantarflexion at late stance. The device may prove to be superior in energy storing and release characteristics over existing devices although this remains to be seen. Koniuk (2002) has stated the claim of adaptation to shoe heel height and walking inclination in a recently patented design that utilizes damping-control. Our design differs from Koniuk's (2002) in that it utilizes stiffness control and biomimetic foot roll-over shape, allowing the device to achieve an ankle-foot roll-over shape similar to that of an able-bodied person's ankle-foot system during walking, while also allowing for energy return and plantarflexion in late stance.

Design and Manufacture of the Invention

[56] This design is realized in a number of ways. Rotational springs, linear springs, or combinations of the two are used to supply the appropriate impedances about the ankle at different stages of the walking cycle. In the following diagrams, however, the concept of the device will be illustrated using linear springs to describe an "equilibrium-point" prosthetic ankle joint.

[57] Figure 1 is an exemplary diagram of the device pointing out the various components of the device. Figure 2 shows how the linear braking mechanism (that is, linear lock/unlock) is represented in Figure 3. Figure 3 shows the action of the ankle-foot device throughout the gait cycle.

[58] Figure 4, as disclosed above, illustrates a torque curve plot of the prior art using two neutralizing springs (NS). Note that the single equilibrium point at ζ. There is no transition point since there is only one plane of movement.

[59] Figure 5, as disclosed above, illustrates a torque curve plot using a single "triceps surae" spring (TS). Note the single equilibrium point at β.

[60] Figure 6 illustrates exemplary torque curve plots of the invention showing that there are two equilibrium points. In Figure 6, the dotted line represents the predicted torque curve of an NS

spring. The dashed line represents the predicted torque curve of a TS spring. The thin solid line represents predicted torque curve of the combination of the NS and the TS. The thick solid line represents an actual torque curve plot showing the transition point (P_t). Figures 6A and 6B show the invention in use on an incline, Figures 6C and 6D show the invention on a level surface. Figures 6E and 6F show the invention in use on a decline. Figures 6B, 6D, and 6F additionally show the path (heavy line) of a single gait cycle; note the transition point (intersection) of the two torque curves. Figures 6B, 6D, and 6F show that the invention can have multiple transition points and that relative position of the transition point on the curve plot is related to the gradient (incline, level, or decline) of the surface. Note also that the torque curve shifts to the left (negative ankle dorsiflexion angle) from going uphill (incline), through level surface, and going downhill (decline).

[61] The springs are chosen to replicate impedance values found for able-bodied human walking (Hansen et al., (2004b) "The Human Ankle During Walking: Implications for Design of Biomimetic Ankle Prostheses and Orthoses" J. Biomech. 37: 1467-1474). These values change somewhat with walking speed but will be designed based on slow to normal walking speeds. The characteristics for extremely fast walking speeds cannot be mimicked using a passive system (Hansen et al., 2004b, *supra*). A diagram of the ankle impedance characteristics found for twenty four able-bodied ambulators (individuals) is shown in Figure 7. Notice how this characteristic matches closely the characteristic drawn in the diagrams of Figures 3-6 showing that the prosthetic system and the ankle-foot device of the invention automatically adapt to different surface conditions.

[62] This concept can also be used in a rotational sense and in the field of orthoses. An equilibrium-point ankle-foot orthosis (AFO) design that uses rotational components is shown in Figure 8.

[63] Figures 35 and 36 illustrate exemplary ankle systems of the invention showing a pylon (**106**); a hinge bar (**107**), a hinge spring (**108**), a cam engagement link (**109**), a drive cam (**110**), a main cam (**111**), a Triceps Surae Spring (TS) (**112**), a footplate (**113**), a foot shell (**114**), an ankle frame (**115**), and a Neutralizing Spring (NS) (**116**), an alternative actuator (**117**), and means for attachment to a leg (**118**).

[64] Figure 35 illustrates an alternative embodiment wherein an actuator moves the descending link. In another alternative, to move the descending link weight activation from beneath the footplate of an orthosis that would interact with the drive cam through an ascending link may be used, wherein the linkage may be restructured to push the drive cam upward during loading. This may be achieved by connecting the posterior pin of the drive cam to the ankle frame and the anterior pin of the drive cam to the ascending link coming up from the footplate load activation system.

[65] Figure 37 shows exemplary incremental gait cycles where the TS can be from between 0° through 5° through 10°, and where the NS can be from 10° plantarflexion through 0° through 10° dorsiflexion.

[66] Figures 38, 39, and 40 show exemplary incremental gait cycles where the TS can be from between 0° and 10°, and where the NS can be from 10° plantarflexion through 0° through 10° dorsiflexion.

Exemplary Embodiments of the Invention

[67] In one preferred embodiment, the range of movable contact of the first cam (for example, the drive cam) in contact with the second cam (for example, the main cam) is not greater than 95°. For example, the range of moveable contact can be >0°, 5°, 10°, 15°, 20°, 25°, 30°, 35°, 40°, 45°, 50°, 55°, 60°, 65°, 70°, 75°, 80°, 85°, 90°, and 95° and any angle therebetween.

[68] In another preferred embodiment, the ankle system has a plantarflexion-dorsiflexion range of from between 80° plantarflexion to about 15° dorsiflexion. For example, the range of plantarflexion can be >0°, 5°, 10°, 15°, 20°, 25°, 30°, 35°, 40°, 45°, 50°, 55°, 60°, 65°, 70°, 75°, and 80° and any angle therebetween. In another example, the range of dorsiflexion can be >0°, 1°, 2°, 3°, 4°, 5°, 6°, 7°, 8°, 9°, 10°, 11°, 12°, 13°, 14°, 15°, 16°, 17°, 18°, 19°, 20°, 25°, 30°, 35°, 40°, and 45° and any angle therebetween. Where there is neither plantarflexion nor dorsiflexion the ankle system is at 0°, neutral.

[69] The expected commercial applications include ankle-foot prostheses and orthoses for persons with disabilities. These components would hopefully improve the mobility of these persons by allowing them to automatically adapt to various walking surfaces while at the same time giving them biomimetic ankle-foot roll-over shape as well as storage and release of energy from the prosthesis at the appropriate times. The device can also allow for automatic adaptation for different heel heights, allowing a user to use a variety of different shoes. The devices can also be used in walking machines, legged robots, and toys.

[70] The prosthetic or orthotic foot can be manufactured from a variety of compositions and a variety of combination of compositions. The prosthetic foot can comprise a composition selected from the group consisting of stainless steel, copper, aluminum, titanium, metal matrix composite, metal alloy, such as NITINOL, DELRIN (acetal), acrylonitrile butadiene styrene (ABS), nylon, polypropylene, polybromate, polycarbonate, glycolised polyethylene terephthalate (PETg) copolyester, polytetrafluorethylene (PTFE), ePTFE, polypropylene, or another polymer, glass fiber-resin composites, other composite materials, and the like, and, optionally, that can be easily machined, compression molded, or injection molded to the required shape.

[71] The prosthetic foot can be shaped and sized for purposes of mass manufacture in a standard size and shape. In the alternative, it can be manufactured to specifications for a single individual.

The prosthetic foot can be manufactured using modular components, the modular components having different shapes, sizes, and compositions.

[72] The ankle of the prosthetic foot can comprise a locking mechanism, for example the locking mechanism can be selected from the group consisting of, a pair of cams, a ratchet mechanism, a ball joint (such as disclosed in US Patent Number 6,217,249 to Merlo, issued April 17, 2001), selectively engageable and disengagable mechanisms, and joint locking mechanisms as disclosed in, for example, US Patent Number 6,159,248 to Gramnas, issued December 12, 2000, US Patent Number 6,436,149 to Rincoe, issued August 20, 2002).The prosthetic system can also be combined with at least one microprocessor comprising a software program or other instructional means that in combination can provide a control means. The control means can measure the torsion within the system and/or the angular movement of the ankle and thereby control the engagement means and the torsional means during each step cycle or gait cycle. Such microproccessors and software programs are well known to those of skill in the art.

[73] There now follows a non-exhaustive list of different devices and/or mechanisms known to those of skill in the art that can be used with the invention.

ENGAGEMENT MEANS

Types of clutch

[74] Automatic clutch, backstopping clutch, ball clutch, bidirectional clutch, brake-clutch combination, cam clutch, cam and roller clutch, centrifugal clutch, cone clutch, detent slip clutch, disc clutch, dog clutch, double clutch, double-spring clutch, dual-spring slip clutch, duplex clutch, driving clutch, eddy current clutch, electrostatic clutch, expanding shoe clutch, externally controlled positive clutch, external control clutch, internal control clutch, fixed-field clutch, fluid clutch, free-wheeling clutch, friction clutch, multiple disc clutch, détente clutch, plate clutch, hysteresis clutch, indexing clutch, internally controlled clutch, jaw clutch, lawnmower clutch, bidirectional locking clutch, locking clutch, magnetic friction clutch, magnetic particle clutch, magnetic fluid clutch, magnetostrictive clutch, mechanical clutch, mercury-gland clutch, multidisk clutch, multistation clutch, one-way clutch, overload relief clutch, overriding clutch, overrunning clutch, planetary transmission clutch, plate clutch, roller clutch, roller clutch, rotating-field clutch, sliding-key clutch, slip clutch, spiral-band clutch, sprag clutch, spring clutch, spring and ball radial detent clutch, station clutch, tooth clutch, torque limiting clutch, trip clutch, wedging ball or roller clutch, and wrap spring clutch.

Types of brake

[75] Air brakes, anti-lock brakes, coaster brakes, disc brakes, drum brakes, eddy current brakes, electric brakes, friction brakes, hub brakes, hydraulic brakes, multi-disc brakes, power brakes, rim brakes, spoon brakes, band brakes, and caliper brakes.

Types of Lock

[76] Cruciform lock, cylinder lock, deadbolt lock, disc tumbler lock, electronic lock, magnetic lock, electric strike lock, level tumbler lock, Chubb detector lock, protector lock, padlock, pin tumbler lock, wafer tumbler lock, warded lock, 5 lever lock, keycard lock, rim lock, combination lock, and pin lock.

TORSIONAL MEANS

Types of spring

[77] Coil or helical spring, tension spring, compression spring, leaf spring, v-spring, spiral spring, clock spring, cantilever spring, Belleville washer spring, spring washer, torsion spring, gas spring, rubber band, elastic elements, bumpers, umbrella springs, conical springs, taper springs, disc spring, and extension spring.

Types of Damper

[78] Backdraft damper, barometric damper, butterfly damper, curtain damper, dual tube damper, flap damper, free-piston monotube damper, guillotine damper, louvre damper, sliding damper, and vibration damper.

REFERENCE NUMERALS

[79] 1. Foot member

[80] 2. Bearing

[81] 3. Arm

[82] 4. First cam

[83] 5. Spacer

[84] 6. Spring or second bumper (Torsion means)

[85] 7. Block

[86] 8. Set screw

[87] 9. Second cam (Engagement means)

[88] 10. Spring or first bumper (Torsion means)

[89] 11. First shaft

[90] 12. Second shaft

[91] 13. Third shaft

[92] 14. Fourth shaft

[93] 15. First aperture

[94] 16. Second aperture

[95] 17. Recess

[96] 18. Link

[97] 19. Housing

[98] 20. Threaded aperture

[99] 21. Bolt

[100] 22. First link aperture

[101] 23. Compression spring

[102] 24. Adaptor

[103] 25. Bolt aperture

[104] 26. First aperture (arm)

[105] 27. Second aperture (arm)

[106] 28. Aperture (first cam)

[107] 29. Surface (adaptor)

[108] 30. Surface (housing)

[109] 31. Bolt aperture (arm)

[110] 32. Internal gear

[111] 33. External gear

[112] 101. Ankle-foot system

[113] 102. "*Triceps surae*" (TS) spring means

[114] 103. Linear Lock/Unlock means

[115] 104. "Neutralizing" spring(s) means

[116] 105. Ankle Joint

[117] 106. Pylon

[118] 107. Hinge Bar

[119] 108. Hinge Spring

[120] 109. Cam Engagement Link

[121] 110. Drive Cam

[122] 111. Main Cam

[123] 112. "*Triceps Surae*" Spring (TS)

[124] 113. Footplate

[125] 114. Foot shell

[126] 115. Ankle Frame

[127] 116. "Neutralizing" Spring (NS)

[128] The invention will be more readily understood by reference to the following examples, which are included merely for purposes of illustration of certain aspects and embodiments of the present invention and not as limitations.

EXAMPLES

Example I: Use of weight-activation to control the ankle mechanism

[129] Engagement can be set to occur upon loading of the device by the user's weight. In this case, a mechanism is in place that engages the *triceps surae* torsional means after a sufficient amount of body weight has been applied to the system. Upon unloading of the device, the engagement reverses (that is the *triceps surae* spring is disengaged from the rest of the system). Examples of this type of engagement are shown in Figures 9, 34, 35, 36, 37, 38, 39, and 40.

Example II: Use of potentiometers or encoders to control locking-unlocking mechanisms

[130] The projected ankle motion of this device is shown in Figure 33. The potentiometers or encoders measure these angles during use of the device. In early stance, the locking mechanism may be unlocked. When the rotational sensor indicated that a minimum dorsiflexion angle is reached (at time 1), the system will signal to engage the locking mechanism. This mechanism remains engaged until this angle is approached at the end of stance phase (at time 2), at which time the system unlocks and allows the neutralizing springs to bring the ankle back to neutral for swing phase.

Example III: Use of forefoot pressure sensors to control locking-unlocking mechanisms

[131] An alternative way to control the locking and unlocking mechanism is to use a forefoot pressure sensor. In early stance, the ankle plantarflexes until the forefoot contacts the walking surface. At this first contact with the forefoot pressure sensor, the locking mechanism may be engaged. Forefoot contact remains until the toe comes off of the ground at the end of stance. At this time, the pressure goes to zero and the locking mechanism could be unlocked, allowing the neutralizing springs to bring the ankle back to neutral for swing phase.

Example IV: Use of pylon moments to control unlocking of a cam mechanism

[132] Devices to measure moments on the pylon maybe used to indicate the time at which a cam locking mechanism should be unlocked. The cam mechanism disclosed herein automatically sets the equilibrium point of the ankle in early stance but needs a control signal at late stance to release the cam. After the middle cam is engaged and the front bumper is compressed, a moment

is produced on the pylon that can be measured. After the load is removed from the leg, this moment should go to zero. Thus a circuit or microprocessor could note the falling edge of a pylon moment and use this falling edge as a trigger to unlock the cam mechanism after toe off.

[133] Figure 1. Illustration of the "Equilibrium-Point" Prosthetic Ankle Joint.

[134] Figure 2. The linear braking mechanism (that is, "linear lock/unlock") is shown in the following figures as clear when it is unlocked and is shown in gray shading when it is locked.

[135] Figures 3A, 3B, and 3C. The initial loading phase for the device. The braking mechanism is unlocked allowing the foot to be lowered to the floor against the resistance of the neutralizing springs. This action mimics what Perry (1992, *supra*) refers to as the first rocker or the heel rocker and corresponds to the first double-support part of the gait cycle.

[136] Figures 3D, 3E, and 3F. Continuing from Figure 3C, when the ankle dorsiflexion angle stops decreasing and begins to increase the braking mechanism locks (left). The person then rolls over on the ankle joint as the triceps surae spring is stretched (middle and right). Perry (1992, *supra*) refers to this as the second rocker or ankle rocker. This period of time corresponds most closely with the single-limb stance period of gait.

[137] Figures 3G and 3H. Continuing from Figure 3F, after the opposite heel contacts (which would be Figure 3J) the load is rapidly removed from the system and some of the stored energy can be released back to the leg. The series of Figures 3G and 3H show this unloading period. At the end of the unloading period, when the dorsiflexion gets near the point where the braking mechanism locked, the brake is released. Perry (1992, *supra*) refers to this period as the third rocker or the forefoot rocker. This period of time corresponds most closely with the second part of double-limb support of walking.

[138] Figures 3I, 3J, and 3K. Continuing from Figure 3H, as the braking mechanism is unlocked the foot is coming off the ground and preparing to swing. In order to avoid stubbing the toes, the ankle needs to go back into a neutral or slightly dorsiflexed position. Since the braking mechanism is unlocked, the neutralizing springs again dominate and pull the foot upwards to a proper position for swing phase.

[139] Figure 7. Average ankle moment versus dorsiflexion angle plot for 24 able-bodied ambulators (adapted from Hansen et al., 2004b). Springs will be selected such that the overall impedance of the ankle-foot device mimics this characteristic. The asterisk shows the time at which opposite heel contact occurs. Theoretical ankle moment versus ankle dorsiflexion characteristics for the ankle joint are shown in Figures 3-6.

[140] Figure 8. Equilibrium-point ankle-foot orthosis (AFO). This design is similar to the equilibrium-point prosthetic ankle-foot mechanism except it uses rotational components instead of translational. The neutralizing springs are not shown but are provided by technology that is already available (Klenzak ankle units). These joints can be altered to allow different amounts of

dorsiflexion or plantarflexion. They contain spring elements that could act as the neutralizing springs. Other neutralizing joints could also be used. The main elements shown here are the rotational "*triceps-surae*" spring in series with a rotational lock-unlock mechanism.

[141] Figure 9. The improved equilibrium-point prosthetic or orthotic ankle joint device that incorporates a nested drive cam within the main cam, as well as the simple hinge is illustrated. Figure 34 illustrates the equilibrium-point prosthetic or orthotic ankle joint device in use showing the positions of the simple spring and the drive cam and main cam through a complete exemplary step cycle. Although the cams illustrated have been found to be shaped for optimal function, Applicants submit that many other shapes and positions may also have optimal characteristics. For example, the sites of contact between the two cams may be smaller, or they may be greater than illustrated. The shape and size of the drive cam may be engineered using methods well know to those of skill in the art resulting in a even more optimal design. The shape and size of the main cam may be engineered using methods well know to those of skill in the art resulting in an even more optimal design. The shape and size of the cams may be optimized for the manufacturing process and may differ from the drawings.

[142] Figures 14 through 20 illustrate different exemplary stages of the invention when being used to walk upon inclined or declined surfaces.

[143] Figures 21 through 31 illustrate different exemplary stages of walking having controlled plantarflexion using neutralizing springs as embodied in the invention.

[144] Figure 32 illustrates experimental data from one subject having unilateral transtibial amputation. Figure 32 shows that the torque curve of the invention used in a single gait on a variety of inclined, level, and declined surfaces shifts to the left (negative) as predicted above in Figure 6.

[145] Figures 34 through 40 illustrate preferred embodiments of the invention.

[146] Those skilled in the art will appreciate that various adaptations and modifications of the just-described embodiments can be configured without departing from the scope and spirit of the invention. Other suitable techniques and methods known in the art can be applied in numerous specific modalities by one skilled in the art and in light of the description of the present invention described herein. Therefore, it is to be understood that the invention can be practiced other than as specifically described herein. The above description is intended to be illustrative, and not restrictive. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

We claim:

1. A self-adapting prosthetic system, the self-adapting prosthetic system comprising a foot shell, an improved passive adaptive ankle-foot prosthesis, and means for attachment to a leg, the ankle foot prosthesis comprising a footplate, an ankle system, the ankle system comprising a housing, a first cam, a second cam, a bracket, wherein the housing and the bracket are fixedly attached to the means for attachment to the leg, wherein the bracket is fixedly attached to the first cam, wherein the first cam is in movable contact with a part of the second cam and the first cam and second cam comprise a cam clutch system, and wherein the footplate comprises an anterior portion and a posterior portion and further comprising an essentially horizontal plantar member, a torsion means, and an essentially vertical member, the vertical member being perpendicular to the horizontal plantar member and operatively attached to the posterior portion of the footplate, the vertical member further comprising an aperture, the aperture shaped and adapted to confine at least one neutralizing element and a spacer, the neutralizing element being operatively connected to the spacer, wherein the spacer is axially connected to the housing, wherein the housing is axially connected to the vertical member of the footplate, and wherein the second cam is axially connected to the vertical member of the footplate and wherein the torsion means is shaped and adapted for confined placement between the second cam and the horizontal plantar member, and wherein the improved passive adaptive ankle-foot prosthesis is shaped and adapted for placement within the foot shell and wherein the foot shell comprises, in part, a flexible material.

2. The self-adapting prosthetic system of claim 1 further comprising a second neutralizing element.

3. The self-adapting prosthetic system of claim 2, wherein the neutralizing elements are selected from the group consisting of a spring, a tunable spring, a clockwork spring, a piston, a damper, a bumper, and an elastomeric material.

4. The self-adapting prosthetic system of claim 1 wherein the torsion means is selected from the group consisting of a spring, a tunable spring, a clockwork spring, a piston, a damper, and an elastomeric material.

5. The self-adapting prosthetic system of claim 1 wherein the neutralizing element and the cam clutch are in-line.

6. The self-adapting prosthetic system of claim 1 wherein the self-adapting prosthetic system comprises a composition selected from the group consisting of stainless steel, copper, aluminum, titanium, metal matrix composite, metal alloy, NITINOL, DELRIN (acetal), acrylonitrile butadiene styrene (ABS),

nylon, polypropylene, polybromate, polycarbonate, glycolised polyethylene terephthalate (PETg) copolyester, polytetrafluorethylene (PTFE), ePTFE, polypropylene, a polymer, glass fiber-resin composites, and carbon fiber resin composites.

7. The self-adapting prosthetic system of claim 1, wherein the second cam comprises an external surface and an internal surface.

8. The self-adapting prosthetic system of claim 7, wherein the first cam is in movable contact with the internal surface of the second cam.

9. The self-adapting prosthetic system of claim 8 wherein the range of movable contact of the first cam in contact with the second cam is not greater than 95°.

10. The self-adapting prosthetic system of claim 1, wherein the ankle system has a plantarflexion-dorsiflexion range of from between 80° plantarflexion to about 45° dorsiflexion.

11. The self-adapting prosthetic system of claim 1, further comprising a foot shell.

12. The self-adapting prosthetic system of claim 1, wherein the means for attachment to a leg are selected from the group consisting of a residual limb socket, direct skeletal attachment to the residual limb, and a leg cuff.

13. A self-adapting orthotic system, the self-adapting orthotic system comprising a footplate, an improved passive adaptive ankle system, and means for attachment to an ankle, the ankle system comprising the footplate, means for attaching to the means for attachment to an ankle, a housing, a first cam, a second cam, a bracket, wherein the housing and the bracket are fixedly attached to the means for attachment to the ankle, wherein the bracket is fixedly attached to the first cam, wherein the first cam is in movable contact with a part of the second cam and the first cam and second cam comprise a cam clutch system, and wherein the footplate comprises an anterior portion and a posterior portion and further comprising an essentially horizontal plantar member, a torsion means, and an essentially vertical member, the vertical member being perpendicular to the horizontal plantar member and operatively attached to the posterior portion of the footplate, the vertical member further comprising an aperture, the aperture shaped and adapted to confine at least one neutralizing element and a spacer, the neutralizing element being operatively connected to the spacer, wherein the spacer is axially connected to the housing, wherein the housing is axially connected to the vertical member of the footplate, and wherein the second cam is axially connected to the vertical member of the footplate and wherein the torsion

means is shaped and adapted for confined placement between the second cam and the horizontal plantar member, and wherein the improved passive adaptive ankle system is shaped and adapted for placement on at least one side of the biological ankle of the user or individual.

14. The self-adapting orthotic system of claim 13 further comprising a second neutralizing element.

15. The self-adapting orthotic system of claim 14, wherein the neutralizing elements are selected from the group consisting of a spring, a tunable spring, a clockwork spring, a piston, a damper, a bumper, and an elastomeric material.

16. The self-adapting orthotic system of claim 13 wherein the torsion means is selected from the group consisting of a spring, a tunable spring, a clockwork spring, a piston, a damper, and an elastomeric material.

17. The self-adapting orthotic system of claim 13 wherein the neutralizing element and the cam clutch are in-line.

18. The self-adapting orthotic system of claim 13 wherein the self-adapting prosthetic system comprises a composition selected from the group consisting of stainless steel, copper, aluminum, titanium, metal matrix composite, metal alloy, NITINOL, DELRIN (acetal), acrylonitrile butadiene styrene (ABS), nylon, polypropylene, polybromate, polycarbonate, glycolised polyethylene terephthalate (PETg) copolyester, polytetrafluorethylene (PTFE), ePTFE, polypropylene, a polymer, glass fiber-resin composites, and carbon fiber resin composites.

19. The self-adapting orthotic system of claim 13, wherein the second cam comprises an external surface and an internal surface.

20. The self-adapting orthotic system of claim 19, wherein the first cam is in movable contact with the internal surface of the second cam.

21. The self-adapting orthotic system of claim 20 wherein the range of movable contact of the first cam in contact with the second cam is not greater than 95°.

22. The self-adapting orthotic system of claim 13, wherein the ankle system has a plantarflexion-dorsiflexion range of from between 80° plantarflexion to about 45° dorsiflexion.

23. The self-adapting orthotic system of claim 14, wherein the improved passive adaptive ankle-foot prosthesis is shaped and adapted for placement on at least one side of the ankle of a user or individual.

24. The self-adapting orthotic system of claim 13, wherein the means for attachment to an ankle are selected from the group consisting of a residual limb socket, direct skeletal attachment to the residual limb, a clamshell socket, and a leg cuff.

25. The self-adapting orthotic system of claim 13, wherein the means for attaching to the means for attachment to an ankle comprises a hinge bar and a hinge spring.

25. The self-adapting orthotic system of claim 13, wherein the orthotic system further comprises an actuator.

26. The self-adapting orthotic system of claim 25, wherein the actuator substitutes for the hinge bar and the hinge spring.

27. A method for providing essentially normal gait in an amputee, the amputee having lost a lower limb extremity, the method comprising (i) providing the self-adapting ankle-foot device of claims 1 or 13; (ii) attaching the self-adapting ankle-foot device to the lower limb of the amputee; (iii) allowing the amputee to ambulate for at least one gait cycle, the gait cycle comprising at least two phases of dorsiflexion over time, whereby a load applied during a first phase of dorsiflexion results in the engagement means engaging and damping movement of the engagement means, wherein during the first phase when the velocity of ankle dorsiflexion angle change equals zero the engagement means engages and dampens fully, and wherein during a second phase of dorsiflexion when the velocity of ankle dorsiflexion angle change equals zero the engagement means disengages and releases fully, the method resulting in providing essentially normal gait to the amputee.

28. The method of claim 27 wherein the gait cycle comprises at least three phases of ankle flexion.

29. The method of claim 28 wherein the engagement and dampening of the engagement means coincides with a first transition point of the torsion curve plot.

30. The method of claim 28 wherein the disengagement and release of the engagement means coincides with a second transition point of the torsion curve plot.

31. The method of claim 28 further comprising a step of determining an equilibrium point, wherein the equilibrium point of the torsion curve plot is at a negative dorsiflexion angle.

32. The method of claim 28 further comprising a step of determining an equilibrium point, wherein the equilibrium point of the torsion curve plot is at a positive dorsiflexion angle.

33. The method of claims 31 or 32 wherein the equilibrium point β of the torsion curve plot is calculated using the equation

$$T_{ts} = k_{ts}(\theta - \beta),$$

where T_{ts} = torque due to *triceps surae* spring(s); θ = ankle dorsiflexion angle; β = ankle angle at a trigger time; and k_{ts} is the impedance factor.

34. The method of claims 31 or 32, wherein the equilibrium point ζ of the torsion curve plot is calculated using the equation

$$T_{ns} = k_{ns}(\theta - \zeta),$$

where T_{ns} = torque due to neutralizing spring(s); θ = ankle dorsiflexion angle; ζ = ankle dorsiflexion bias; and k_{ns} is the impedance factor.

35. The method of claims 33 or 34 wherein a toe-off and the trigger time occur in continuous and alternating order.

36. The method of claim 35 wherein the method provides automatic adaptation in the sagittal plane of the self-adapting ankle-foot device.

37. The method of claim 35 wherein the method provides the self-adapting ankle-foot device that adapts to three-dimensional changes in terrain.

38. The method of claim 35 wherein three-dimensional changes in terrain is selected from the group consisting of side slopes, and combinations of side and upward sloping surfaces.

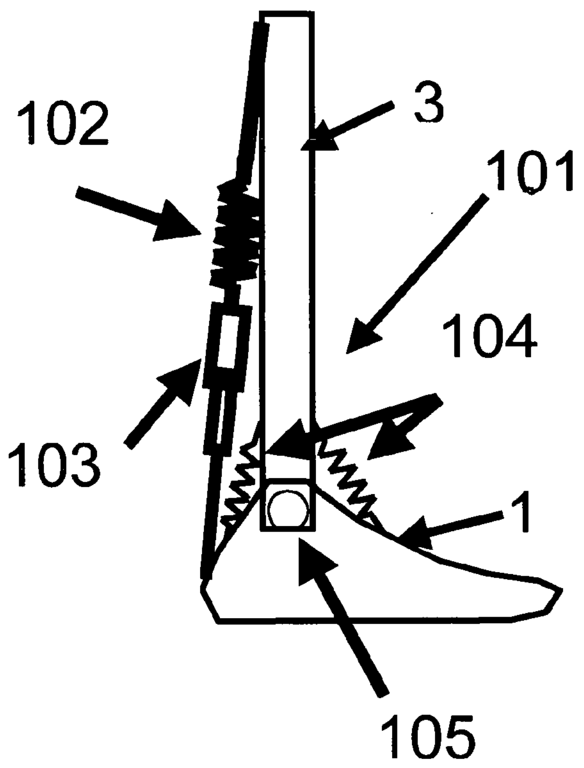


Fig 1

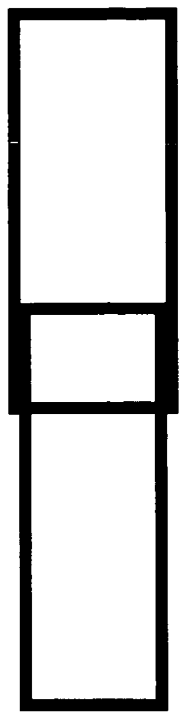


Fig 2a

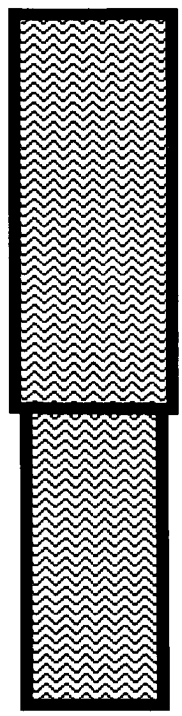


Fig 2b

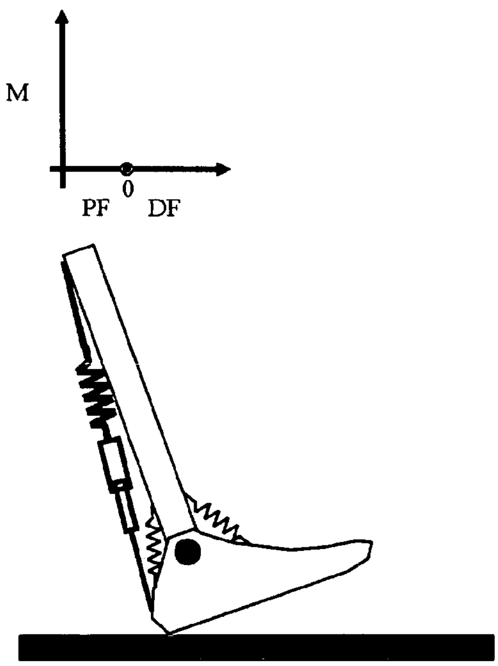


Fig 3A

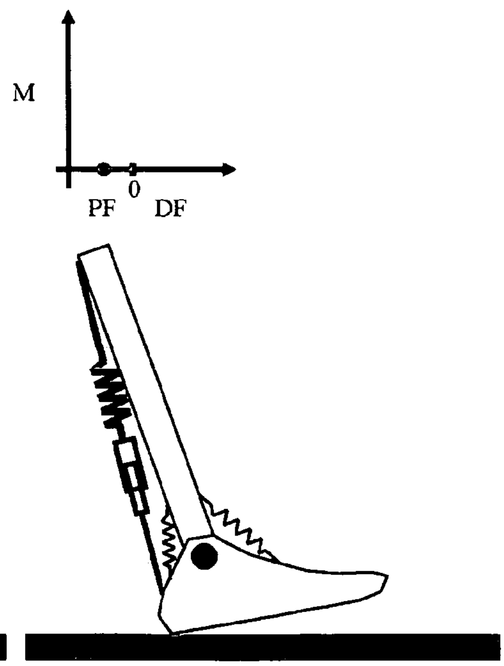


Fig 3B

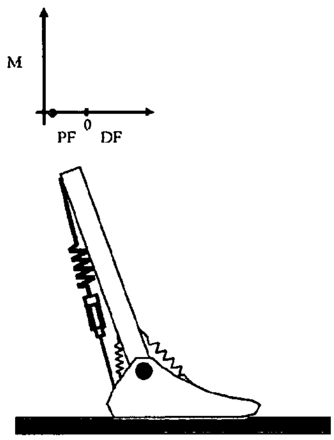


Fig 3C

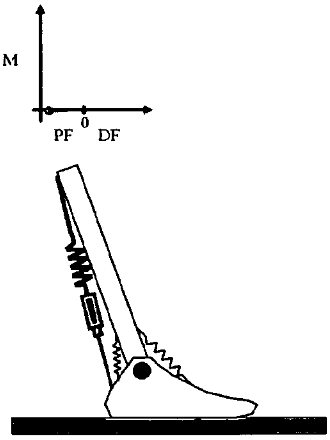


Fig 3D

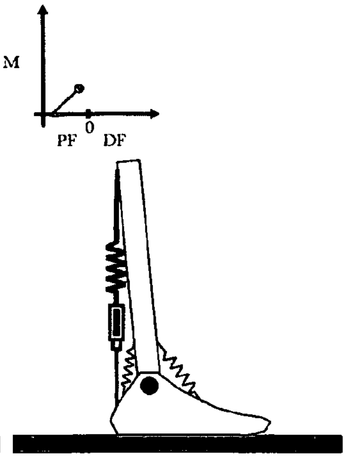


Fig 3E

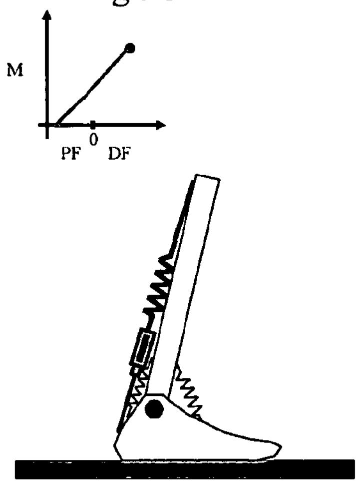


Fig 3F

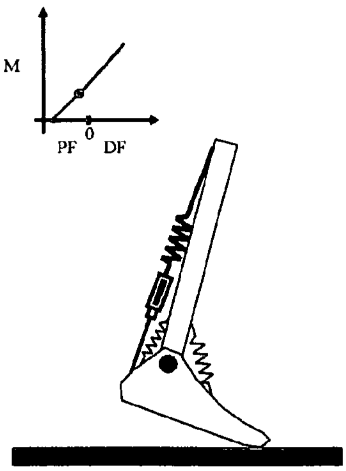


Fig 3G

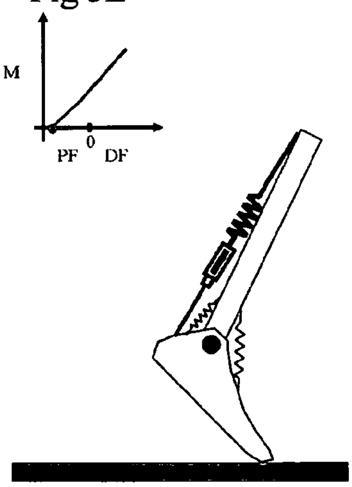


Fig 3H

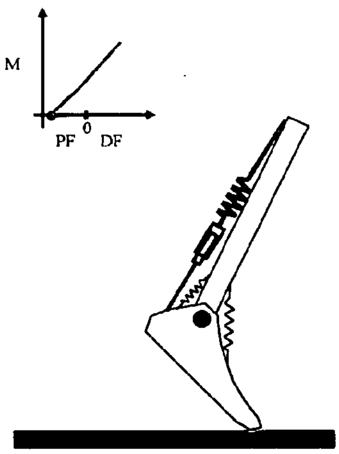


Fig 3I

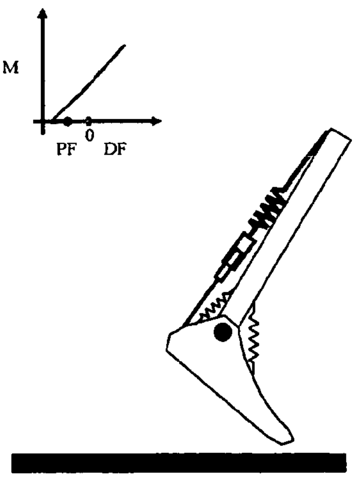


Fig 3J

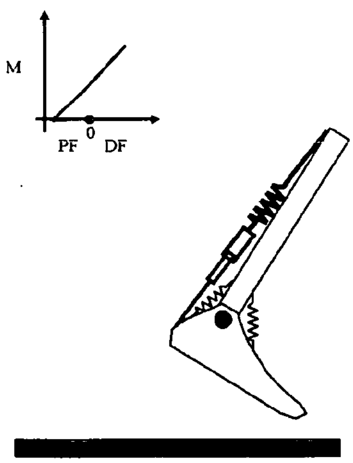


Fig 3K

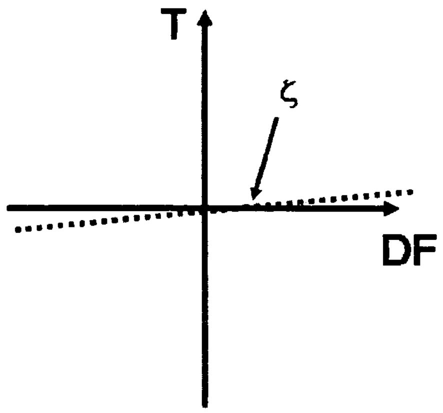


Fig 4

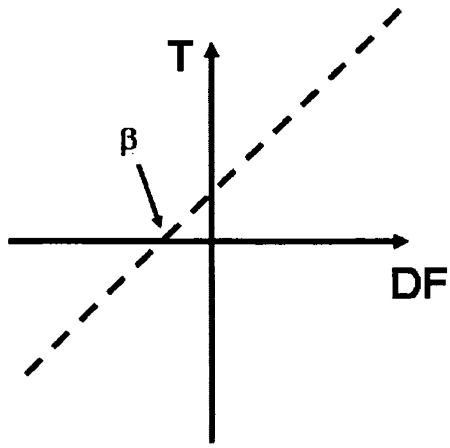


Fig 5

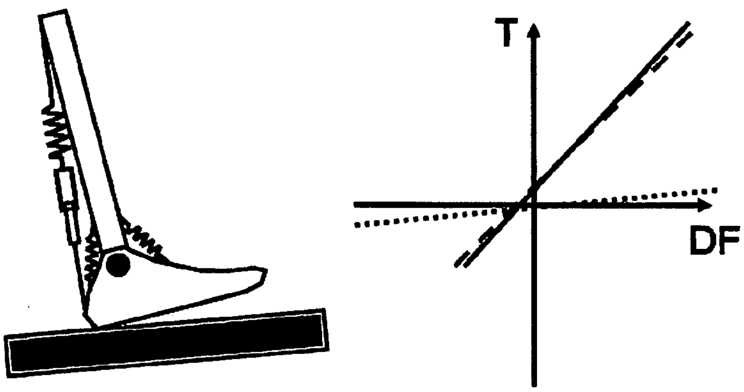


Fig 6A

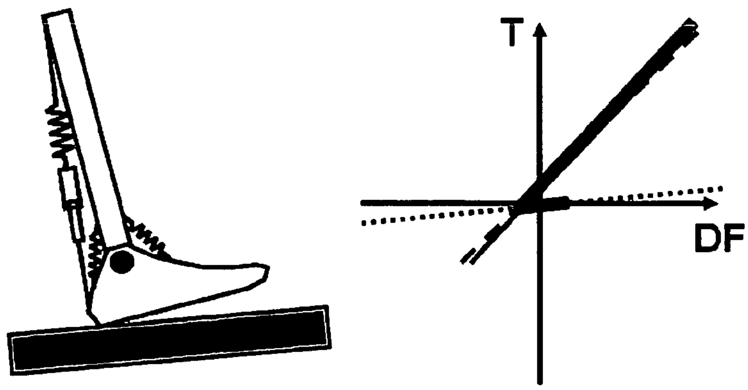


Fig 6B

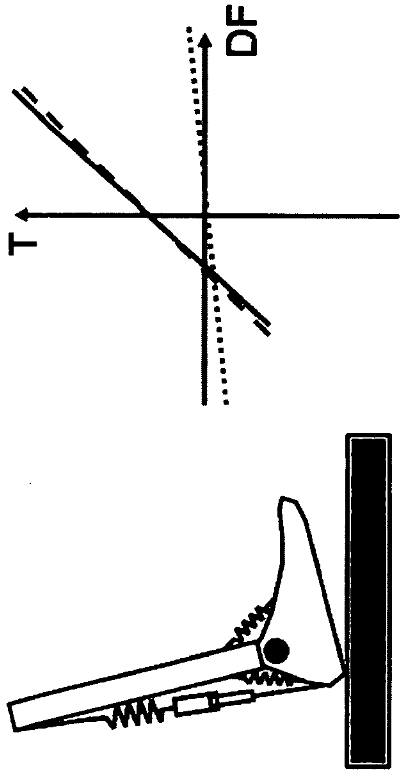


Fig 6C

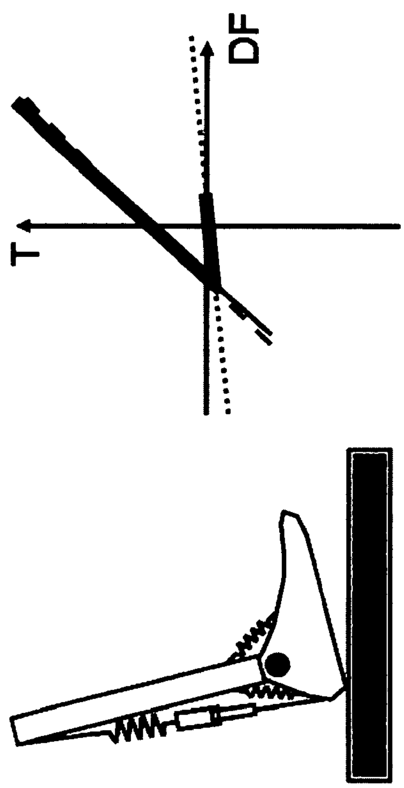


Fig 6D

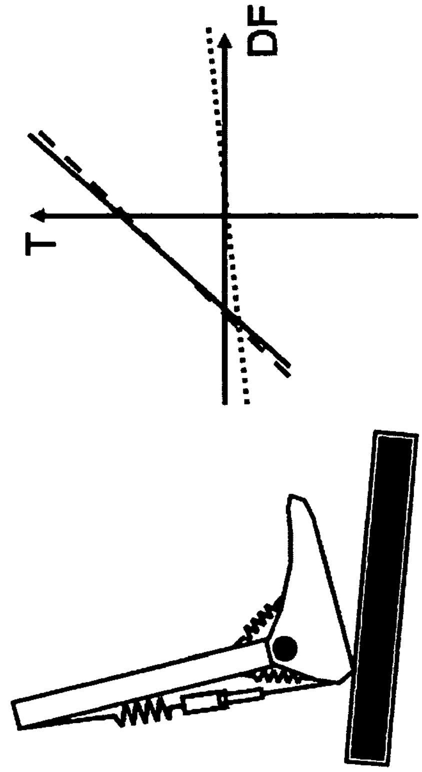


Fig 6E

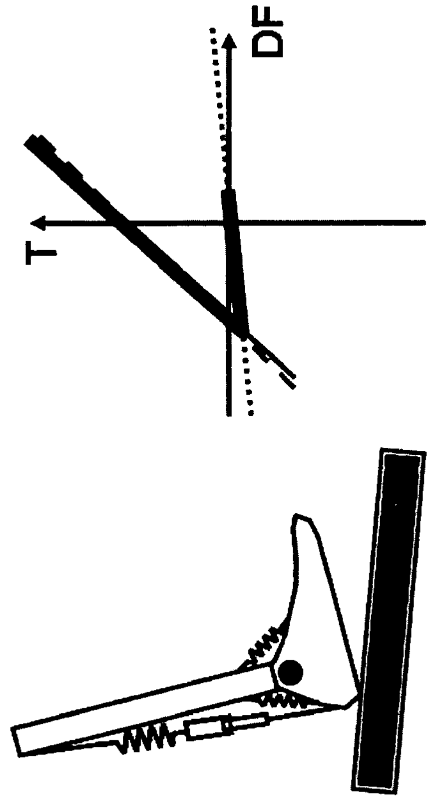


Fig 6F

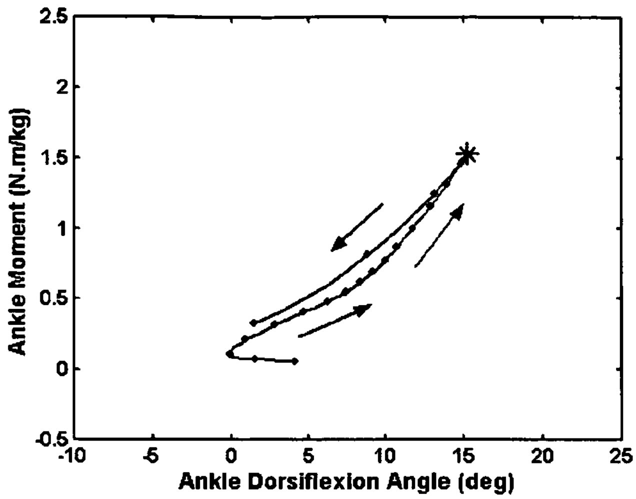


Fig 7

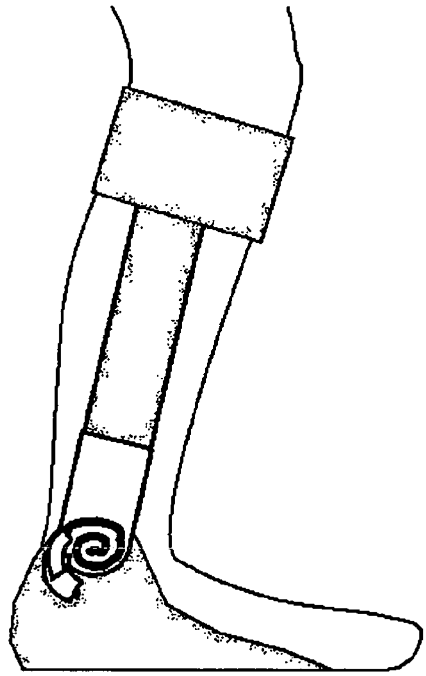


Fig 8A

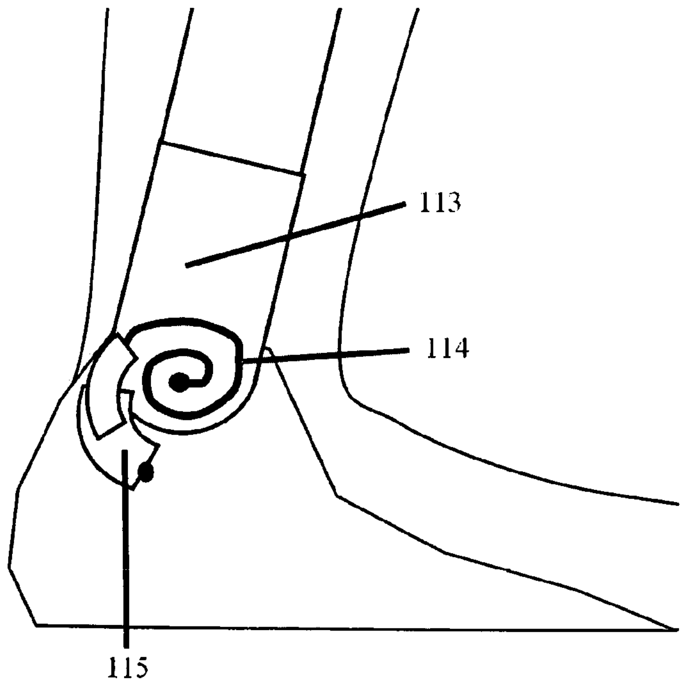


Fig 8B

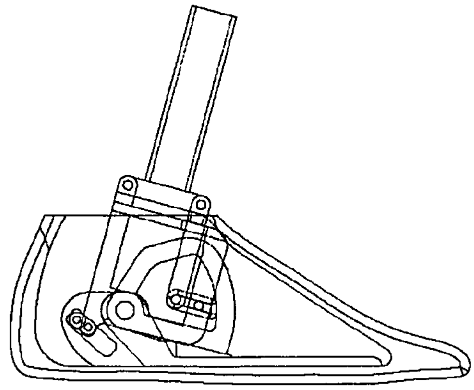


Fig 9

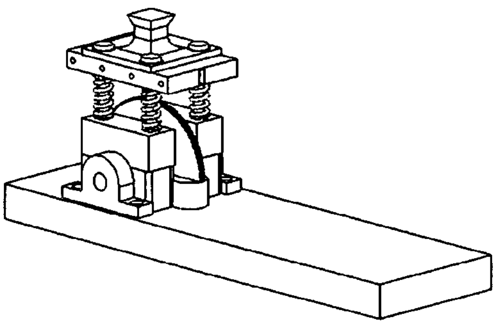


Fig 10A
PRIOR ART

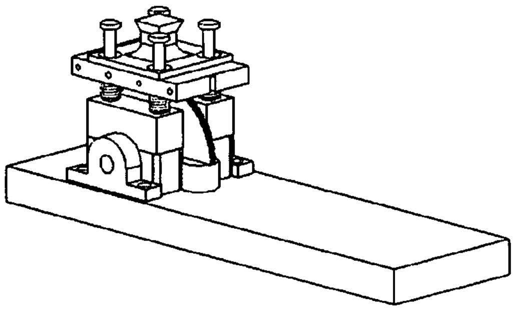


Fig 10B
PRIOR ART

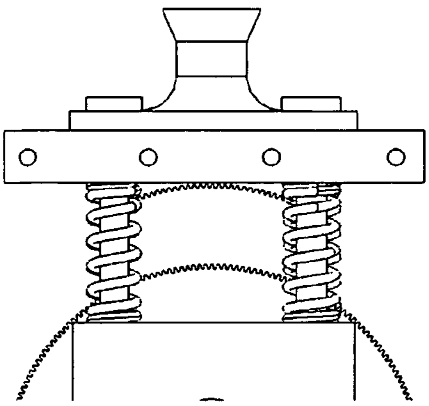


Fig 11A
PRIOR ART

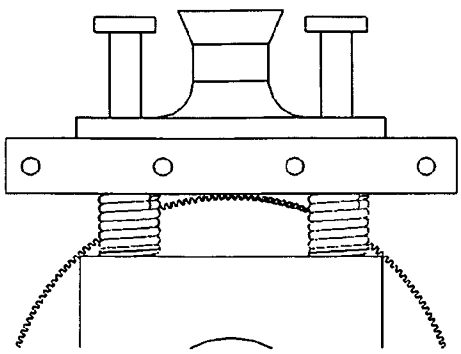


Fig 11B
PRIOR ART

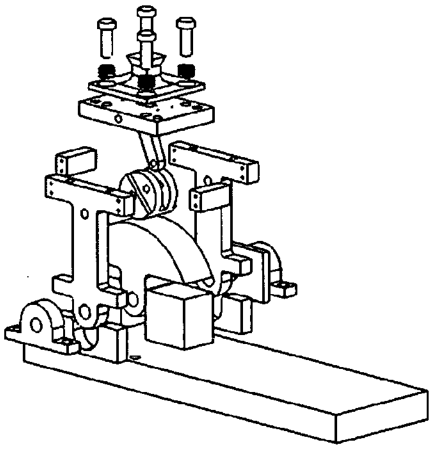


Fig 12A
PRIOR ART

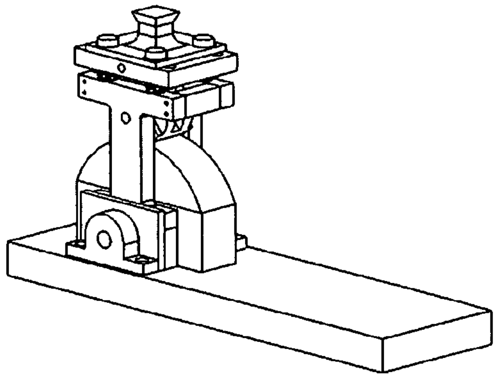


Fig 12B
PRIOR ART

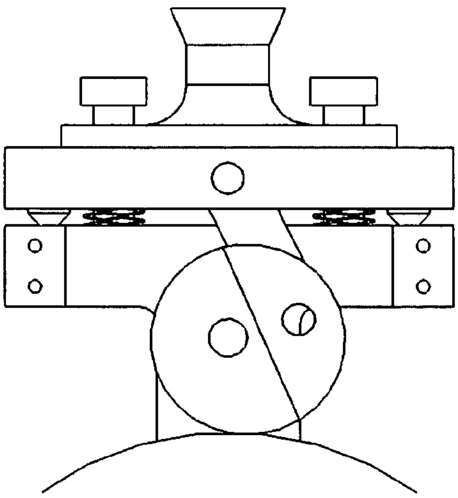


Fig 13A
PRIOR ART

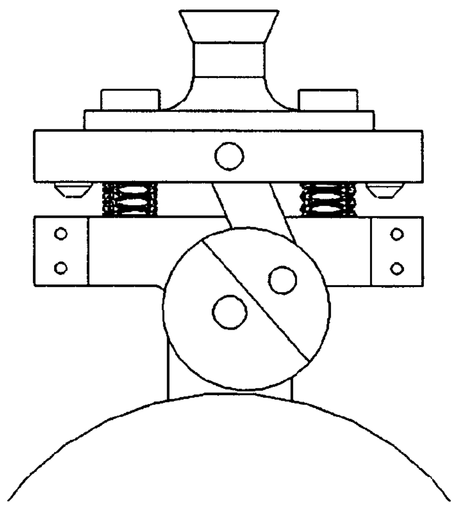


Fig 13B
PRIOR ART

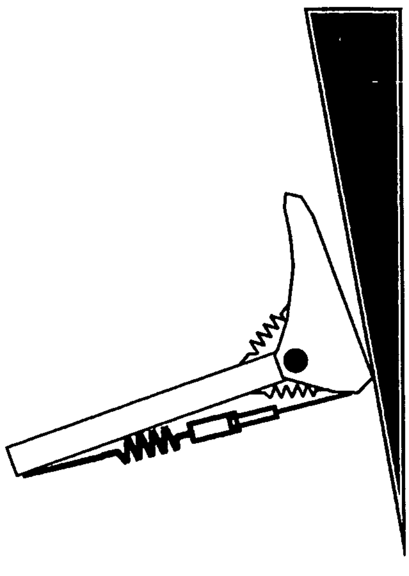


Fig 14

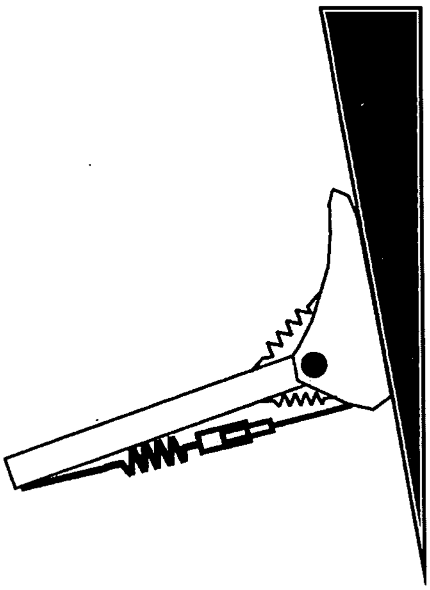


Fig 15

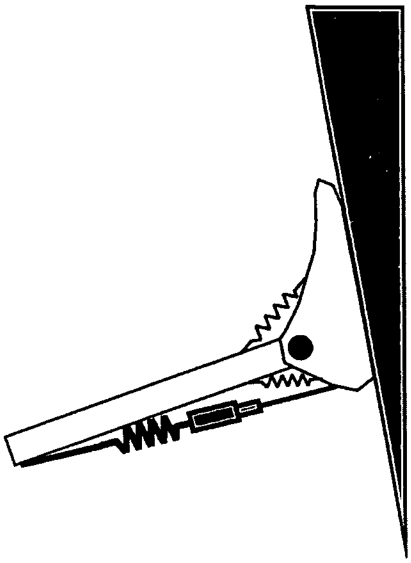


Fig 16

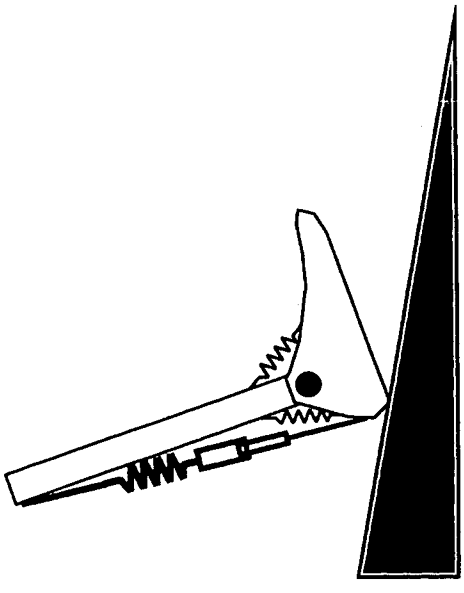


Fig 17

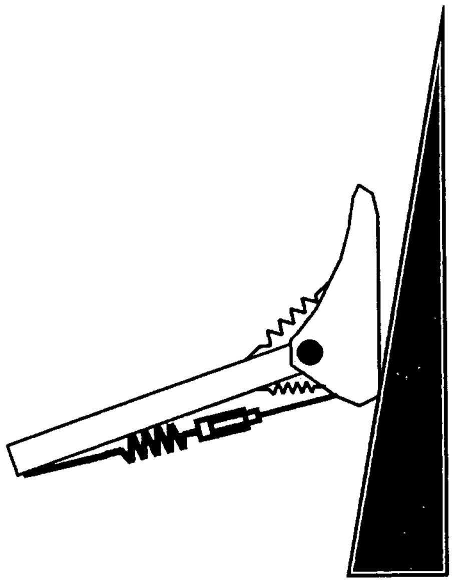


Fig 18

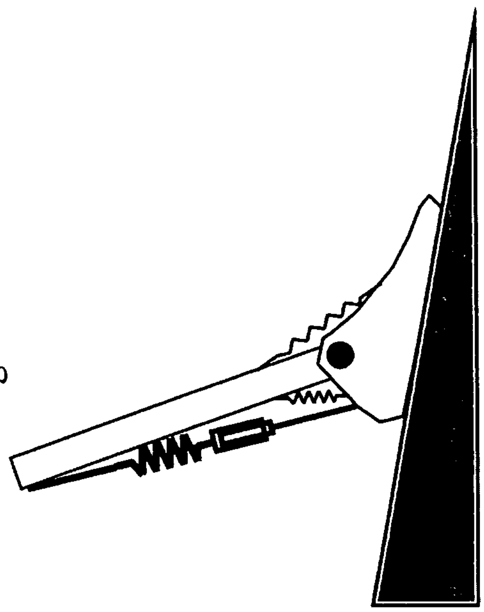


Fig 19

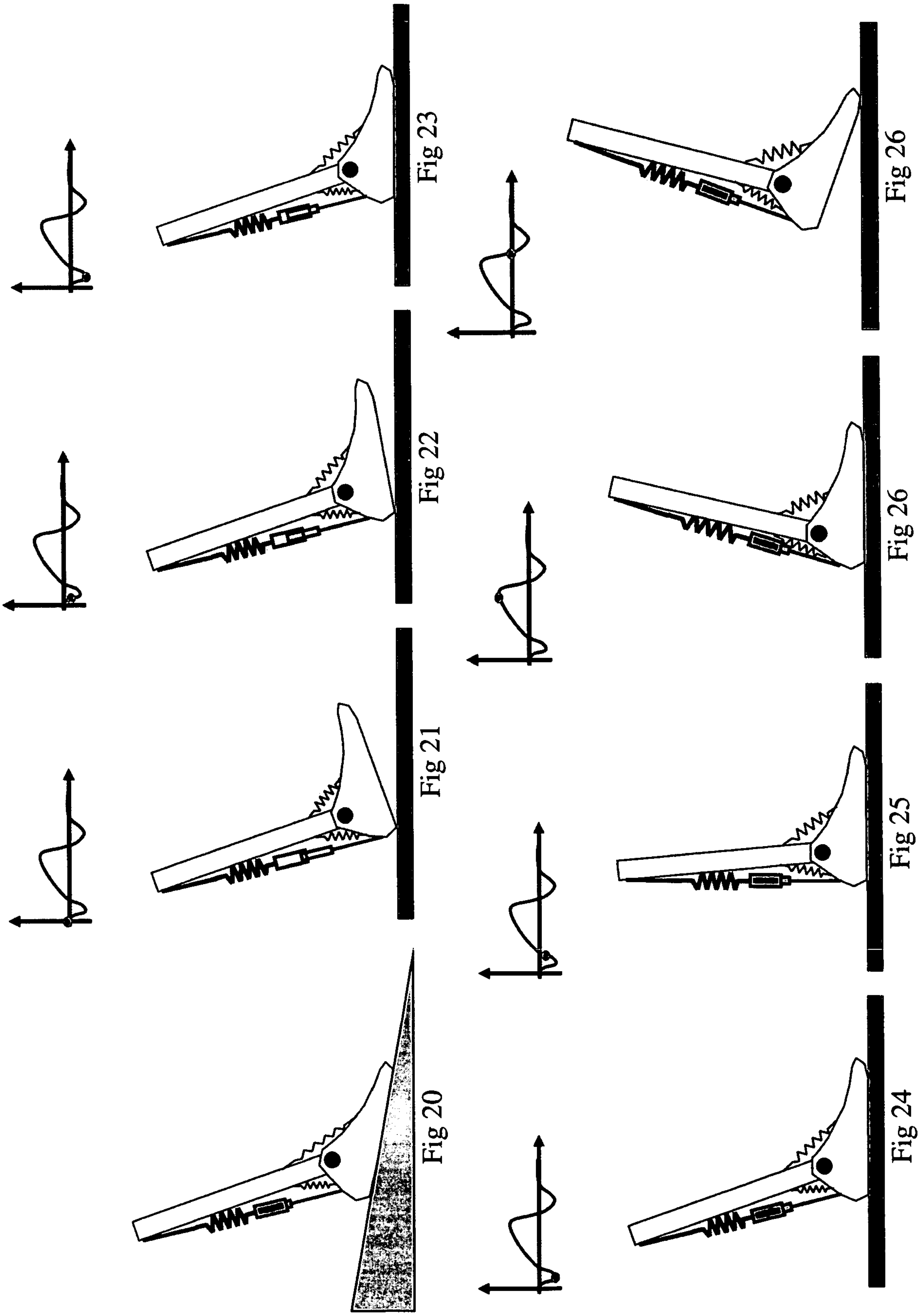


Fig 20

Fig 21

Fig 22

Fig 23

Fig 24

Fig 25

Fig 26

Fig 26

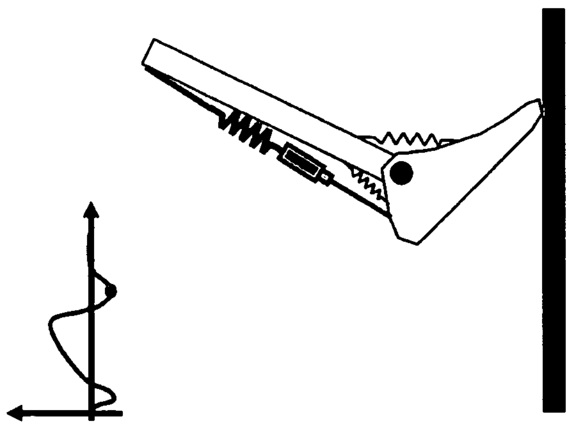


Fig 28

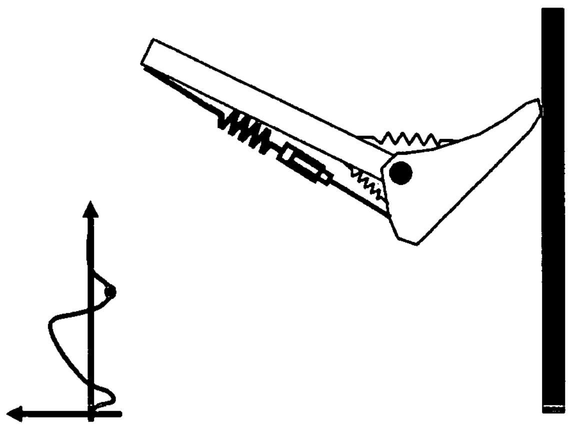


Fig 29

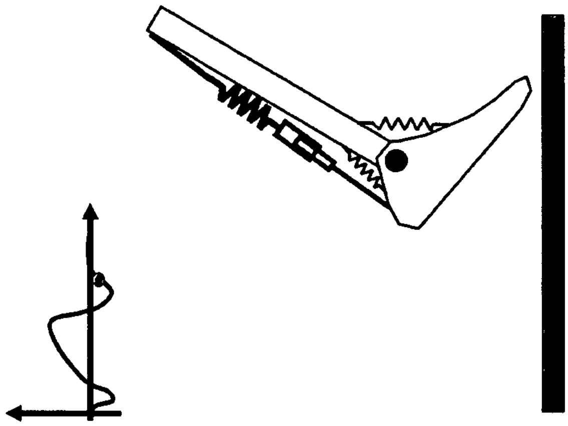


Fig 30

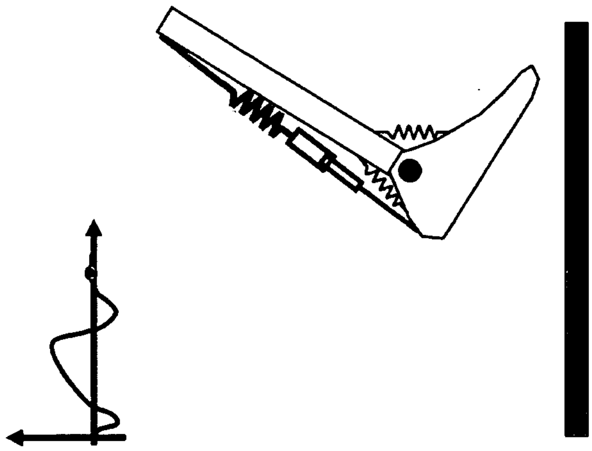


Fig 31

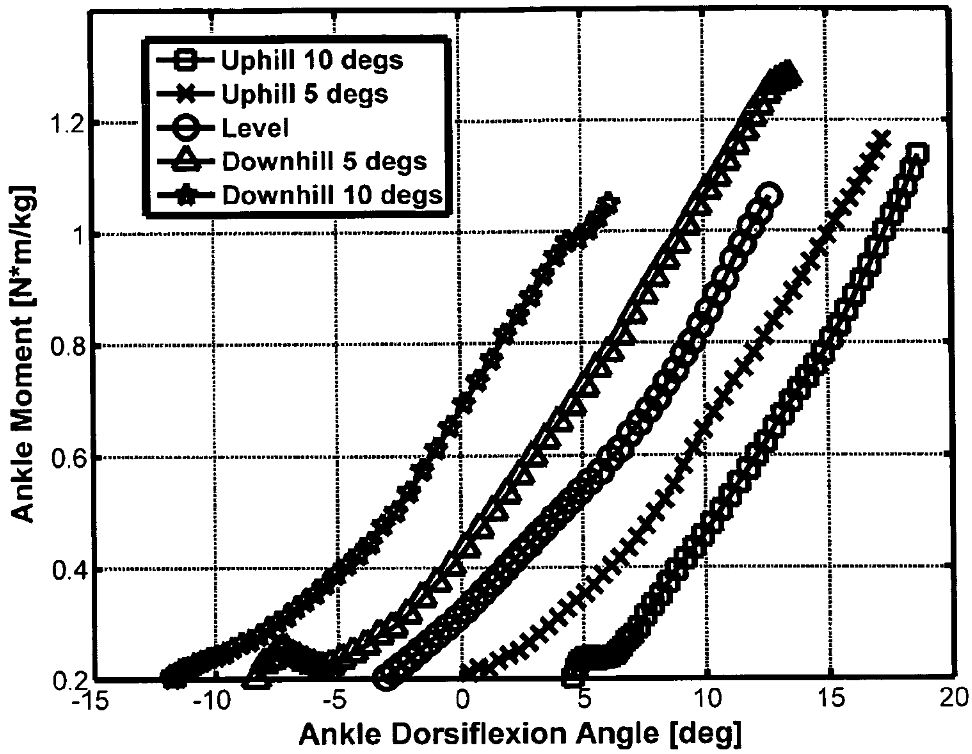

Uphill 10 degs
Uphill 5 degs
Level
Downhill 5 degs
Downhill 10 degs
Ankle Moment [N*m/kg]
1.2
1
0.8
0.6
0.4
0.2
-15
-10
-5
0
5
10
15
20
Ankle Dorsiflexion Angle [deg]

Fig 32

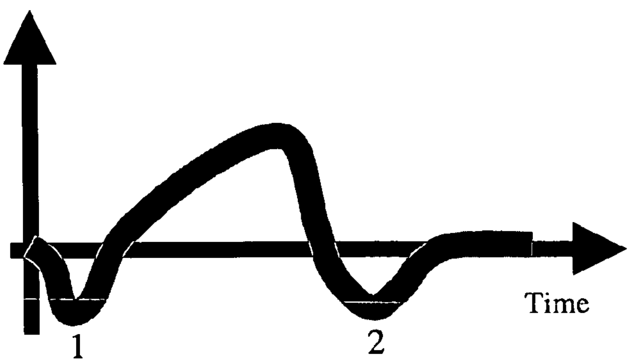
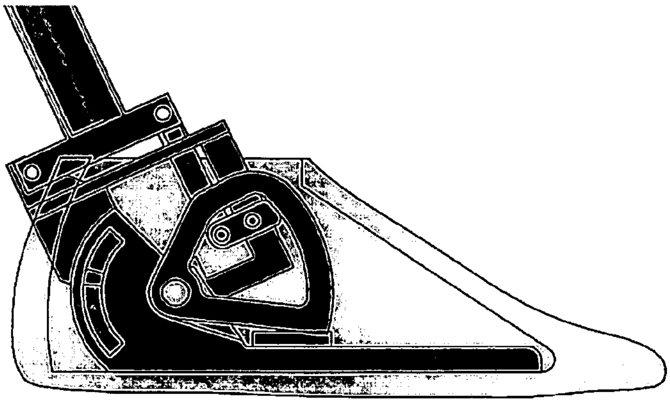
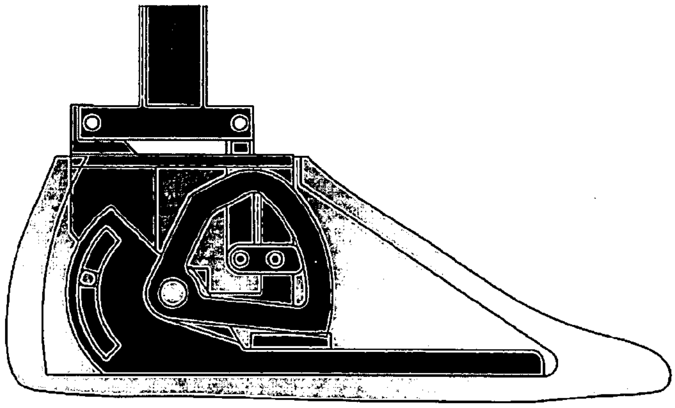

Time
1
2

Fig 33



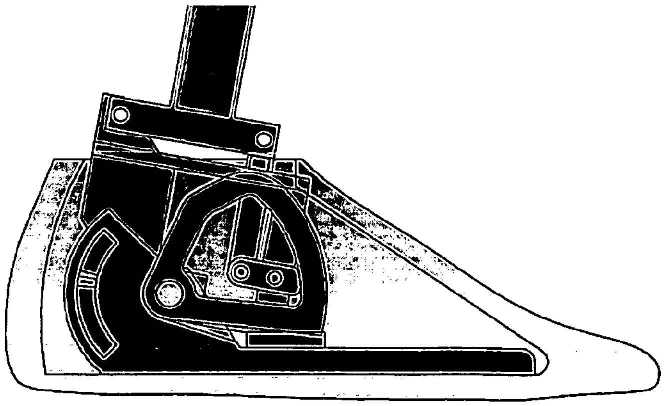
25° Plantarflexion

Fig 34A



Neutral

Fig 34B



10° Dorsiflexion

Fig 34C

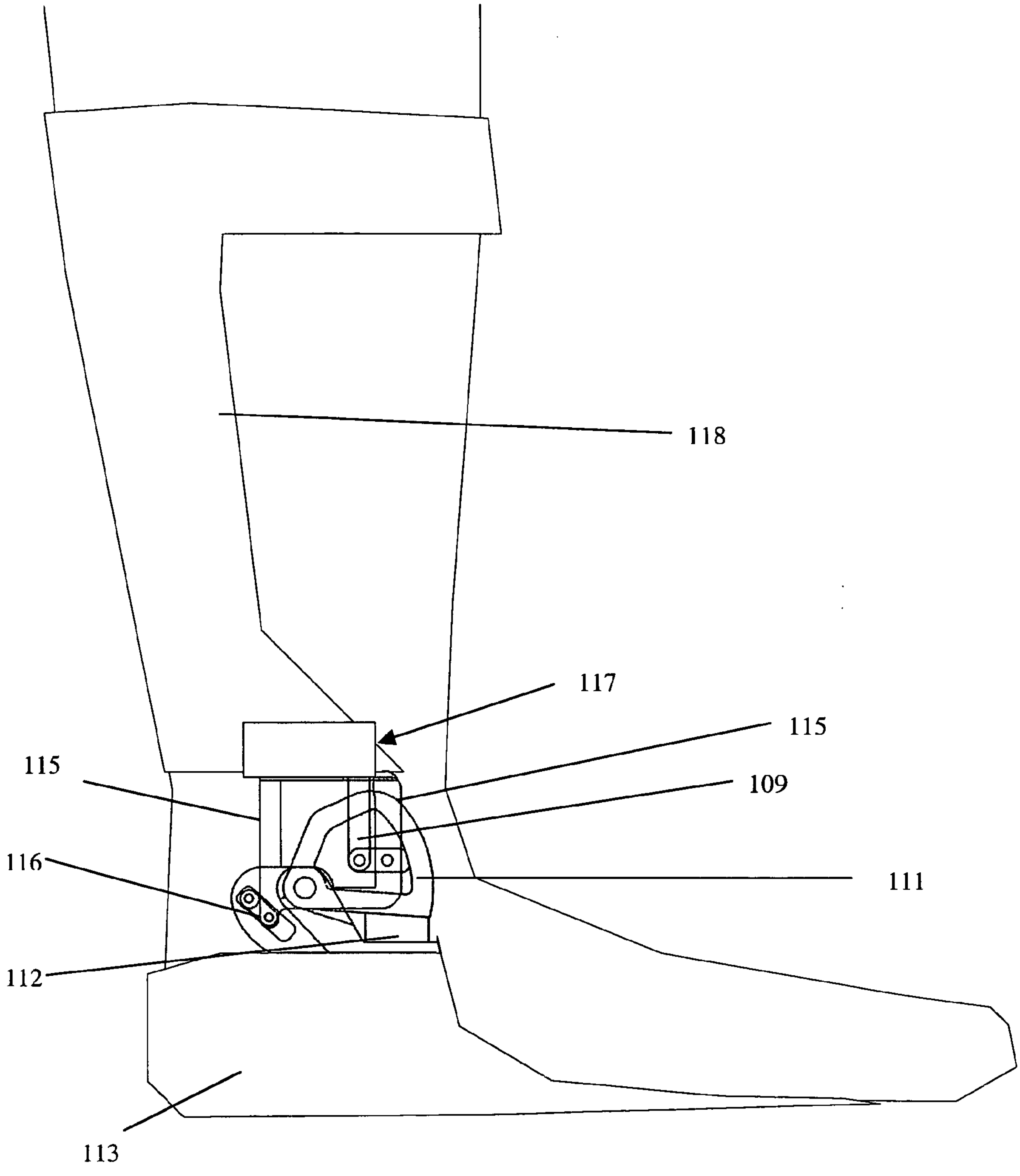


Fig 35

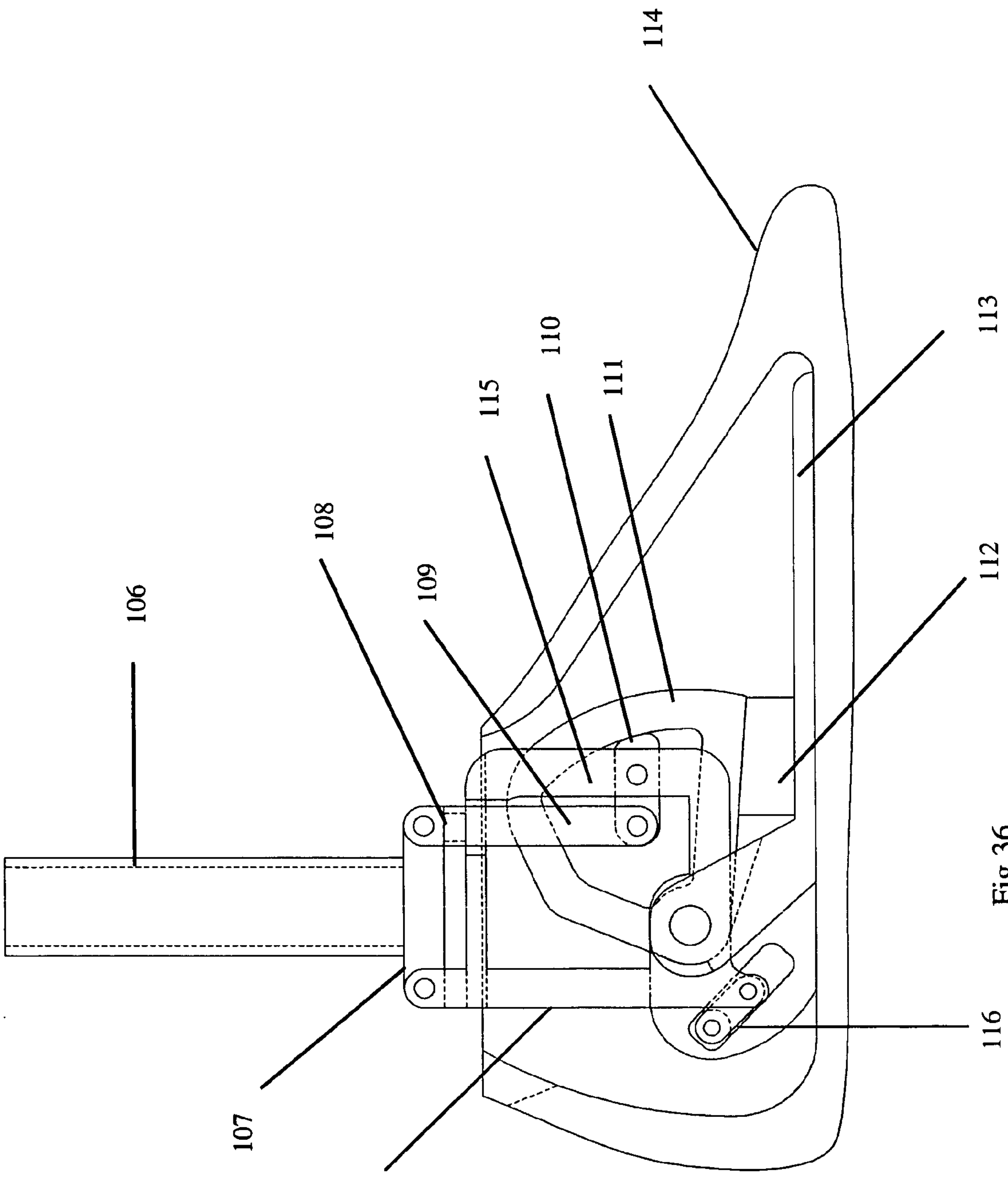


Fig 36

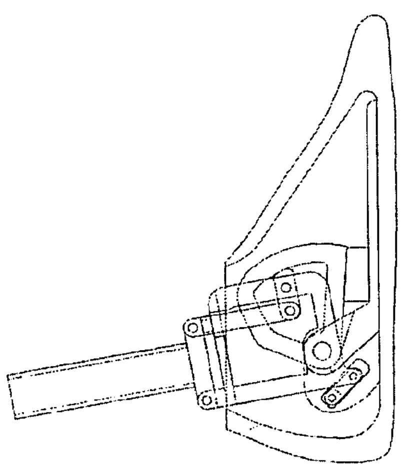


Fig 37A

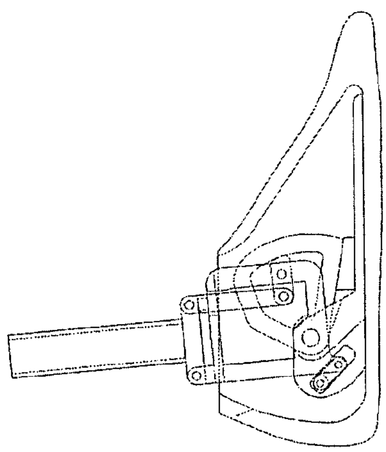


Fig 37B

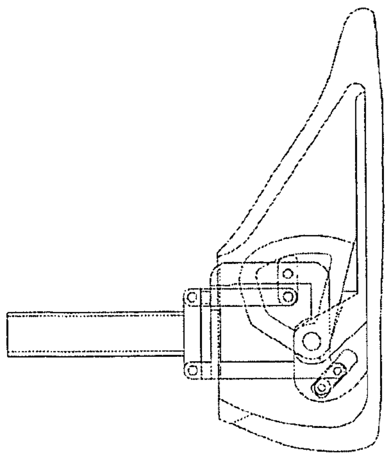


Fig 37C

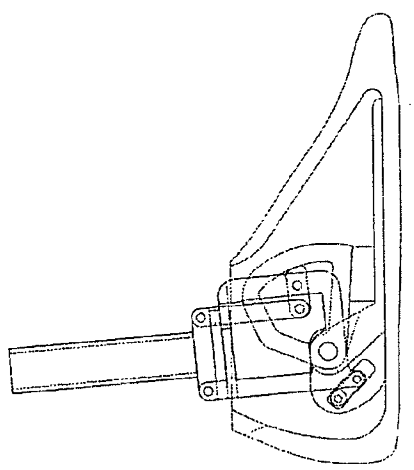


Fig 37D

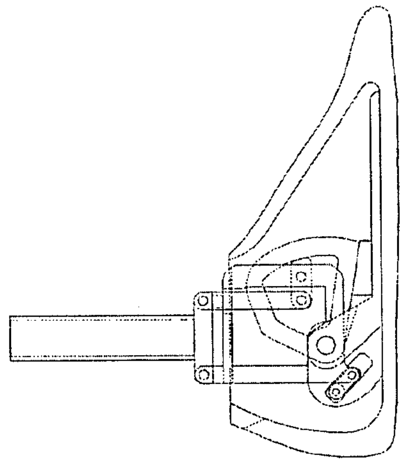


Fig 37E

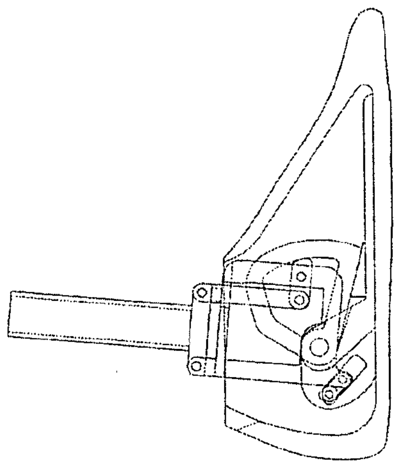


Fig 37F

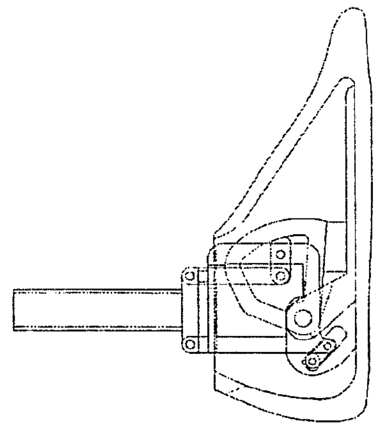


Fig 37G

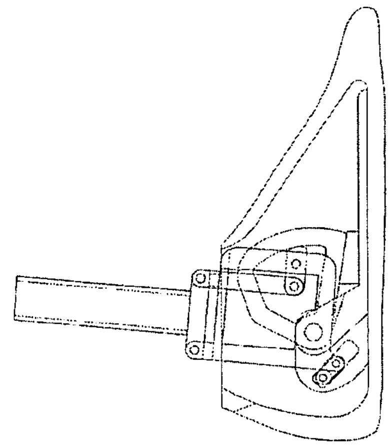


Fig 37H

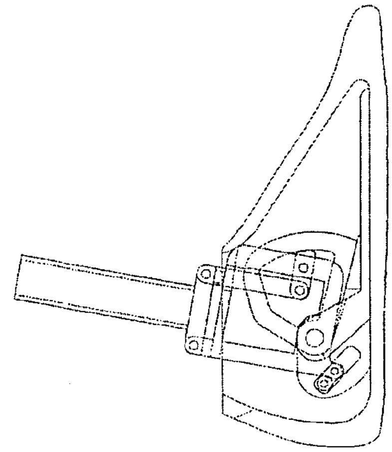


Fig 37I

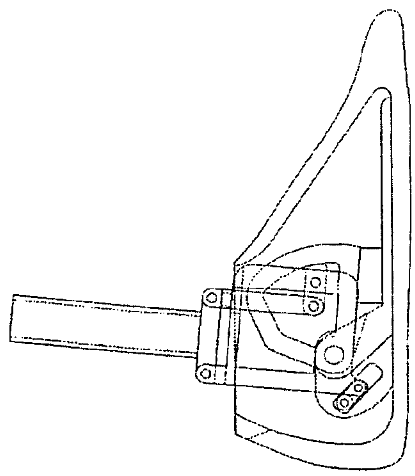


Fig 37J

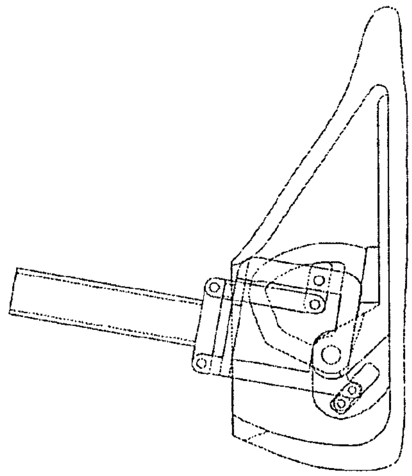


Fig 37K

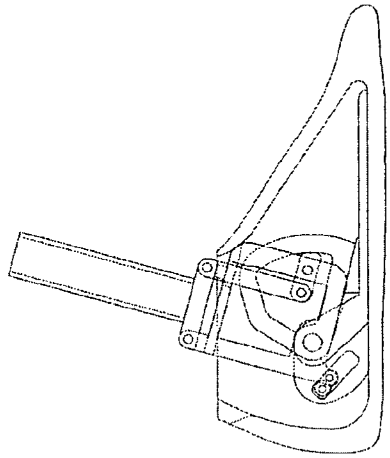


Fig 37L

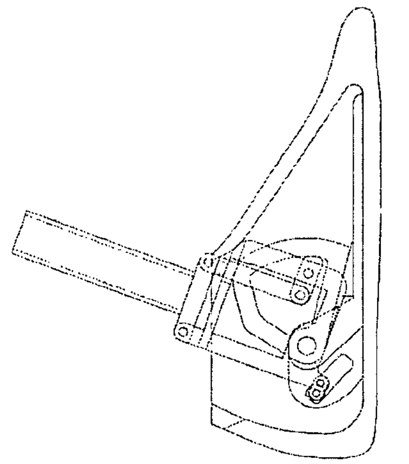


Fig 37O

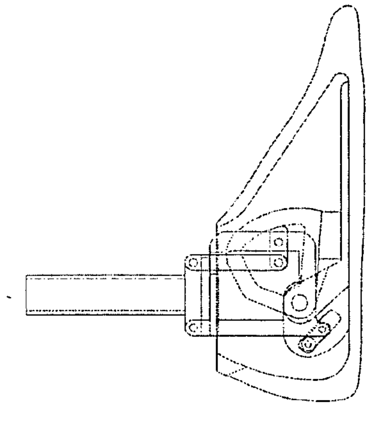


Fig 38C

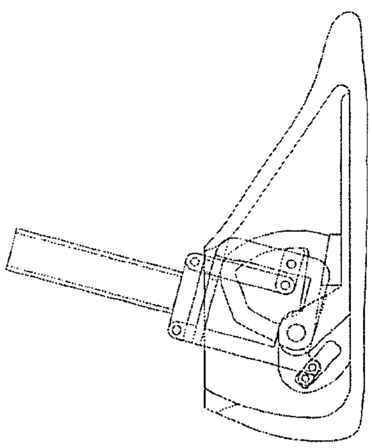


Fig 37N

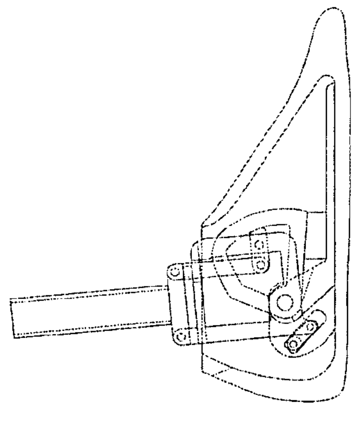


Fig 38B

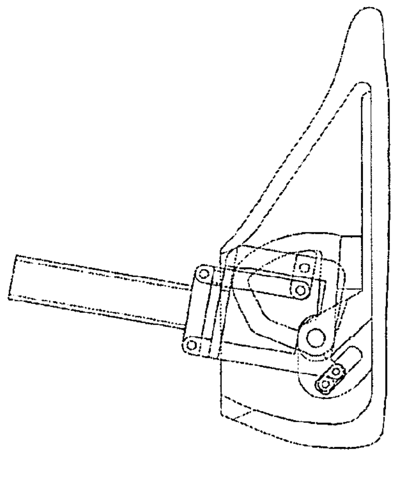


Fig 37M

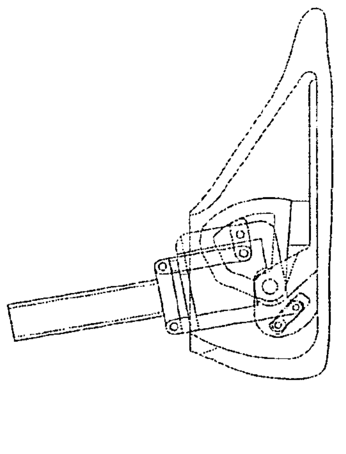


Fig 38A

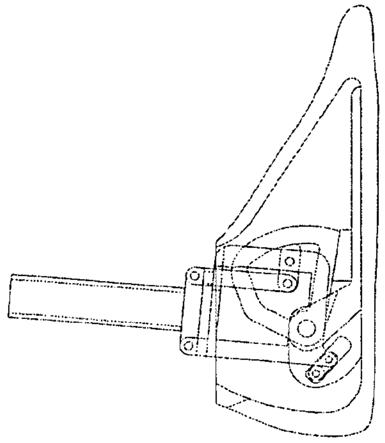


Fig39C

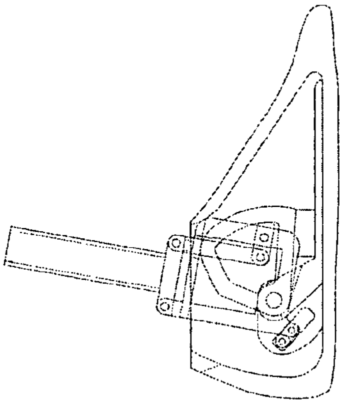


Fig 38E

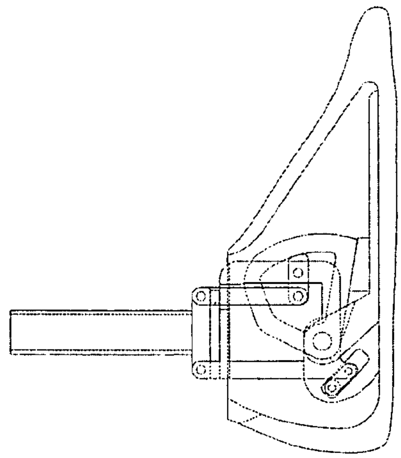


Fig 38B

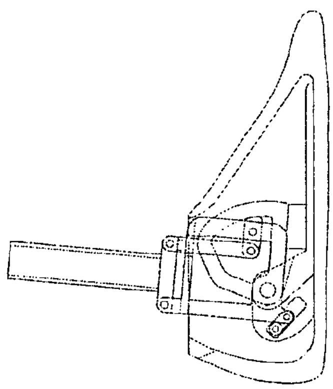


Fig 38D

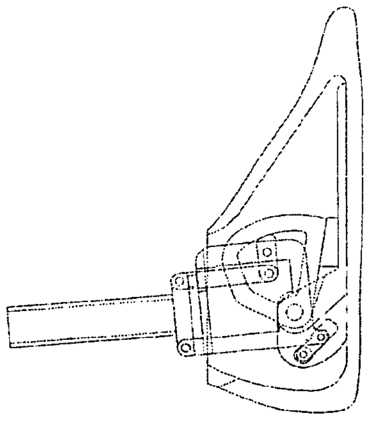


Fig 39A

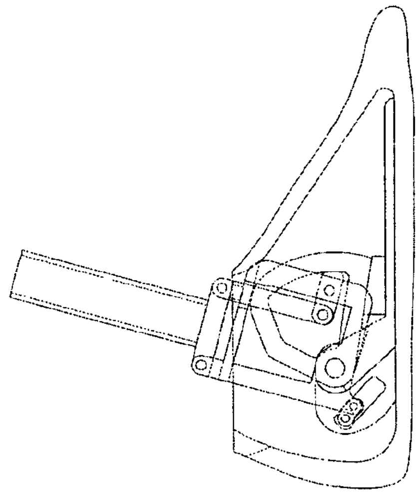


Fig 38E

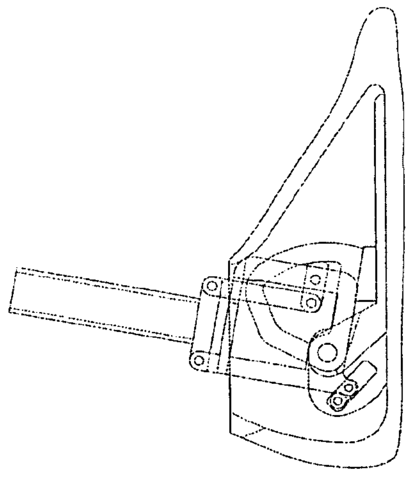


Fig 39D

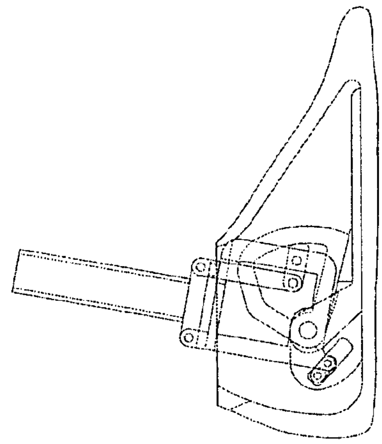


Fig40C

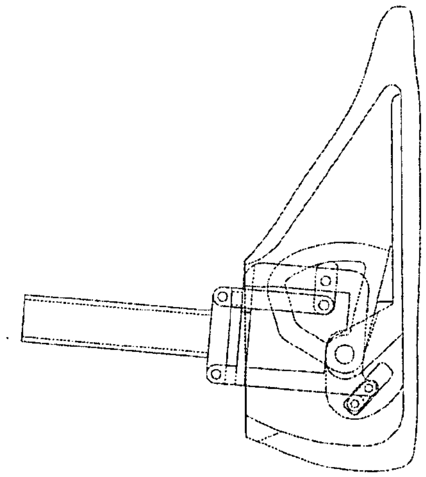


Fig 40B

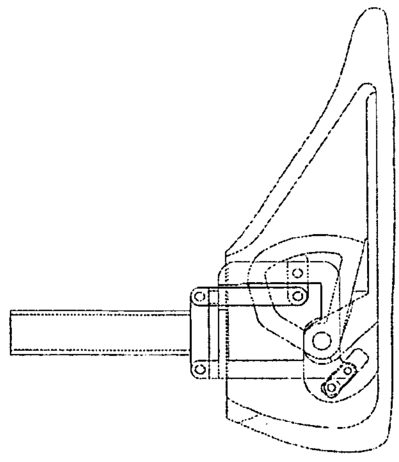


Fig 40A

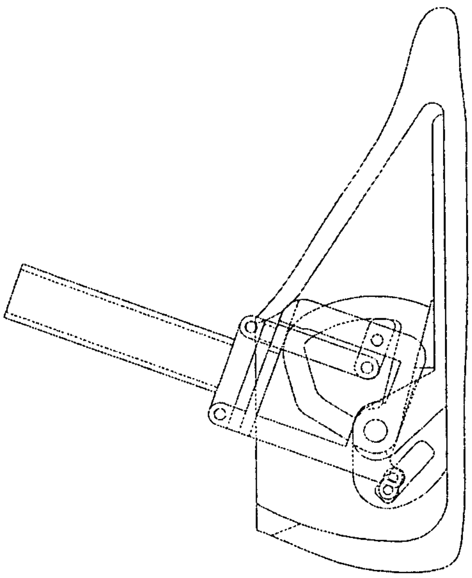


Fig 40E

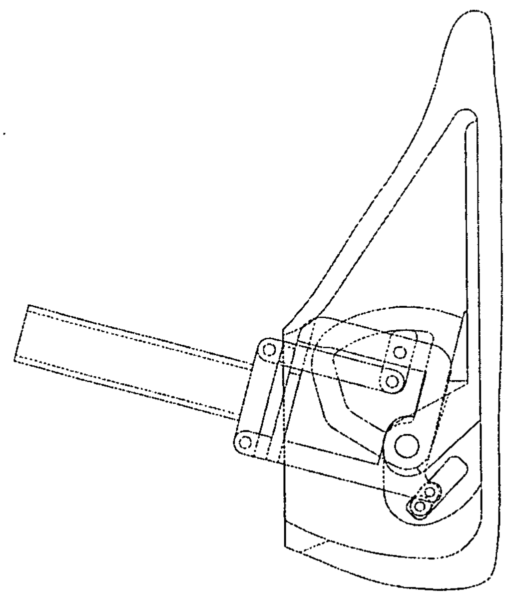


Fig 40D