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Barredo

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[54] BELOW-THE-KNEE PROSTHESIS

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[52] **U.S. Cl.** .... **3/16;** 3/2; 3/17 R
[51] **Int. Cl.²** **A61F 1/08;** A61F 1/02
[58] **Field of Search** 3/2, 6, 7, 16–20

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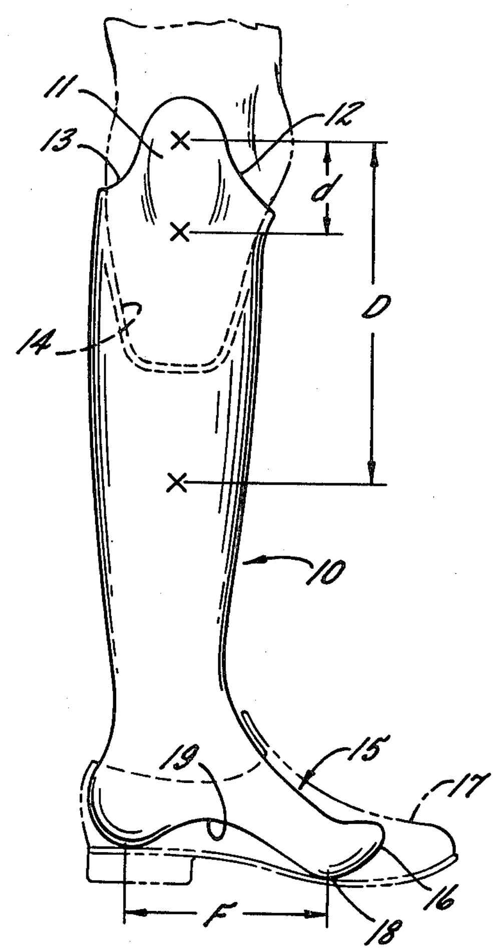
[57] **ABSTRACT**

A hollow, rigid, lightweight nonarticulated prosthesis with a foreshortened foot fits the stump of a below-the-knee amputee and has an optional simple above the knee-cap holding strap to secure the prosthesis when the knee is straightened. The center of mass of the prosthesis is much closer to the knee than is the center of mass of a natural leg.

4 Claims, 6 Drawing Figures



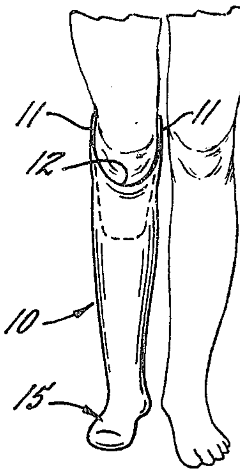


Fig. 1.

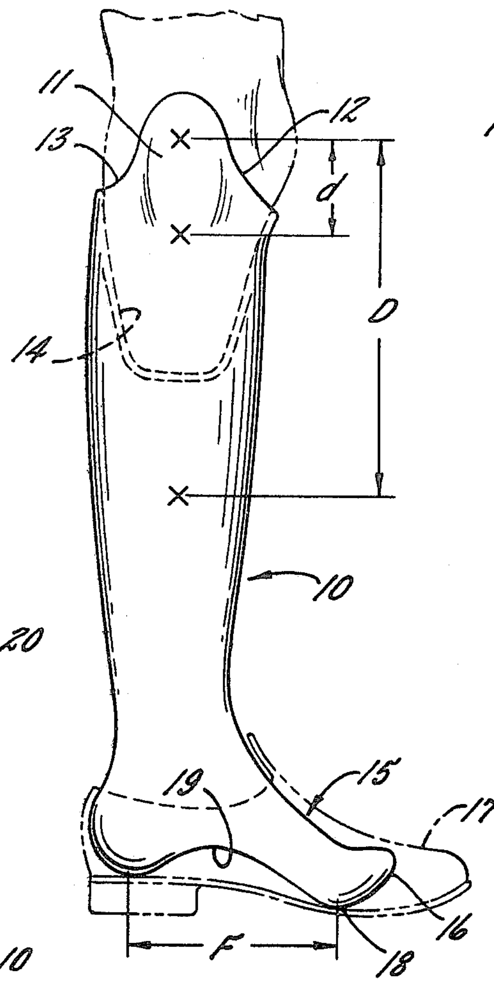


Fig. 2.

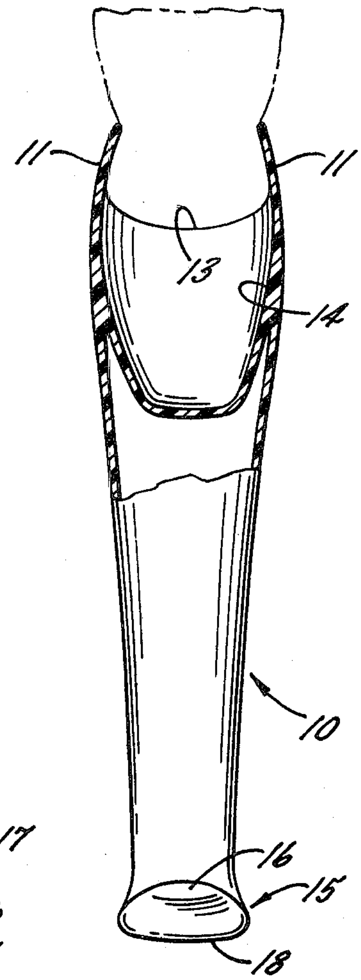


Fig. 3.

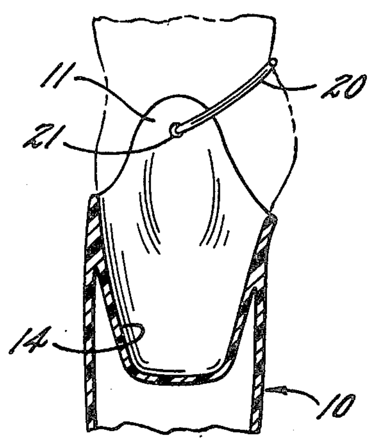


Fig. 4.

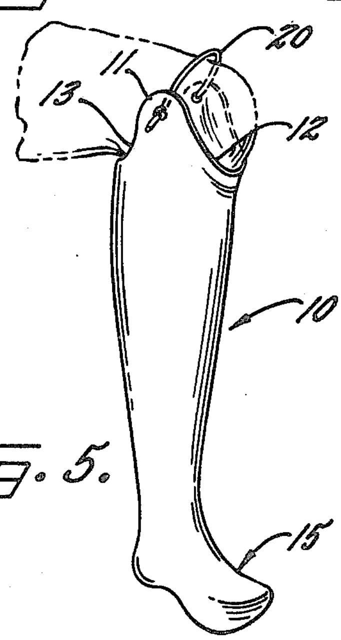


Fig. 5.

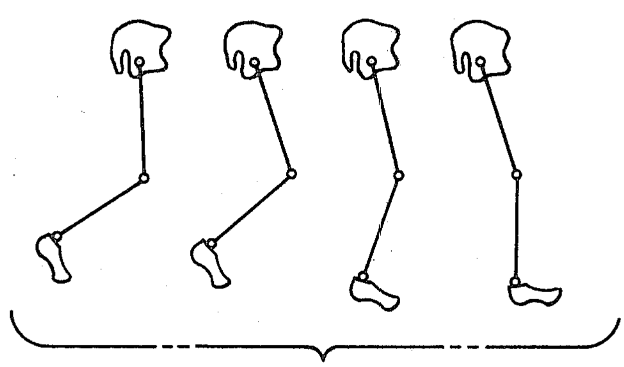


Fig. 6.

BELOW-THE-KNEE PROSTHESIS

This invention relates to an improved below-the-knee prosthesis.

An artificial leg for a person such as myself who has a below-the-knee amputation and has tissues sensitive to the pressures and friction associated with a use of a prosthesis presents a particularly vexing problem if a reasonably full use of the knee is to be preserved. A prosthesis can usually be fitted to the stump of the leg below the knee and strapped to the leg above the knee so that use is made of the knee in walking. With approved prostheses now available, this typically results in much more expenditure of energy for walking at the same comfortable speed that the user would enjoy with natural limbs. If demands on the heart of the conventional prosthesis wearer do not prevent his escape from invalidism, fatigue and discomfort are likely from extended use, and pathological conditions—cysts, blisters, edema, and infections—may result from friction or pressure by the artificial leg and harness against the skin and other tissues.

Moreover, when peripheral vascular diseases lead to amputation of the lower extremity, it is well known that the more distal the site of the amputation the greater the incidence of poor healing, while the more proximal the site of amputation, the better the potential for healing but the higher will be the expenditure of energy in walking and the greater will be the degree of invalidism. Thus, the surgeon and his patient face the difficult choice of saving length at the risk of impaired wound-healing, or sacrificing length at the risk of impaired function. No available prosthesis was heretofore designed to eliminate this hard choice.

The direction of development in artificial legs has generally been from the simple to the complex, with more or less articulated toe and ankle action in an attempt to initiate nature by duplicating the functions of the natural foot. The importance of the cosmetic aspects is not to be denied, beyond a certain point simulating the joints and weight of the natural leg is self-defeating a certain point. The prosthesis is not a natural limb and cannot function in all respects as a natural, integral limb. Disfiguring or distracting impediments in the user's gait and carriage are a significant cosmetic fault likely to accompany the relatively heavy, jointed prosthesis. Problems have also been introduced in attempts to simplify the prosthesis. A currently favored simplification is the SACH (Solid Ankle, Cushioned Heel) foot designed to be fixed to the prosthesis. The SACH ankle, being solid, does not pivot or hinge to change the attitude of the foot as the heel engages the surface being walked upon, Instead the resilient cushioned heel yields to absorb the energy of the impact of the mass of the user's body. To some extent, the impact energy stored in natural walking speed without additional energy expenditure in an elastic heel facilitates pushing the heel end of the prosthesis upward as weight is transferred to the other leg in walking, depending upon the walking step and speed. The energy required to accelerate or decelerate the mass of the prosthesis in walking is by no means negligible, but less appreciated is the fact that the wearer of the prosthesis must stabilize his body to counteract the forces of deacceleration as well as acceleration, and the tissues of the stump or the knee of the fitted leg may be unduly stressed. Elaborate or close fitting harnesses must often be employed to better accommodate the control of the prosthesis and distribute the reaction forces, as well as to keep the prosthesis from flying off during vigorous movements.

It is the purpose of my invention to provide a below-the-knee prosthesis which permits the user to walk at a natural walking speed without additional energy expenditure than in walking with natural limbs and which minimizes discomfort and other ill effects suffered by users of conventional prostheses.

It is likewise a principal object of my invention to provide a new type of below-the-knee prosthesis that accommodates a proximal site of amputation without increasing the expenditure of energy in walking or the degree of invalidism. It permits walking with the same comfortable walking speed (CWS) as a normal person.

My new prosthesis eliminates the excess expenditure of energy with existing prostheses which, besides loading the heart, produces such pathological conditions as blisters, edema, and infections. My new type of prosthesis avoids the need of eliminating the knee joint when the length of the stump would be too short to walk with the existing type of prosthesis.

I have approached the design of my prosthesis by recognizing that (1) the mechanics of walking with an artificial leg be considered from an entirely different viewpoint than walking with a natural leg, and (2) that fatigue and possible pathological events associated with the harness on the above-the-knee tissue supporting the below-the-knee prosthesis follows from the forces involved in the mechanics of walking with the prosthesis. The key to accommodating both lies in minimizing the prosthesis acceleration and deceleration forces encountered in walking at normal speeds to thus minimize the prosthesis reaction forces against the supporting tissues. The lesser energy expenditure lessens the load on the heart involved of the cardiac patient whose use of a conventional prosthesis is otherwise severely restricted.

As a rule of thumb, this approach calls for a high location of center of mass of the combined stump and prosthesis so that the distance between the hinge of the knee and the center of mass is small. The prosthesis itself must be structured (a) to be very light and (b) to have itself a relatively high (i.e., towards the knee end) center of mass. As far as my design is concerned. any theory that the weight and weight distribution of the prosthesis should approximate that of the limb it replaces is completely wrong.

To further control acceleration forces so as to limit friction and pressures on the tissues of the prosthesis user, I have foreshortened the foot portion to eliminate that length corresponding to the toes of the natural foot and have made the prosthesis rigid with neither an ankle joint nor cushion heel. Following these principles permits elimination of the prosthesis harness, or if the user feels more secure if a harness is used, the use of a vastly simplified harness, which may consist of a simple loop attached to the upper sides of the prosthesis for riding the leg tissue above the knee cap. FAtigue and pathological problems associated with extended reliance upon a prosthesis are minimized and with a desired simplicity, economy, and preservation of cosmetic values. Other advantages and objects of my invention will become apparent in the following detailed description of a preferred embodiment of my invention as read in connection with the accompanying drawings, in which:

FIG. 1 is a perspective view, partially cut away, of a strapless below-the-knee prosthesis embodying my invention;

FIG. 2 is a side view of the prosthesis of FIG. 1 illustrating how it fits the knee joint and also showing the foreshortened foot portion of the prosthesis with a lightweight shoe in dotted outline;

FIG. 3 is a front view of the strapless prosthesis of FIG. 1 partially in action to show the socket for the stump;

FIG. 4 is a side view of the upper portion of a prosthesis generally similar to that of FIG. 1 but incorporating a simple strap;

FIG. 5 shows the FIG. 4 prosthesis with harness strap on the leg of a user whose knee is bent as during a sitting position;

FIG. 6 is a series of leg and hip schematic sketches showing, from right to left, successive stages in a walking step.

Turning now to FIGS. **1**, **2**, and **3**, a below-the-knee prosthesis for an artificial leg **10** is shown in the form of a unitary hollow shell preferably formed of fiberglass over a mold. The outer surface of the fiberglass is preferably smoothly finished and colored for the desired cosmetic effect. The prosthesis wall thickness may be conveniently small, for example, on the order of one-eighth inch or even smaller, and yet be both strong and rigid without resort to internal bracing. As a result, the prosthesis is several times lighter than the natural leg. which is one of the design objectives. In my own case, as an adult male weighing **160** pounds with a short below-the-knee stump as in FIG. **2**, I am accustomed to a normal walking rate and to going up and down stairs with a fiberglass prosthesis embodying my invention which weighs only **19** ounces. This has proven more than adequate in strength, durability, and comfort. I do not wish to suggest that **19** ounces is or should be a lower weight limit, and the economic availability of other materials and manufacturing processes may make lighter weights practical. The prosthesis is significantly not only several times lighter than the natural leg but also several times lighter than the usually prescribed prosthesis with resulting beneficial decrease of accelerating and decelerating forces during walking.

For external fitting, the prosthesis has concave side extensions or caps **11** at the top of the prosthesis which extend above the cut-down front portion **12** and back portion **13** to fit closely over the ends of the knee hinge. The side portions **11** are sufficiently resilient to grip the sides of the knee sufficiently to hold the prosthesis in place. The front portion **12** of the prosthesis must be cut away enough so that it does not bear against the patella and the rear portion is cut away enough to avoid the top of the prosthesis bearing against the upper leg tissues when the knee is bent.

A smooth surfaced socket **14**, also suitably molded of fiberglass, is secured to the upper end of the prosthesis to receive the stump. The stump socket **14** is preferably custom molded as by making a plaster replica of the stump as the form for the socket. The socket is then cemented in place in the prosthesis. The socket is designed for a snug fit but does not clamp the stump. The usual precautions for controlling perspiration problems are followed, it being common to stretch a knit stocking over the stump before inserting it in the socket or to provide vents in the socket itself.

The shape and rigidity of the foot portion **15** of the prosthesis, and not only its lightness, are of considerable importance for ease of walking and comfort, Overall, it is a lightweight, rigid shell and an integral part of the prosthesis. It may be made lighter by apertures (not shown) in the arch of the prosthesis or elsewhere not distractingly noticeable in the foot portion. Very significantly, the foot portion is also foreshortened at the toe end **16** by a length approximately equal to the toes of the natural foot. As a cosmetic necessity, a lightweight shoe **17** (FIG. **2**), matching the shoe on the user's other natural foot, is worn over the prosthesis. While any shoe weight at all offsets in part the desirable weight reduction and weight distribution achieved by the construction of the prosthesis, this only emphasizes the importance of weight control in the prosthesis itself in order that the shoe weight can be better tolerated. In my own case I have found an inexpensive **10** -ounce medium size men's shoe to be quite satisfactory.

The shoe on the prosthesis should be sufficiently flexible (as is normally the case in an inexpensive, lightweight shoe) to bend easily at the toe end when worn over the prosthesis during walking. The toe end of the foot **15** is not only shortened, but the bottom of the front portion **18** of the foot desirably curves upward rather sharply as shown within the normally dimensioned confines of the shoe. This shape defines a curved fulcrum about which the foot may rock as the angle of the prosthesis foot with respect to the ground changes during walking.

The wearer of the prosthesis, whether or not he is wearing a shoe over the prosthesis, benefits in walking on the foreshortened length of the prosthesis foot. The foreshortened prosthesis foot avoids the hip elevation and additional acceleration forces which would be encountered in walking with a longer foot. The lightweight shoe **17** has no provision for large heel resilience, nor is any sought since the acceleration caused by the release of energy of a very resilient cushion is more tiring to the prosthesis wearer than any shock occurred when the substantially uncushioned rigid heel contacts the ground during walking.

As may be noted further in FIG. **2**, the arch **19** of the foot portion of the prosthesis is preferably greater in height than that of the normal foot, the smaller radius of curvature lending itself to a stronger structure for a given amount of material.

A slightly different version of the prosthesis is shown in FIGS. **4** and **5** where a strap is provided to hold the prosthesis in place against the forces of gravity and other accelerations without reliance upon a close fit between the upper side extensions of the prosthesis and the ends of the knee hinge. This may be advantageous where the knee hinge convexity is not pronounced, where the user would rather avoid close contact between the prosthesis and the knee hinge, or simply where the user feels insecure without the more assurance provided by this strap. The strap **20** shown in FIGS. **4** and **5** is suitably a plastic covered wire or other smooth surfaced cord having its ends inserted in apertures **21** at the sides of the prosthesis near its top. In this model the upper portions may curve outward from the knee hinge rather than contact it, and may be less in height so as to terminate below the hinges. For convenience the cord ends are inserted through the apertures from an inside surface of the leg and then knotted outside the prosthesis to maintain a support loop of the desired length. As shown further in FIG. **4**, the cord **20** must be long enough to pass around the front of the leg just above the knee cap, the knee cap preventing the cord from slipping down. The risk of irritation due to the force of the cord against the leg tissues has thus far proven surprisingly small. The cord need not be under any appreciable tension; when the wearer is seated with the knee bent, the cord may be so comfortably loose as to be lifted from the leg as shown in FIG. **5**.

The elimination of the SACH foot and the light weight of the prosthesis as a whole work in a helpful direction reducing both the prosthesis mass and its center of mass distance from the knee. The relatively short distance d from the center of mass of a short stump to the knee hinge is assompanied by the relatively short distance D from the center of mass of the prosthesis to the knee hinge (d and D are indicated in FIG. **2**). A lesser rather than greater amount of energy need be transmitted between the stump and the prosthesis to provide the sometimes surprisingly high accelerating and decelerating forces involved in normal walking. A long stump and a relatively short prosthesis may result in higher mass and radius values than would a short stump and longer lightweight prosthesis, although I am unaware of any appreciation of this concept in prosthesis design prior to my invention.

In the design of the prosthesis of my invention I have arrived at the low mass and high center of mass by consideration of the basic physics— the forces, masses, and motions—of walking. Fitting and alignment, which usually receive a great deal of attention in the use of conventional prostheses, are essentially variables of secondary importance made unnecessarily prominent by slighting consideration of the primary physical variables. Consider, for example, that the shorter the walking leg swing time T, the obviously greater the maximum acceleration and deceleration forces which must be accommodated. The stump functions at least in part as a lever for lifting, kicking, or stopping the motion of the artificial leg. The ratio D/d, although minimized in the design of my prosthesis by a relatively short D, illustrates the multiplication of the forces on the stump tissues. The desirably small amplitude of the prosthesis mass m, which operates on or is operated by the lever, must be taken into effect. The forces called for by the feedback signals sent to the brain by the neurovascular system during walking are largely controlled by these factors. The measure of these forces can be approximated in part by consideration of the relationship $m\ 4\pi^2D^3/T^2d$. The human brain considers a great number of relationships and factors in reaching an end result such as the commodation of time T to the natural gait of the walker. The brain as a computer takes into account, for example, the different dimensions in walking barefoot and walking with heavy shoes. The design of the prosthesis by considering the physics elements, gives the human brain a greater range of freedom or effectiveness in realizing a natural gait within reasonable limits of fatigue and tissue stress.

As further shown in hip and leg sketches of FIG. **6**, the prosthesis also operates to reduce unnecessary vertical displacements of the body with resulting greater ease in walking. Thus, as shown in the righthand figure of FIG. **6**, the user is kicking his leg to begin a step. In this part of walking, the prosthesis is being thrown forward at an appreciable angular velocity around the knee hinge. Acceleration of the prosthesis causes reaction forces on the leg stump which can be comfortably borne since the center of mass of the prosthesis is fairly near that of the stump and because the mass itself is not high. The deceleration of the leg at the end of the kick by which the leg is thrown forward in walking again causes a reaction force of the prosthesis or the prosthesis strap against the leg, and again the low mass of the prosthesis keeps this force within comfortable limits. The next stick figure from the right in FIG. **6** illustrates the following engagement of the prosthesis foot with the ground after the kick. Contact is made with the heel, and the foot rocks forward over its curved front portion (the foreshortened foot length F is indicated in FIG. **2**; the FIG. **6** foot diagrams have no useful scale). The heel does not yield as in a SACH foot and the user's center of gravity (the hip hinge) changes only slightly. In the third sketch from the right in FIG. **6**, the prosthesis is not accelerated forward nor is the knee bent as much as it would otherwise be at the end of the step due to the foreshortened foot. In the fourth sketch from the right in FIG. **6**, the leg begins to swing from the thigh for the next step to begin. The knee is not bent as much as it would have been because of the short foot, and the energy of the next kick about the knee axis will not be as high.

The fairly constant level of the hip, which the short foot assists, accommodates walking with the prosthesis with a less awkward and more natural gait. The gait is not perfectly natural because the leg is not natural. What is important is that a new accommodation has been made which minimizes both energy expenditure and transmittal forces on the leg tissue.

The principles of my invention may be applied to other prostheses on a moving extremity but it is necessary that the problem be recognized if the prosthetic solution is to be helpful as in the foregoing illustration of a below-the-knee example.

Wherefore, I claim as my invention:

1. A walking prosthesis for fitting a below-the-knee stump comprising a hollow, one-piece, rigid, lightweight leg corresponding generally in form to the human leg having a socket fitted to receive the stump, and with a weight several times less than that of the natural leg and the foot portion shortened at the toe end by an amount approximating the natural toe length.

2. The prosthesis of claim **1** in which the bottom of the foot portion curves upward at the toe end to provide a rocking surface.

3. The prosthesis of claim **1** with a strap loop secured at its ends to the sides of the hollow leg near its top and with a length short enough to engage the wearer's leg above the knee cap when the knee is straightened for holding the prosthesis in place.

4. The prosthesis of claim **1** with knee-hinge engaging facing concave side extensions to grasp the ends of the knee-hinge for holding the prosthesis in place.

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